PUBLIC SESSION MINUTES

Thursday, January 31, 2013

Department of Consumer Affairs
1625 North Market Blvd.
Sacramento, CA 95834

Members Present: Charles B. Spearman, MSEd, RCP, RRT, Vice President
Lupe V. Aguilera
Rebecca Franzoia
Mark Goldstein, RRT, RCP
Alan Roth, MS MBA RRT-NPS FAARC

Staff Present: Stephanie Nunez, Executive Officer
Christine Molina, Staff Services Manager
Liane Freels, Staff Services Manager

THURSDAY, JANUARY 31, 2013

CALL TO ORDER

The Public Session was called to order at 12:00 p.m. by Ms. Aguilera.

Ms. Aguilera stated the Board did not have a quorum, however, another Board Member was expected to arrive shortly. The final member, Vice President Spearman, joined the meeting at 1:15p.m., and a quorum was present before any items were discussed and voted upon.

Ms. Nunez explained that public comment would be allowed on agenda items, as those items are discussed by the Board during the meeting. She added that under the Open Meeting Act, the Board may not take action on items raised by public comment that are not on the Agenda, other than to decide whether to schedule that item for a future meeting.

NEW MEMBER INTRODUCTIONS

Ms. Nunez introduced and welcomed the new Board Members:
Alan Roth, MS, MBA, RRT-NPS, FAARC; Mark Goldstein, BS, RRT, RCP; and Rebecca Franzoia.

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PUBLIC COMMENT

Public comment was received by Respiratory Care Practitioner, John Basile. Mr. Basile addressed the Board concerning requested changes to its current practice of posting disciplinary information indefinitely for public access on the Board's website. Mr. Basile stated he had been denied interviews and turned down for employment based on the disciplinary action documented on the Board's website.

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STRATEGIC PLANNING SESSION

The Board convened into Strategic Planning Session, at 12:42 p.m. and reconvened into Public Session at 1:39 p.m.

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CERTIFIED AND REGISTERED PULMONARY FUNCTION TECHNICIANS/TECHNOLOGIST: Consideration for Partial Exemption

Ms. Nunez stated the Los Angeles County Department of Health Services (DHS) has requested the Board to provide an exemption for twenty DHS Pulmonary Physiology Technicians (PPTs) by waiving licensing requirements for these individuals based on their pulmonary function testing experience.

Ms. Nunez explained that the Board had, in the past, pursued legislation to exempt CPFT and RPFT for certain procedures. This proposal was rejected, primarily because it was convoluted by too many caveats for training and education. The feedback, at the time, was that it was more appropriate for those requesting the exemption to be the one's seeking it.

Comments were heard from Sara Saheeb, an SEIU representative, and Andre Marshall and Melvin Chin, two of the impacted PPTs.

Mr. Marshall, a RPFT for 32 years and a Pulmonary Physiology Technician Supervisor for LA county USC Medical Center, requested that the Board look at the work experience of the group and provide education waivers to allow them to continue to work in the pulmonary function lab.

Vice President Spearman expressed his concern that experience at the level presented before the Board, suddenly be halted. He explained that the discussion needs to remain open to find a solution; however, this change will take time as it will require a legislative change.

Ms. Nunez explained that DHS has the option to seek out a legislator to author legislation, with DHS as the sponsor, and the RCB will then take a position either in support or opposition.

Vice President Spearman further stated the Board would discuss future intentions regarding this issue during Strategic Planning, and may decide at that time if a committee to further explore this issue be established. In the meantime, it is the intent of the Executive Committee to maintain open communication with the Los Angeles DHS through the Executive Officer.

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STRATEGIC PLANNING SESSION

The Board reconvened into Strategic Planning Session, at 3:00 p.m. and recessed at 5:00 p.m. until 8:30 a.m. on Friday, February 1, 2013.

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PUBLIC SESSION MINUTES

Friday, February 1, 2013

Department of Consumer Affairs
1625 North Market Blvd.
Sacramento, CA 95834

Members Present:	Charles B. Spearman, MSEd, RCP, RRT, Vice President
	Lupe V. Aguilera
	Rebecca Franzoia
	Mark Goldstein, RRT, RCP
	Alan Roth, MS MBA RRT-NPS FAARC
Staff Present:	Dianne Dobbs, Legal Counsel
	Stephanie Nunez, Executive Officer
	Christine Molina, Staff Services Manager
	Liane Freels, Staff Services Manager

CALL TO ORDER

The Public Session was called to order at 8:33 a.m. by Vice President Charles Spearman.

PUBLIC COMMENT

Vice President Spearman explained that public comment would be accepted after each agenda item. He added that under the Open Meeting Act, the Board may not take action on items raised by public comment that are not on the Agenda, other than to decide whether to schedule that item for a future meeting. In order to allow the board to conduct scheduled business the public comment may be limited.

APPROVAL OF MAY 18, 2012 MINUTES

Ms. Aguilera moved to approve the May 18, 2012 Public Session minutes as written.

M/Aguilera /S/Goldstein
In favor: Aguilera, Franzoia, Goldstein, Roth, Spearman
MOTION PASSED

EXECUTIVE OFFICER'S REPORT

(Nunez)

a. BreEZe Online Application/License System

Ms. Nunez explained that the BreEZe system would be replacing the Board's CAS and ATS systems which currently store all of the Board applicant, licensing and enforcement records. BreEZe is

anticipated to be more efficient and provide online access for application, renewal and allow for the tracking of other transactions. Ms. Nunez indicated the rollout date, initially scheduled for February 19, has been pushed back. The new date is unknown at this time. The Board periodically sends updates to program directors and has included information in the newsletter, and on the website home page. For those renewing their license on-line, Ms. Nunez asked that licensees be aware that the current on-line system for renewal will be unavailable for a period of about two months during the transition to BreEZe.

Ms. Nunez thanked the NBRC for their cooperation in working with DCA to modify data so that information can be shared electronically with BreEZe.

b. New Regulations (Effective 6/24/12): Implementation Status

i. Recognition of Military Experience

Ms. Nunez explained the prior changes in CoARC accreditation and the law requiring a degree for licensure, resulted in stumbling blocks for military trained applicants. Regulations had addressed most of the issues; however some military personnel were still affected. Military personnel have always been held in high regard by the Board and the State. The Board moved forward with new regulations, implemented last July, modifying the waiver language which has resolved all issues.

Ms. Nunez further stated that two bills, AB 1588 and AB 1904 provided additional exemptions for military personnel on active duty and a provision to speed application processing for spouses or unified partners of military personnel. The Board's website has been updated with notices to applicants and licensees.

ii. Ethics Course (Revision scheduled for 1/1/14)

Ms. Nunez stated the Ethics Course is scheduled for revision and should be available by January 1, 2014. Ms. Nunez gave some background information for new Board Members explaining; the Board's Law and Professional Ethics Course was developed and implemented in 2006 and is designed to educate applicants and licensees on ethics in the workplace, their responsibility to report illegal activities, and acts that jeopardize their licensure status. The course may only be offered by the AARC and CSRC. Licensees must complete the course as part of their continuing education required for licensure renewal every other renewal cycle (about every four years).

Ms. Nunez stated Liane Freels, the RCB's Enforcement Manager, will be coordinating the efforts between the AARC and the CSRC and will work with the Board's Professional Qualifications Committee on the revisions to the Ethics Course prior to Board approval. Ms. Nunez concluded the course should be in its final format and approved by the Board no later than the last meeting this year (approximately October 2013).

iii. Cease Practice Notices for Major Violations

Since the Board updated its Disciplinary Guidelines (adding Major Violations allowing the automatic suspension of a probationer's license), there have been approximately seventeen cease practice notices issued. Seven have been lifted and ten have been transmitted to the Attorney General's Office for further disciplinary action. The major violation: "Failure to make daily contact as directed…" has caused some discussion and some cases have been lifted depending on the circumstances, background and history of the probationer. This may be re-examined in future Disciplinary Guideline revisions.

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iv. Citation and Fine

Citation and Fine regulations were streamlined to provide clarity for staff and the maximum fine was increased to $5,000, as authorized by law.

v. Application and Initial Licensing Fee

The Board eliminated the initial licensing fee and increased the application fee, decreasing the amount of time it takes for an applicant to get licensed by approximately 3 weeks.

"TRANSITIONING THE RESPIRATORY THERAPIST WORKFORCE FOR 2015 AND BEYOND" UPDATE

(Spearman)

Vice President Spearman gave some background on the three conferences and subsequent articles concerning the changes to the roles and responsibilities of respiratory therapists' in the future health care system, and the competencies and education to support those changes. As a result, several recommendations were made by the 2015 Conference Group to the AARC Board of Directors). Vice President Spearman highlighted a few, including:

The RRT be the only credential
The Baccalaureate degree be established as an entry level requirement

Vice President Spearman discussed the NBRC's plans regarding changes to the examinations for the CRT and RRT credentials. One exam will be given, graded on a two tiered level, differentiating the CRTs from those who become eligible to take the clinical simulation examination and potentially achieve the RRT credential.

Vice President Spearman stated, with everything he has read, it only emphasizes, in his opinion, that there is no reason for the CRT credential, taking to account and excluding the CRT's who are currently in the workforce.

Vice President Spearman discussed a letter of non-support from the AARC to the Ohio Board for Respiratory Care concerning the minimum requirement of RRT for licensure and stated that it is an important consideration for this Board to have the support of the national respiratory care association.

Spearman opened the discussion to the public. Comments were received by:

Barry Westling, CSRC Delegate to the American Association for Respiratory Care
Donna Murphy, President, California Society for Respiratory Care
Robby Nijjar, Committee Chair, California Society for Respiratory Care
Michael Monasky, RCP, RRT-NPS

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CSRC Position Paper for RRT as Minimum Requirement for Licensure

Vice President Spearman opened the discussion concerning the proposal to consider moving to the RRT as the minimum requirement for licensure.

Ms. Nunez stated the Board may want to consider RRT as minimum licensure based on the fact that education varies among the different schools especially in the clinical practice area. Since an RRT is required to pass clinical simulation testing, they enter the profession at higher documented level and are prepared to practice. She added this could lower practice related complaints for incompetency, and also believes this could help the Board be more proactive in protecting the public.

Vice President Spearman commented that all programs now teach to the RRT level.

Public comments were received by:

Abbie Rosenberg, Executive Director, CSRC
Ricardo Guzman, San Joaquin Valley College Program Director, Education Committee Chair, CSRC
Russ McCord, CSRC
Robby Nijjar, Committee Chair, CSRC
Donna Murphy, President, CSRC
Michael Monasky, RCP, RRT-NPS

Discussion ensued by Board Members.

Mr. Goldstein moved that the Respiratory Care Board recognize the RRT examination as the minimum requirement for licensure for new candidates and to investigate the timeline for implementation.

All were in favor. No one opposed.
M/Goldstein /S/Roth
In favor: Aguilera, Franzoia, Goldstein, Roth, Spearman
MOTION PASSED

ELECTION OF OFFICERS FOR 2013

Mr. Spearman opened the floor for nominations for the Respiratory Care Board President. Mr. Goldstein moved to nominate Charles Spearman for President. No other nominations were presented. Mr. Spearman accepted the nomination.

All were in favor. No one opposed.
M/Goldstein /S/Roth
In favor: Aguilera, Franzoia, Goldstein, Roth, Spearman
MOTION PASSED

Mr. Spearman opened the floor for Nominations for the Respiratory Care Board Vice President. Mr. Spearman move to nominate Mark Goldstein for Vice President. No other nominations were presented. Mr. Goldstein accepted the nomination.

All were in favor. No one opposed.
M/Spearman /S/Roth
In favor: Aguilera, Franzoia, Goldstein, Roth, Spearman
MOTION PASSED

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2013 MEETING DATES: CALENDAR

The next Public Meeting will be on May 6, 2013 to coincide with the CSRC's Annual Meeting in San Diego. Mr. Roth stated it would be advantageous for the individuals attending the CSRC meeting to see the faces of the RCB Members and would encourage public participation in future RCB Public Meetings.

The final meeting for the year was scheduled for November 8th to coincide with the AARC Meeting in Anaheim, CA.

2012-13 SUNSET REVIEW/HEARINGS

(Nunez)

Ms. Nunez stated the Sunset Review Hearings will be held on March 11 and March 18, 2013. The Board is scheduled to present on March 18. Ms. Nunez requested that any available Executive Committee Members plan to attend to answer any questions which fall outside of the scope of her technical knowledge. Both President Spearman and Vice President Goldstein volunteered to attend and assist with the presentation.

FISCAL REVIEW/CONSIDERATION TO REDUCE RENEWAL FEE

(Nunez)

Ms. Nunez provided a brief background concerning renewal fees. Since 2002, the fee has stood at $230. This fee has remained untouched for 11 years. A provision in Section 3775 subsection (d) indicates that the Board shall decrease fees if estimated expenditures result in the fund exceeding a six month reserve. Agenda materials provided the Board Members with fund expenditure projections and other pertinent fund information. Ms. Nunez recommended that the Board tentatively move forward with a one-time fee reduction of $30 or $40 over a 2 year cycle versus a continuous fee reduction, but requested additional time to complete an investigation as to the current impact to the BreEZe system implementation, to complete additional expenditure projections, and for the completion of strategic planning.

Discussion ensued, and it was agreed that the reduction of renewal fees will tentatively be decreased by $30.

ENFORCEMENT DISCIPLINARY PROCESS OVERVIEW

(Nunez)

Ms. Nunez provided an explanation of the complaint/disciplinary process flow chart.

Ms. Dobbs, Legal Counsel, provided clarification concerning Penal Code 23 stating the Board's interests are that any criminal activities a person is involved with, affects Public Health and Safety.

Ms. Nunez summarized the process flow and the actions that may result as a consequence of formal disciplinary actions.

Discussion for various subject matter clarification ensued with explanations offered by Ms. Nunez.

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CLOSED SESSION

No Closed Session was held.

PUBLIC COMMENT ON ITEMS NOT ON THE AGENDA

No public comment was provided at this time.

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STRATEGIC PLANNING SESSION

The Board convened into Strategic Planning Session, at 11:17 p.m. and reconvened into Public Session at 12:35 p.m.

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FUTURE AGENDA ITEMS

Mr. Roth indicated that he would like to place the white paper from AARC concerning productivity, therapy and standards of consistency on future agenda items for review.

Ms. Nunez would like to add the discussion of her updated issue paper concerning RRT.

ADJOURNMENT

The Public Session Meeting was adjourned by President Spearman at 3:47 p.m.

CHARLES B. SPEARMAN	STEPHANIE A. NUNEZ
President	Executive Officer

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FUND CONDITION
BASED ON PROJECTED EXPENDITURES AND REIMBURSEMENTS

No Renewal Fee Reduction

	2011/12*	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19
Beginning Reserve, July 1	$2,176,618	$2,401,037	$2,514,095	2,461,890	$2,318,761	$2,175,632	$2,086,363	$1,997,094
Prior Year Adjustments	$38,185							
Revenues	$2,658,814	$2,689,710	$2,716,055	2,716,055	$2,716,055	$2,716,055	$2,716,055	$2,716,055
Interest		$24,010	$25,141	24,619	$24,619	$24,619	$24,619	$24,619
TOTAL RESOURCES	**$4,873,617**	**$5,114,757**	**$5,255,291**	**5,202,564**	**$5,059,435**	**$4,916,306**	**$4,827,037**	**$4,737,768**
Budget Expenditure[1]	$2,680,172	$2,754,662	**$2,909,401**	**2,996,683**	$2,996,683	$2,996,683	$2,996,683	$2,996,683
Disbersements[2]	$11,908							
BreEZe Funding[1]		$45,000	$62,000	63,860	$63,860	$10,000	$10,000	$10,000
BreEZe Credit Card[1]		$21,000	$42,000	43,260	$43,260	$43,260	$43,260	$43,260
Reimbursements	($219,500)	($220,000)	($220,000)	(220,000)	($220,000)	($220,000)	($220,000)	($220,000)
TOTAL EXPENDITURES	**$2,472,580**	**$2,600,662**	**$2,793,401**	**2,883,803**	**$2,883,803**	**$2,829,943**	**$2,829,943**	**$2,829,943**
RESERVE, JUNE 30	**$2,401,037**	**$2,514,095**	**$2,461,890**	**2,318,761**	**$2,175,632**	**$2,086,363**	**$1,997,094**	**$1,907,825**
MONTHS IN RESERVE [3]	9.1	9.4	8.9	8.4	7.9	7.6	7.2	6.9

* Actual

1 BreEZe funding is identified separately (below)

FY 13/14 expenditures reflect a $70k increase in personnel services (5% PLP & 3% COLA), actual BreEZe expenses, and a 3% increase in overall expenditures.

FY 14/15 expenditures reflect a 3% projected increase in overall expenditures.

2 Represents FSCU (State Operations) and FISC (State Controller Operations) disbursements

3 Months in Reserve are calculated based on actual budget schedule amounts for FY 12/13 and FY 13/14 and then a one-time projected increase of 3% for FY 14/15. FY 12/13: $3,189,000; FY 13/14: $3,269,000; and FY 14/15 (and thereafter): $3,367,070

With ONE-TIME $30 Reduction over Two-Year Cycle (1/1/2014 - 12/31/15)

	2011/12	2012/13*	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19
Beginning Reserve, July 1	$2,176,618	$2,401,037	$2,514,095	$2,323,890	$1,903,381	$1,620,872	$1,530,223	$1,439,574
Prior Year Adjustment	$38,185							
Revenues	$2,658,814	$2,689,710	**$2,578,055**	**$2,440,055**	**$2,578,055**	$2,716,055	$2,716,055	$2,716,055
Interest		$24,010	$25,141	$23,239	$23,239	$23,239	$23,239	$23,239
TOTAL RESOURCES	**$4,873,617**	**$5,114,757**	**$5,117,291**	**$4,787,184**	**$4,504,675**	**$4,360,166**	**$4,269,517**	**$4,178,868**
Budget Expenditure[1]	$2,680,172	$2,754,662	$2,909,401	**$2,996,683**	$2,996,683	$2,996,683	$2,996,683	$2,996,683
TOTAL EXPENDITURES	**$2,472,580**	**$2,600,662**	**$2,793,401**	**$2,883,803**	**$2,883,803**	**$2,829,943**	**$2,829,943**	**$2,829,943**
RESERVE, JUNE 30	**$2,401,037**	**$2,514,095**	**$2,323,890**	**$1,903,381**	**$1,620,872**	**$1,530,223**	**$1,439,574**	**$1,348,925**
MONTHS IN RESERVE	9.1	9.4	8.4	6.9	**5.9**	5.5	5.2	4.9

ENFORCEMENT STATISTICS

Data through March 31, 2013

Applicant Licensed Unlicensed	CASELOAD	FY 03/04	FY 04/05	FY 05/06	FY 06/07	FY 07/08	FY 08/09	FY 09/10	FY 10/11	FY 11/12	FY 12/13
A	Applications Received	713	853	1003	1283	1359	1360	1443	1357	1593	1110
L	Total Licensed	23,674	24,408	25,246	26,338	27,545	28,847	30,120	31,511	32,825	34,134
A L U	Enforcement Budget	$436,421	$494,771	$514,365	$557,312	$584,409	$579,161	$640,576	$661,077	$664,403	$675,023
L	Licenses Active	15,367	15,503	15,835	16,511	17,202	18,077	18,803	19,658	20,390	21,270
A	Applicants Investigated (RCB Staff)	113	141	205	238	269	270	311	260	254	186
A	Applicants Denied/Initial	19	11	23	19	31	46	35	21	12	22
L U	Complaints Received	521	515	495	476	472	493	583	575	621	448
A L U	Cases to Investigation (sworn investigators)	0	4	3	9	5	11	3	6	1	2
L U	Citations Issued	68	99	57	71	63	102	75	96	69	52
A L	Cases to the DAG	125	46	56	71	64	99	69	80	69	60
L	Prob. Cases to AG for Revocation	15	13	13	10	9	17	23	9	10	10
A L U	Cases to the DA	1	0	1	0	1	0	0	1	0	0
L	Accusations Filed	102	60	34	51	51	46	42	58	51	45
A	Statement of Issues Filed	17	9	15	21	22	40	29	20	13	12
L	Petitions to Revoke Probation Filed	12	11	18	8	9	11	**21**	9	10	7
A L	Stipulated Settlements	85	71	34	46	59	61	57	50	47	31
A L	Disciplinary Hearings Completed/Final Decisions	19	11	13	7	14	9	20	17	16	17
L	Revocations/Surrenders	36	31	27	24	29	30	45	32	39	30
A	Applications Denied (Final Decision)	2	0	3	2	3	1	6	5	4	3
A L	Public Reprimands	50	20	5	6	9	6	4	10	4	3
A L	Probationers (New)	38	53	27	32	40	48	39	29	36	23
L	Probationers (Active)	81	100	80	77	84	108	92	84	86	80
L U	Fines Imposed	$51,600	$61,050	$33,600	$33,413	$32,450	$60,950	$123,975	$51,450	$25,950	$18,450
L U	Fines Reduced, Withdrawn, Dismissed	$1,550	$1,350	$900	$900	$1,225	$2,715	$400	$3,500	$75,325	$0
L U	Fines **Collected**	**$23,386**	**$41,942**	**$37,941**	**$31,919**	**$31,061**	**$30,121**	**$41,863**	**$41,378**	**$28,646**	**$18,375**
A L	Cost Recovery Requested	$213,720	$233,873	$198,758	$183,032	$208,563	$198,892	$263,848	$267,310	$328,341	$249,407
A L	Cost Recovery Awarded	$195,354	$223,996	$173,771	$174,142	$168,976	$184,082	$214,040	$245,009	$259,648	$187,721
A L	Cost Recovery **Collected**	**$130,994**	**$130,378**	**$142,061**	**$120,820**	**$96,454**	**$55,820**	**$81,483**	**$84,285**	**$92,673**	**$73,476**
L	Probation Monitoring Costs **Collected**	**$83,447**	**$100,746**	**$102,596**	**$81,613**	**$79,748**	**$85,176**	**$90,316**	**$87,604**	**$89,714**	**$61,503**
A L U	Franchise Tax Board **Collected**	**$16,064**	**$13,676**	**$20,288**	**$13,542**	**$17,697**	**$10,440**	**$8,796**	**$8,826**	**$29,755**	**$12,916**
A L U	Collection Agency **Collected ***	**$17,402**	**$32,285**	**$56,826**	**$19,414**	**$22,568**	**$2,292**	**$1,100**	**$11,216**	**$5,584**	**$2,949**

* Amount recovered by the Board's collection agency. This amount is also reflected in Fines, Cost Recovery, or Probation Monitoring Costs Collected depending on the account in which the money was ordered.

Agenda Item: 6
Meeting Date: 05/06/13

Registered Respiratory Therapist Examination/Credential Minimum Standard for Licensure Transition Planning

On February 1, 2013, the Respiratory Care Board passed a motion that the Board recognize the Registered Respiratory Therapist (RRT) examination as the minimum requirement for licensure for new candidates and to investigate the timeline for implementation. At the request of the Executive Committee, this paper was developed to revisit the "Contingencies" and "Considerations" that were documented in the Board's prior report titled, "Consideration to Require Passage of RRT Examination as Part of State Licensure" presented to the full Board on May 10, 2011.

Currently, the Board requires the passage of the National Board for Respiratory Care's (NBRC's) Certified Respiratory Therapist (CRT) examination prior to licensure. The CRT examination is a written examination taken in one sitting. The Board is now moving toward replacing the CRT examination with the successful completion of the RRT examination prior to licensure. The RRT examination consists of a written portion, as well as a clinical simulation portion, each taken at different sittings.

This purpose of this paper is to provide current information and data to assist the Board in determining a date to transition from the CRT examination to the RRT examination. The attached proposed legislative and regulatory amendments were developed solely to further discussion among members and stakeholders and is subject to change.

High Level Overview of Implementation Timeline Sample

June 2013	Request additional staffing (already in process for unrelated workload)
September 2013	Prepare and submit proposed legislative package
November 2013	Use various media to provide notice of upcoming change
December 2013	Dept. of Finance approves/denies request for additional staff
Jan-Feb 2014	Secure bill author
Jan-Mar 2014	Begin rulemaking process to make regulatory changes
May-July 2014	Governor's budget approved with/without approval for additional staff
Feb-Sep 2014	Actively support legislation
October 2014	Presume legislation chaptered
July-Nov 2014	Amend NBRC Contract (currently scheduled to expire June 2015)
July-Nov 2014	Modify BreEZe system
January 2015	Change to RRT Exam in Effect
FY 14/15	Regulatory changes in effect (not required to implement change)

If the Board wanted to implement the new requirement by 1/1/15, ideally they should begin the process in September of this year. However, it could be started as late as January 2014. The key factor in timing implementation is the legislative cycle. If we align implementation with the legislative process, all other required changes can be made within this time frame.

NBRC Requirements

As Reported May 10, 2011

The proposed alternative is contingent upon conferring with the National Board for Respiratory Care, Inc. (NBRC) and its acceptance to waive all eligibility requirements to sit for the RRT examination.

Currently, the NBRC has several policies to be eligible to sit for the RRT examination that are not compatible with state licensure including:

- Requirement to pass the RRT examination within three years from graduation or recredentialling as a CRT. A new graduate who passes the CRT but then fails to pass the RRT examination within three years would be required to retake the CRT examination.
- Requirement to hold a current CRT credential. In order to maintain a CRT credential, holders must pay an annual $25 fee.
- Several other eligibility requirements that could pose a conflict with other respiratory care statutes.

The philosophy to retake an examination or pay annual fees to qualify for a required licensure examination, has not been shared by the California legislature in the past, and is inconsistent with California licensure laws in general. Additional legislative changes would be required to accommodate NBRC's existing policies and it is unlikely the legislature would approve such changes.

The NBRC has a history of being cooperative with the Board in contract negotiations. So long as the Board is not attempting to completely bypass the requirement to take and pass the CRT examination, the NBRC may be open to waiving all other eligibility requirements to sit for the RRT examination.

May 6, 2013 Update

The NBRC announced in its *Horizons* newsletter (Third Quarter 2012 issue) that it was making conceptual changes to its CRT and RRT written examinations. Rather than maintaining each examination independent of one another, the NBRC is combining the written portion of the exams into one examination. The score of the new exam will dictate whether the test taker simply passed the CRT portion or if the test taker achieved a high enough score to also pass the RRT portion of the exam. The NBRC states that the higher score demonstrates an increased level of proficiency. Of course, the RRT examination will still consist of the written examination and a separate clinical simulation examination.

The NBRC will be launching this new examination on January 17, 2015 (there will be a dark period from January 1-16, where no examinations will be given). Fees to take the examination will also be adjusted *(details discussed later).*

Discussions with Gary Smith, NBRC's Chief Executive Officer and Executive Director in April 2013, revealed that the NBRC was willing to continue to meet the needs of the Board through the contractual process whenever the Board decided to implement the higher threshold of the RRT examination. Mr. Smith noted opposition to increasing the minimum exam threshold for licensure; largely expressing concern for further review of reciprocity issues and potential workforce shortages. However, he also stated that he understood that each state was independent and that the NBRC would continue to support California in providing examination services specific to California's requirements.

The new combined CRT/RRT examination that will be implemented in 2015 and Mr. Smith's willingness to continue to support California in its examination needs, completely eliminates the concerns and contingencies raised in Contingency 1, NBRC Requirements as reported on May 10, 2011.

Legislative and Regulatory Authority

As Reported May 10, 2011

The proposed alternative is contingent upon approval of legislation by the California Legislature and Governor Edmund G. Brown, Jr., and regulations by the California Office of Administrative Law.

May 6, 2013 Update

Attachments A and B provide new proposed legislative and regulatory amendments to implement the Board's motion to make the RRT examination the minimum exam requirement for licensure. This proposed language reflects an effective date of January 1, 2015, though this date has NOT been established by the Board. While the provisions proposed should be reviewed in detail by the Board, the language currently allows the Board to implement this change through the legislative process with regulatory changes *following* implementation.

Obtaining legislative authority remains a contingency in implementing any increase in the threshold for the minimum exam requirement. The process is usually a year long and includes submitting proposals in the Fall, securing an author during Winter, passing through Committees in Spring and Summer and hopefully, securing the Governor's signature by the following Fall. However, there are instances where the process can be shortened, but it must still go through legislative channels in Summer and Fall.

Staff Resources

As Reported May 10, 2011

Should the NBRC agree to waive RRT eligibility requirements for the purposes of California licensure, staff will need to explore the method in which that will be used to schedule candidates for the examination. Currently, 99% of all applicants may apply for the CRT exam directly through NBRC. However, NBRC's electronic scheduling system may not accommodate departures from the NBRC's eligibility requirements. It will need to be determined how many candidates may have to be scheduled by Board staff.

In addition, staff will need to explore additional workload associated with extending work permits or issuing permits for a greater period of time. Work permits are currently issued for a period of 90 days for new graduates and for all others (upon receipt of certain background clearances). In most instances, this time period allows a candidate to pass the entry level examination and ensure all required documentation is submitted; A work permit extension is rarely necessary. However, by requiring the passage of an additional examination, staff will need to explore whether or not a work permit should be issued for a greater period of time or determine the workload that would be associated with extending work permits. Additional workload will likely result in the need for an additional staff person. In order to obtain an additional staff person, staff must submit a request 18 months in advance, and for the past several years, requests to increase staffing have been largely denied.

May 6, 2013 Update

Given the changes the NBRC is making to the CRT/RRT exam structure, and the willingness of NBRC to continue to accommodate California's needs, eligibility requirements, as described above, are no longer a concern.

However, additional workload will be associated with extending work permits if the Board chooses to keep the provision (included in the attached proposed legislative language) to extend a work permit if an applicant shows evidence of passing the CRT written examination. Board staff are currently attempting to secure additional personnel for the Licensing Unit that could absorb this increase in workload. ***The Board will need to determine if it should eliminate, modify or keep the work permit provision contained in the attached proposed legislative language.***

Graduates from Entry Level Programs

As Reported May 10, 2011

The last group of students to graduate from an entry-level educational program will be in December 2012. However, should these applicants not become licensed by December 31, 2013, they will be required to take and pass the RRT examination. These candidates will have much more difficulty in passing the RRT examination and most will not be equipped with the education and/or training needed to pass the examination. Is one-year sufficient time to require licensure? If an applicant had a personal crisis or situation that prevented them from passing the examination in this one-year period, it would virtually eliminate or make it very difficult for them to obtain licensure without further education.

May 6, 2013 Update

At this time, it appears, the earliest date for implementation would be January 1, 2015. This would give the last graduating class in December 2012, two years to pass the CRT examination that is currently required for licensure. The attached proposed legislation also provides a provision to allow a "one-time" work permit to be issued for up to six months from the date an application is filed if the applicant shows evidence of passing the CRT examination. ***The Board will need to determine if two years is a sufficient amount of time for graduates to apply for licensure and pass the CRT examination. The Board also needs to determine if it should eliminate, modify, or keep the work permit provision.*** Regardless, of the date of implementation, the Board should consider providing notice on its website and in newsletters for a suggested one year period, prior to implementation.

Fees

As Reported May 10, 2011

Considering the most recent proposed regulatory changes to the Board's fee schedule, an applicant will pay the following fees prior to licensure (not taking into account the need to retake the examination, if applicable):

Application Fee (to Board):	$300
Examination Fee (to NBRC):	$190
Fingerprint Fees:	$ 71
Other Document Fees:	$ 20
Total:	$581

This proposal would tack on addition $390 in fees paid to the NBRC ($190 for the RRT written exam and $200 for the RRT clinical simulation exam). The total fees would then be **$971** (not including fees associated with retaking any examinations).

May 6, 2013 Update

The NBRC will be modifying its fee structure with the implementation of the new CRT/RRT written examination. Only one written exam fee will be applied. However, if the applicant does not pass the RRT examination, he/she will no longer be able to pay the reduced re-exam fee ($150), rather, he/she will need to pay the entire fee again ($190). Following is a comparison of current fees to those that would be paid if the Board were to increase the exam requirement effective January 1, 2015:

Fee Type	Current	Proposed
Application Fee (to Board)	$300	$300
CRT Written Examination Fee (to NBRC)	$190	n/a
RRT Written Examination Fee (to NBRC)	n/a	$190
RRT Clinical Simulation Exam Fee (to NBRC)	n/a	$200
Fingerprint Fees	$ 71	$ 71
Totals	$561	$761

Database Requirements

As Reported May 10, 2011

Staff will need to work with the Department of Consumers Affairs to make minor changes to the ATS database.

May 6, 2013 Update

The new BreEZe system that will replace the current ATS and CAS databases is expected to "go live" in July 2013. The Board will need to work with the Department of Consumer affairs to make necessary changes to the BreEZe system. Staff expect that three months notice would be sufficient time to make necessary changes.

Out-of-State Applicants/Reciprocity

As Reported May 10, 2011

While the proposal provides an exemption for out-of-state applicants who hold a current and valid license in another state that was issued prior to January 1, 2014, there will undoubtedly be qualified applicants without current licensure in another state or who were licensed after January 1, 2014 who will be required to take the RRT examination. Should additional exemptions be considered for out-of-state applicants, as well as, previously California licensed RCPs who may have inadvertently allowed their license to cancel?

May 6, 2013 Update

The attached proposed legislative language includes provisions with a suggested resolution to this issue (Section 3735). Primarily it provides that on or after January 1, 2015 any person applying for licensure or who has an application pending must pass the RRT exam. But, it also provides that any person who can provide evidence that he or she passed the CRT examination prior to January 1, 2015, may not be required to pass the RRT exam, provided there is no disciplinary history. ***The Board will need to determine if it would prefer to modify or keep this provision that would be applied to all California and out-of-state applicants.***

The proposed work permit provision fits nicely here, in that any applicant licensed in another state after January 1, 2015 would qualify for an extended work permit allowing some additional time to pass the RRT examination (the work permit provision is also applicable to California candidates).

RCP Workforce Shortage

As Reported May 10, 2011

Will the impact of requiring the advanced level exam be a temporary shortage of licensees or could the requirement have a permanent impact? Would any permanent shortage of licensees outweigh the need for advanced level competency requirements given the advancements in the profession and the need for public safety?

May 6, 2013 Update

In 2006, the Board contracted the services of the Institute for Social Research of the California State University, Sacramento to conduct a study to forecast the State's RCP workforce needs. The Study was completed in 2007 and found "the potential for a 'perfect storm' scenario driven by a constellation of factors that would create serious shortages of RCPs available to meet the needs of the California population in the coming decades." Key factors identified were:

- The age distribution of the current RCP workforce, suggesting a large group about to leave the workforce through retirement;

- Indication that a significant portion of those in education programs, about to enter the profession, is comprised of older individuals returning to school, which will result in shorter career spans for individuals entering the profession as new licensees; and

- A growing California population and within California's growing population, a disproportionately larger number of 65 and older individuals who consume an especially large portion of available respiratory care services.

The workforce study was prepared prior to the Affordable Care Act and therefore, no consideration was given to the workforce demands that the Act will present.

At the time the study was completed, the Board had approximately 15,000 active licensees. The Study projected that the Board would need:

16,665 licensees by 2015; 18,000 by 2020; 19,000 by 2025; and 21,000 by the year 2030.

The Board currently has over 20,000 active licensees, and expects to be at the Study's projected growth needs for the year 2030 within the next 11 months.

The number of active licensees has grown significantly and is largely attributed to new applications for licensure. Since 2002, the number of applications received each year has nearly tripled from approximately 600 applications received in 2002 to nearly 1,600 applications received last fiscal year.

There are a number of efforts that may have contributed to this jump including:

1) The US Department of Labor's publication of the RCP shortage as found in the Board's 2007 Workforce Study;

2) The number of education programs increasing from 25 in 2005 to 36 in 2012 and 39 in 2013 *(records indicate the Board has had anywhere from 26-28 education programs from 1996-2002)*;

3) Significant outreach conducted by the Board including attendance at numerous high school fairs and career search events in 2006 and 2007. And of course, many of our education programs have and continue to attend various career fairs as well; and

4) In 2009, the Board developed and partially implemented a marketing plan to recruit new students into RCP education programs. The Board was able to distribute approximately 370 media kits to high schools throughout California. *(Administrative directives halted the full implementation of the marketing plan.)*

In regard to the Affordable Care Act (ACA), the Board believes California's Respiratory Care Practitioners play a key role in filling the workforce gap to meet the demand of an estimated 4-7 million more California consumers who will be seeking care. However, it is surmised that it would be extremely difficult, if not impossible, to accurately determine at this time, the number of RCP providers that will be needed, given the fact that planning is still underway as to how to fully implement the ACA. ***The Board may also consider conducting another workforce study with the knowledge that this process takes approximately two years to complete in which the availability of impact data from the implementation of the ACA may be limited.***

Another area for consideration are the concerns that have been expressed concerning the quality of the clinical education programs have provided. Employers have reported the need to provide significant training to new graduates, despite having passed the CRT examination. Whereas the RRT examination, actually tests for competency through clinical simulation. ***The Board may want to consider the impact of this change and the benefits to employers and consumers (patients).***

Additional data for consideration is the projected decline in the number of new licenses that will be issued annually once this new requirement is implemented. Below are the pass rates published by the NBRC for the fourth quarters in 2008, 2009, and 2010. Using the averages of these pass rates along with actual data, we can get a ballpark estimate of how increasing the exam requirement to the RRT will affect the number of new licensees each year. Currently the Board licenses 1,313 new applicants each year (and 1,351 CA residents have passed the exam). Once the RRT examination for licensure is implemented, it is estimated that Board would license near 900 new applicants each year (with 922 CA residents passing the exam), for a difference of 413 less new licensees a year.

	Oct 1–Dec 31, 2008	Oct 1–Dec 31, 2009	Oct. 1-Dec 31, 2010	Avg.
CRT Examination				
Entry Level Graduates:				
New Candidates	77.7%	75.9%	80.6%	78.1%
Repeat Candidates	24.7%	28.5%	28.7%	27.3%
Advanced Level Graduates:				
New Candidates	71.9%	69.9%	71.8%	71.2%
Repeat Candidates	22.8%	21.7%	23.1%	22.5%
RRT Therapist Written Examination				
New Candidates	61.9%	64.8%	57.6%	61.4%
Repeat Candidates	36.3%	33.2%	32.6%	34.0%
RRT Clinical Simulation Examination				
New Candidates	54.4%	52.3%	53.0%	53.2%
Repeat Candidates	49.8%	45.8%	48.6%	48.1%

ACTUAL
New Licensees Annually
(Based on CA FY 11/12 CRT Actual Data)

CRT EXAMINATION			
	Attempts	**Pass Rate**	**# Passed**
New	1443	79.83%	1152
Repeat	638	31.19%	199
Total	**2,081**		**1,351**

PROJECTED
New Licensees Annually
(Based on CA FY 11/12 CRT Actual Data)

RRT WRITTEN EXAMINATION			
	Attempts	**Pass Rate**	**# Passed**
New	1443	61.4%	886
Repeat*	904	34.0%	307
Total	2,347		1,193
RRT CLINICAL EXAMINATION			
New	1193	53.2%	635
Repeat**	597	48.1%	287
Total	**1,790**		**922**

* Repeat Takers 904 = 638+266 (the difference between the number of candidates that passed the CRT and RRT on the first attempt)
**Repeat Takers 597 = 50% of New Candidates

DIFFERENCE (Annually)	
Current CRT Passages (actual)	1,351
Estimated RRT Passages	922
DIFFERENCE	**429**

NEW LICENSES ISSUED			
FY 09/10 Actual	**FY 10/11 Actual**	**FY 11/12 Actual**	**w/RRT Projected**
1,272	1,391	**1,313**	**900**

Proposed Legislative Changes

§ 3718.2. Military Personnel

The board may waive requirements for initial licensure or license renewal for military personnel as prescribed by regulation.

§ 3730. Issuance of license; Filing of application; Fee

All licenses for the practice of respiratory care in this state shall be issued by the board, and all applications for those licenses shall be submitted directly to and filed with the board. Except as otherwise required by the director pursuant to Section 164, the license issued by the board shall describe the license holder as a "respiratory care practitioner licensed by the Respiratory Care Board of California."

Each application shall be accompanied by the application fee prescribed in Section 3775, shall be signed by the applicant, and shall contain a statement under oath of the facts entitling the applicant to receive a license without examination or to take ~~an~~ one or more examinations.

The application shall contain other information as the board deems necessary to determine the qualifications of the applicant.

Added Stats 1982 ch 1344 § 1, operative July 1, 1983. Amended Stats 1988 ch 1396 § 2, effective September 26, 1988; Stats 1989 ch 645 § 2, ch 886 § 71 (ch 645 prevails); Stats 1990 ch 1072 § 1 (AB 3256), ch 1207 § 3.2 (AB 3242); Stats 1991 ch 654 § 14 (AB 1893); Stats 1994 ch 1274 § 6 (SB 2039).

§ 3735. Successful completion of written examination prerequisite to license

(a) Except as otherwise provided in this chapter, no applicant shall receive a license under this chapter without first successfully passing the national certified respiratory therapist examination ~~conducted by those persons, and in the manner and under the rules and regulations, as the board may prescribe~~.

(b) Notwithstanding subdivision (a), any person applying for licensure or any person who has an application pending, on or after January 1, 2015, shall not receive a license under this chapter without first successfully passing both the written and clinical simulation portions of the advanced level national registered respiratory therapist examination.

(c) Notwithstanding subdivision (b), any person applying for licensure who provides evidence that he or she passed the National Board for Respiratory Care's certified respiratory therapist examination prior to January 1, 2015, may not be required to pass the registered respiratory therapist examination, provided there is no evidence of prior license or job-related discipline, as determined and at the discretion of the board.

Added Stats 1982 ch 1344 § 1, operative July 1, 1983. Amended Stats 1991 ch 654 § 19 (AB 1893); Stats 1994 ch 1274 § 10 (SB 2039).Amended Stats 2005 ch 621(sb 1111).

§ 3735.5. ~~Equivalent examination for credentialing~~ State of Emergency: Temporary Practice

~~The requirements to pass the written examination shall not apply to an applicant who at the time of his or her application has passed, to the satisfaction of the board, an examination that is, in the opinion of the board, equivalent to the examination given in this state.~~

~~Added Stats 1985 ch 422 § 2, effective July 30, 1985. Amended Stats 1994 ch 1274 § 11 (SB 2039)~~.

Any person practicing respiratory care in California, pursuant to section 900, shall submit verification of licensure from his or her home state to the board.

§ 3739. Practice by graduate prior to receipt of license

(a)~~(1)~~ Except as otherwise provided in this section, every person who has filed an application for licensure with the board may, between the dates specified by the board, perform as a respiratory care practitioner applicant under the direct supervision of a respiratory care practitioner licensed in this state provided he or she has met education requirements for licensure as may be certified by his or her respiratory care program~~, and if ever attempted, has passed the national respiratory therapist examination~~.

(b) The board may extend the dates an applicant may perform as a respiratory care practitioner applicant:

(i) for causes completely outside the control of an applicant, to complete the application for licensure process;

(ii) in cases where the applicant can provide evidence that he or she has successfully passed the national certified respiratory therapist examination and has otherwise, completed the application for licensure process and has not previously been authorized to practice as a respiratory care practice applicant under this subdivision.

(c) Authorization to practice as a respiratory care practitioner applicant pursuant to subdivision (b) (ii) shall not exceed six months from the date of graduation or the date the application was filed, whichever is later.

~~(2)~~ (d) During this period the applicant shall identify himself or herself only as a “respiratory care practitioner applicant.”

~~(3)~~ (e) If for any reason the license is not issued, all privileges under this subdivision shall automatically cease on the date specified by the board.

~~(b) If an applicant fails the national respiratory therapist examination, all privileges under this section shall automatically cease on the date specified by the board.~~

~~(c)~~ (f) ~~No applicant for a respiratory care practitioner license shall be authorized to perform as a respiratory care practitioner applicant if cause exists to deny the license.~~ Nothing in this section shall prohibit the board from denying or rescinding the privilege to work as a respiratory care practitioner applicant for any reason, including but not limited to, failure to pass the registered respiratory therapist examination or if cause exists to deny the license.

~~(d)~~ (g) “Under the direct supervision” means assigned to a respiratory care practitioner who is on duty and immediately available in the assigned patient care area.

Added Stats 1985 ch 422 § 4, effective July 30, 1985. Amended Stats 1991 ch 654 § 22 (AB 1893); Stats 1994 ch 26 § 130 (AB 1807), effective March 30, 1994, ch 1274 § 14 (SB 2039). Amended Stats 2005, ch 621 (SB 1111).

Proposed Regulatory Changes

§1399.351. Approved CE Programs.

(a) Any course or program meeting the criteria set forth in this Article will be accepted by the board for CE credit.

(b) Passing an official credentialing or proctored self-evaluation examination shall be approved for CE as follows:

(1) ~~Registered Respiratory Therapist (RRT) - 15 CE hours if not taken for licensure;~~
Adult Critical Care Specialty Examination (ACCS)

(2) Certified Pulmonary Function Technologist (CPFT) - 15 CE hours;

(3) Registered Pulmonary Function Technologist (RPFT) - 15 CE hours;

(4) Neonatal/Pediatric Respiratory Care Specialist (NPS) - 15 CE hours;

(5) Sleep Disorders Testing and Therapeutic Intervention Respiratory Care Specialist (SDS)

~~(5)~~ (6) Advanced Cardiac Life Support (ACLS) - number of CE hours to be designated by the provider;

~~(6)~~ (7) Neonatal Resuscitation Program (NRP) - number of CE hours to be designated by the provider; and

~~(7)~~ (8)Pediatrics Advanced Life Support (PALS) - number of CE hours to be designated by the provider.

~~(8)~~ (9) Advanced Trauma Life Support (ATLS) - number of CE hours to be designated by the provider

(c) Any course including training regarding the characteristics and method of assessment and treatment of acquired immune deficiency syndrome (AIDS) meeting the criteria set for in this Article, will be accepted by the board for CE credit.

(c) Examinations listed in subdivisions (b)(1) through (b)~~4~~(5) of this section shall be those offered by the National Board for Respiratory Care and each successfully completed examination may be counted only once for credit.

(d) Successful completion of each examination listed in subdivisions (b)~~(5)~~(6) through (b)~~(8)~~(9) of this section may be counted only once for credit and must be for the initial certification. See section 1399.352 for re-certification CE. These programs and examinations shall be provided by an approved entity listed in subdivision (h) of Section 1399.352.

(e) The board shall have the authority to audit programs offering CE for compliance with the criteria set forth in this Article.

Note: Authority cited: Sections 3719 and 3722, Business and Professions Code. Reference: Sections 32 and 3719, Business and Professions Code.

§1399.352. Criteria for Acceptability of Courses.

Acceptable courses and programs shall meet the following criteria:

(a) The content of the course or program shall be relevant to the scope of practice of respiratory care. Credit may be given for a course that is not directly related to clinical practice if the content of the course or program relates to any of the following:

(1) Those activities relevant to specialized aspects of respiratory care, which activities include

education, supervision, and management.

(2) Health care cost containment or cost management.

(3) Preventative health services and health promotion.

(4) Required abuse reporting.

(5) Other subject matter which is directed by legislation to be included in CE for licensed healing arts practitioners.

(6) Re-certification for ACLS, NRP, PALS, and ATLS.

(7) Review and/or preparation courses for credentialing examinations provided by the National Board for Respiratory Care, excluding those courses for entry-level or advance level respiratory therapy certification.

(b) The faculty shall be knowledgeable in the subject matter as evidenced by:

(1) A degree from an accredited college or university and verifiable experience in the subject matter, or

(2) Teaching and/or clinical experience in the same or similar subject matter.

(c) Educational objectives shall be listed.

(d) The teaching methods shall be described, e.g., lecture, seminar, audio-visual, simulation.

(e) Evaluation methods shall document that the objectives have been met.

(f) Each course must be provided in accordance with this Article.

(g) Each course or provider shall hold approval from one of the entities listed in subdivision (h) from the time the course is distributed or instruction is given through the completion of the course.

(h) Each course must be provided or approved by one of the following entities. Courses that are provided by one of the following entities must be approved by the entity's president, director, or other appropriate personnel:

(1) Any post-secondary institution accredited by a regional accreditation agency or association recognized by the United States Department of Education.

(2) A hospital or health-care facility licensed by the California Department of Health Services.

(3) The American Association for Respiratory Care.

(4) The California Society for Respiratory Care (and all other state societies directly affiliated with the American Association for Respiratory Care).

(5) The American Medical Association.

(6) The California Medical Association.

(7) The California Thoracic Society.

(8) The American College of Surgeons.

(9) The American College of Chest Physicians.

(10) Any entity approved or accredited by the California Board of Registered Nursing or the Accreditation Council for Continuing Medical Education.

(i) Course organizers shall maintain a record of attendance of participants, documentation of participant's completion, and evidence of course approval for four years.

(j) All program information by providers of CE shall state: "This course meets the requirements for CE for RCPs in California."

(k) All course providers shall provide documentation to course participants that includes participants name, RCP number, course title, course approval identifying information, number of hours of CE, date(s), and name and address of course provider.

(l) For quarter or semester-long courses (or their equivalent), completed at any post-secondary institution accredited by a regional accreditation agency or association recognized by the United States Department of Education, an official transcript showing successful completion of the course accompanied by the catalog's course description shall fulfill the requirements in subdivisions (i), (j) and (k).

(m) The board may audit providers offering CE for compliance with the criteria set forth in this Article.

Note: Authority cited: Sections 3719 and 3722, Business and Professions Code. Reference: Section 3719, Business and Professions Code.

§1399.395. Fee Schedule.

The following schedule of fees is hereby adopted pursuant to sections 3775 and 3775.5 of the B&P:

~~List of Application~~ Application Type		Fees
(a) Application fee		$ 300
(b) Examination fee	Actual cost	~~$ 190~~
(c) Re-examination fee	Actual cost	~~$ 150~~
(d) Renewal fee for licenses expiring on or after January 1, 2002		$ 230
(e) Delinquency fee (not more than 2 years after expiration)		$ 230
(f) Delinquency fee (after 2 years but not more than 3 years after expiration)		$ 460
(g) Inactive license fee.		$ 230
(h) Duplicate license fee		$ 25
(i) Endorsement fee		$ 25

Note: Authority cited: Sections 3722, Business and Professions Code. Reference: Sections 3775 and 3775.5, Business and Professions Code.

Coalition Chronicle

Coalition for Baccalaureate and Graduate Respiratory Therapy Education

March 31, 2013 Volume 2 (3)

RRT Required to Practice Respiratory Therapy in Ohio

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On April 14, 2013, the Ohio Respiratory Care Board (ORCB) filed new rules that will require successful completion of the RRT exam in order to obtain a new license to practice respiratory care in Ohio. The filing of this rule represents the culmination of many years of work by the ORCB, and a major step forward in the advancement of respiratory care practice in the state. Marc Mays, MS, RRT, RCP has served as the chair of the ORCB through the process of establishing the new rule, and Sarah Varekojis, PhD, RRT, RCP has actively represented the Ohio Society for Respiratory Care (OSRC) as a stakeholder through the ORCB's process. We are CoBGRTE members and are excited to share some of the process with other members.

"Why did the ORCB decide to pursue requiring the RRT for initial licensure?"

Marc Mays: The ORCB has regularly monitored the outcomes of the RT educational programs in Ohio for many years. The reports of the ORCB Education Committee and the Education Consultant to the ORCB (Herb Douce, MS, RRT, RCP, FAARC, CoBGRTE member) have consistently reported that between 2004 and 2009, some educational programs were not meeting the CoARC minimum RRT pass rates. The ORCB was concerned that these programs were maintaining their CoARC accreditation despite these deficiencies. We discussed two potential solutions. The ORCB could assume direct responsibility for monitoring schools, or change the licensing exam from the CRT to the RRT. Both would require a change to an Ohio Administrative Code rule. In addition, assuming responsibility for monitoring schools would necessitate establishing a new bureaucracy for evaluating educational programs. We determined that this option would be too costly and time consuming. The

option to change the licensing exam to the RRT would not require any additional cost or time on the part of the ORCB, and would also hold graduates accountable for the intended outcome of all educational programs in Ohio, since all are CoARC accredited as RRT programs.

"What led the ORCB to ultimately pursue the new rule requiring the RRT for initial licensure?"

Marc Mays: In June 2010 the ORCB reviewed the CoARC position statement on eliminating the RRT examination as a program outcome measure for respiratory care education programs. Most ORCB members felt the position statement was a step backward. One of the reasons for the change in monitoring cited in the CoARC position statement was that programs have no control over graduates taking the RRT examination since no state requires the examination for licensure. It was at this point that the ORCB began to seriously consider a rules change to require RRT examination as the minimum licensure examination, and directed the Rules Committee to look into drafting a new rule.

"What steps did the ORCB take next?"

Marc Mays: The ORCB wanted to be sure to involve as many stakeholders as possible in the process, and started by inviting educators from Ohio's programs to the ORCB's regular meeting in August 2010. Those in attendance heard from the ORCB that we strongly believed that failure to have a measure that holds educational programs accountable for the exam outcome that represents the level to which they purport to prepare students is not acceptable. The majority of those present supported the concept, some very strongly. In addition, the ORCB formed the Ohio Examination Workgroup in December 2010. Respiratory therapy managers and educators, hospital human resources managers, the Ohio Hospital Association, the OSRC, CoARC, the NBRC and the AARC were all invited to participate, and only the AARC and CoARC declined participation in the Workgroup.

"What role did the Workgroup play in advancing the rule change?"

Sarah Varekojis: Among other things, the Workgroup was charged to determine the current needs and trends related to minimum competency expectations of the workforce.

Sarah Varekojis

Herb Douce and I developed and administered a survey of respiratory therapy employers in Ohio to assess the impact of and need for requiring the RRT for initial licensure. The results of the survey were shared, and the Workgroup came to the following conclusions:

Herb Douce

• CRTs practicing in Ohio are over-utilized, as evidenced by more than 50% of respondents indicating that licensed respiratory care professionals with the CRT credential practice in Ohio at an advanced level, defined as engaging in all 10 of the advanced competencies identified in the AARC's White Paper on the RRT Credential.

• Employers that require RRT for all employees in Ohio report overwhelmingly positive impacts on their department or organization, including improved patient care, increased patient safety, reduced liability, and enhancing professionalism, all of which result in an increased quality of care provided at these facilities and organizations.

• Negative impacts of requiring RRT anticipated by employers in Ohio that do not currently require the RRT have not been realized by those that do. Difficulty filling future staffing vacancies has not been experienced, and any increase to staffing costs was reported to outweigh the positive impacts of a higher credential level for staff.

At the conclusion of the 3rd Workgroup meeting, participants were asked about their position on the ORCB proposal to require successful completion of the RRT to qualify for an initial Ohio respiratory care license. The representative from the Ohio Hospital Association indicated a neutral position, the NBRC representative indicated opposition to the proposal, and all other participant indicated their support of the proposal, including the OSRC representatives. It is important to note that the AARC and CoARC did not have representatives present at this meeting, and that the AARC indicated through several letters to the ORCB and through several subsequent public testimonies they were not in support of this rules change.

"What role did the OSRC play in advancing the rule change?"

Sarah Varekojis: In 2010, the OSRC Board of Directors, under then-President Craig Black, PhD, RRT, RCP, FAARC (CoBGRTE member), was made aware of the ORCB's intention to review the current licensing. The OSRC felt that the change to the licensing examination requirement was aligned with the OSRC mission to "promote and advance the professionalism and practice of respiratory care in the state of Ohio". The OSRC Board of Directors unanimously voted to approve a resolution in support of the changes being considered by the ORCB. This resolution was forwarded to the ORCB in August of 2010. The OSRC was also actively involved in the Workgroup, with five former and current Board members participating, including two CoBGRTE members, and all OSRC representatives supported the recommendation of the Workgroup that the ORCB move forward with the rules change. I also represented the OSRC's support of the rules change at several public hearings, including the final hearing before the Joint Committee on Agency Rule Review (JCARR), a joint committee of members from the Ohio House of Representatives and the Ohio Senate, in February 2013.

"Were other OSRC members were involved planning for the rule change?"

Craig Black: Elizabeth (Beth) Cooper was President of the OSRC during 2011 and 2012, and was very instrumental in determining the representatives to the Workgroup. In addition, she led a discussion about the current status of the rule change at every OSRC Board meeting during her term and she worked hard to identify supporters and encourage OSRC members to present testimony at the public hearings.

At the ORCB public hearing held in February 2013, testimony in support of the change was presented by the following OSRC members: Beth Cooper (Cincinnati Children's Hospital Medical Center), Sarah Varekojis, Herb Douce, Susan Ciarlariello (Dayton Children's), Georgianna Sergakis (The Ohio State University), Nancy Colletti (Kettering College), and I (University of Toledo). In addition, the room was filled with many other OSRC members that did not provide oral testimony, but were physically present to indicate their support of the rule change.

"When does the new rule go into effect?"

Marc Mays: Since JCARR did not find any reason to oppose the rule change, the final rule filing occurred on March 14, 2013, and the new rule goes into effect in January 2015. It is important to note that the new rule will have no impact on persons currently licensed in the State of Ohio or persons currently licensed in other states prior to the full implementation date in January 2015. The new rule essentially aligns the core goals and objectives of accredited respiratory care education with the competencies that programs are intended to achieve by preparing graduates to practice as RRTs. This rule, while not supported by the NBRC, the AARC and a few individuals, was supported by the majority of stakeholders involved in this process. Further, surveys found that trends in Ohio seem to support a move toward higher competency expectations at the point of graduation as verified by the RRT credential. Nationally, similar surveys also seem to support this expectation by 2015. The Board understood that this action was somewhat controversial and Ohio would be the first state to consider such an initiative. However, the Board felt strongly that these rules were necessary to assure greater consistency in the competency expectations of our future graduates from respiratory care educational programs.

LOS ANGELES COUNTY DEPARTMENT OF HEALTH SERVICES
PULMONARY FUNCTION TECHNICIAN EXEMPTION LANGUAGE
Senate Bill 305 (Price)

Section 3765 of the Business and Professions Code is amended to read:

3765. Acts Not Prohibited

This act does not prohibit any of the following activities:

(a) The performance of respiratory care that is an integral part of the program of study by students enrolled in approved respiratory therapy training programs.

(b) Self-care by the patient or the gratuitous care by a friend or member of the family who does not represent or hold himself or herself out to be a respiratory care practitioner licensed under the provisions of this chapter.

(c) The respiratory care practitioner from performing advances in the art and techniques of respiratory care learned through formal or specialized training.

(d) The performance of respiratory care in an emergency situation by paramedical personnel who have been formally trained in these modalities and are duly licensed under the provisions of an act pertaining to their specialty.

(e) Respiratory care services in case of an emergency. “Emergency,” as used in this subdivision, includes an epidemic or public disaster.

(f) Persons from engaging in cardiopulmonary research.

(g) Formally trained licensees and staff of child day care facilities from administering to a child inhaled medication as defined in Section 1596.798 of the Health and Safety Code.

(h) The performance by a person employed by a home medical device retail facility or by a home health agency licensed by the State Department of Health Services of specific, limited, and basic respiratory care or respiratory care related services that have been authorized by the board.

<u>(i) The performance of pulmonary function testing by persons who are currently employed by Los Angeles county hospitals and have performed pulmonary function testing for at least 15 years.</u>

Pulmonary Function Testing Exemption Never Enacted

1989 LANGUAGE

§ 3762.
Nothing in this chapter is intended to limit, preclude, or otherwise interfere with the practices of other licensed personnel in carrying out authorized and customary duties and functions. Further, nothing in this chapter is intended to limit, preclude, or otherwise interfere with the practice of those personnel who are employed to perform **specific** pulmonary diagnostic and testing techniques under medical direction.

Amendments:
1986 Amendment: Added "pulmonary" in the second sentence.
1994 Amendment: Deleted the former second sentence which read: "Further, nothing in this chapter is intended to limit, preclude, or otherwise interfere with the practice of those personnel who are employed to perform specific pulmonary diagnostic and testing techniques under medical direction."

2012 LANGUAGE

§ 3762.
Nothing in this chapter is intended to limit preclude, or otherwise interfere with the practices of other licensed personnel in carrying out authorized and customary duties and functions.

History: Added Stats 1982 ch 1344 § 1, operative July 1, 1983. Amended Stats 1986 ch 1347 § 6; Stats 1994 ch 1274 § 25 (SB 2039).

Notes:

- There is no evidence that any regulatory action was ever taken to define "specific." Therefore, it may be presumed that this section was never officially enacted.

- In 1994, SB 2039 deleted this exemption. There were numerous amendments in this bill, with the focus on a provision to require Administrative Law Judges to revoke licensees with sex-related offenses. In fact, that appears to have been the focus of all testimony and letters of support. There are absolutely NO references, not even an initial request, to delete the pulmonary exemption in the Board's files. The California Society for Respiratory Care (CSRC) supported this bill.

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Review of Unlicensed Personnel in The Practice of Pulmonary Function Testing

SUMMARY

In 2001, the Respiratory Care Board (Board) noted its concern with the unlicensed practice of respiratory care in many areas, including Pulmonary Function Testing (PFT), in its report to the Joint Legislative Sunset Review Committee (JLSRC). In response, the JLSRC included in its 2002 recommendations to support the Board's effort to review the function and skill of currently unlicensed technicians and further study to determine the need for regulation of these technicians. This paper documents the Board's findings.

PFT employs a variety of diagnostic tests useful in: (1) identifying and classifying certain types of lung disease, (2) evaluating the effectiveness of treatment, (3) documenting the progress of pulmonary disease, (4) providing a yardstick for compensating the disabled, and (5) assessing risk factors prior to surgery. In order for pulmonary function tests to be useful, there must be assurance that they have been properly performed on accurate, well-calibrated equipment by educated and trained personnel.[1]

PFT is a component of the respiratory care scope of practice, requiring licensure as a respiratory care practitioner **(RCP).** However, the Board estimates there are 163 unlicensed personnel performing all levels of PFT in laboratories **plus** hundreds, possibly thousands of unlicensed personnel performing basic and limited PFT in physician offices, jeopardizing the health, safety and welfare of California consumers.

The Board has received increasing reports of inaccurate and unreliable PFT results and infection control guidelines not being followed. ***Inaccurate and unreliable PFT results has been the primary concern among the respiratory medical community.*** Another concern is the technician's inability to recognize hazards and properly intervene if necessary. Though it is an extremely rare occurrence, failure to react and react properly could lead to permanent patient injury or even death. Inaccurate test results can lead to the improper diagnosis and treatment of a patient if not detected, as well as add to health care costs.

The Board believes the active promotion of Chronic Obstructive Pulmonary Disease (COPD) testing through "office spirometry," has contributed to the growing increase in unlicensed personnel performing "basic and limited" PFTs. In 2000, the National Lung Health Education Program (NLHEP) published a consensus statement on Office Spirometry for Lung Health Assessment in Adults with recommendations to support prevention of and early intervention for COPD. The NLHEP recommends primary-care physicians perform an office spirometry test in patients with respiratory symptoms in order to detect asthma or COPD or a global health (risk) assessment. The NLHEP notes that although simple to learn, spirometry is an effort-dependent test that requires a cooperative patient and a ***trained person*** capable of administering the test.

While "standards" for training and education of pulmonary personnel as well as oversight by medical directors exist, standards are not enforceable and not all physicians follow such standards. "Supervision" is often referred to in both regulations and standards, but rarely, if ever, enforced. Generally, supervision consists of a physician's overall direction and physical presence at the site is not required. Physician responsibility or liability is virtually non existent if challenged; the error of an unlicensed person who is not properly supervised rarely, if ever, results in physician discipline (though cases of severe patient harm may be tried in the civil arena).

The U.S. Food and Drug Administration's MAUDE database reports negligence and failing to follow infection control

[1] Thomas A. Barnes. *Respiratory Care Practice.* Chicago: Year Book Medical Publishers, Inc., 1988

guidelines in relation to PFT. Medicare has issued two “fraud alerts” for labs submitting claims to Medicare for tests either not ordered by the referring physician of record or not performed at all. There was also litigation by a former physician of a pulmonary lab claiming the lab failed to follow generally accepted standards for spirometry testing as promulgated by the American Thoracic Society specifically, failing to ensure proper calibration of the testing equipment, failing to perform the recommended three successive tests, and allowing medical assistants who were not properly trained to perform these tests. As a result, it was alleged, the spirometry testing that was performed yielded inherently unreliable data, and therefore charging the Medicare program for poor quality tests violated the False Claims Act. However, the judge hearing the case found that there was not enough evidence to show that the defendants *knowingly* submitted reimbursement claims for worthless services.

The National Institute for Occupational Safety and Health (NIOSH), an affiliate of the Centers for Disease Control and Prevention (CDC), and the American Association for Respiratory Care (in connection with the NLHEP) have developed/are developing 1-2 day courses as it relates to spirometry training to increase reliable results.

The Board is recommending that exemptions to the Respiratory Care Practice Act be provided to allow credentialed personnel to perform PFT and non-credentialed personnel with board-approved (i.e. NIOSH/AARC) training and direct supervision to perform the most limited and basic PFT. The Board believes this recommendation is the least burdensome method in addressing the issue of greatest concern, competency. This alternative supports the early detection and intervention of COPD and prevents unemployment of competent persons. This alternative will increase accurate diagnoses which will provide greater protection for California consumers and reduce health care costs. If approved by the Legislature, the Board further recommends that it review the effectiveness of the exemptions, within 4 years from the date they take effect, to determine if amendments are needed or regulation of this specific practice is warranted.

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Review of Unlicensed Personnel in The Practice of Pulmonary Function Testing

April 2005

ISSUE

Pulmonary function testing **(PFT)** is a component of the respiratory care scope of practice, requiring licensure as a respiratory care practitioner **(RCP),** however a growing number of unlicensed personnel are conducting pulmonary function tests, most predominantly in physician offices, which has resulted in an increase in unreliable PFT results jeopardizing the health, safety and welfare of California consumers.

PULMONARY FUNCTION TESTING

PFT is useful in: (1) identifying and classifying certain types of lung disease, (2) evaluating the effectiveness of treatment, (3) documenting the progress of pulmonary disease, (4) providing a yardstick for compensating the disabled, and (5) assessing risk factors prior to surgery. In order for pulmonary function tests to be useful, there must be assurance that they have been properly performed on accurate, well-calibrated equipment by educated and trained personnel.[1]

PFT has historically been performed primarily in hospital or independent laboratories and is occurring more often within physician offices. Patients are coherent and alert during testing except in extremely rare instances when specialized PFT is needed in critical cases, such as in an intensive care unit or the PFT causes an adverse reaction (generally caused by inappropriate testing techniques).

BACKGROUND

In 2001, the Board began to receive an unusual amount of inquiries as to the qualifications required to perform PFT as well as many concerns regarding unlicensed personnel producing unreliable PFT results, which prompted it to take a closer look at issues surrounding PFT. One of its initial findings was that prior to 1995, the Respiratory Care Practice Act (**RCPA)** included an exemption for unlicensed personnel to perform "specific" pulmonary diagnostic and testing techniques under medical direction. However, "specific" was never defined. As a result of SB 2039 (statutes of 1994), this exemption was repealed, effective January 1, 1995, establishing the practice of pulmonary function testing solely within the scope of a respiratory care practitioner. While the Board, made up of almost entirely new members since 1995, was not familiar with this prior exemption, no information could be found as to why the exemption was repealed in 1995.

Also in 2001, the Board noted its concern with the unlicensed practice of respiratory care in many areas, including PFT, in its report to the Joint Legislative Sunset Review Committee (JLSRC). In response, the JLSRC included in its 2002 recommendations to support the Board's effort to review the function and skill of currently unlicensed technicians and further study to determine the need for regulation of these technicians. While the Board is aware of a growing number of unlicensed personnel performing PFTs, it has not sought civil or criminal remedies pending review of the matter.

STANDARDS

California Thoracic Society (CTS) - Pulmonary Physiology Laboratory Personnel Qualifications

The CTS (chapter of the American Thoracic Society) issued a position paper in 1987 with revisions made as recent as 2004, titled "Pulmonary Physiology Laboratory Personnel Qualifications" (**Attachment 1,** also available at: http://www.thoracic.org/chapters/california_adobe/physiology.pdf). In reviewing the practice of PFT, the Board relied

[1] Thomas A. Barnes. *Respiratory Care Practice.* Chicago: Year Book Medical Publishers, Inc., 1988

upon these guidelines as a basis for evaluating the need for regulation of personnel performing PFT at each of these levels. The position paper provides:

> "High quality testing provided in a safe manner requires properly functioning and standardized equipment operated by qualified personnel, who perform under the medical direction of a physician who is knowledgeable in pulmonary physiology and its testing procedures. Such personnel might include pulmonary technologists, respiratory care practitioners, registered nurses or others with similar training. Technical personnel in such a laboratory must meet minimum standards of competence, and should achieve this through standardized education and training, followed by appropriately supervised clinical experience. Continuing proficiency is assured by continuing education and ongoing assessment of skills by the Medical Director of the laboratory."

The paper recommends minimum education to consist of a high school diploma, one or more years of college in math, science and/or health preferred, as well as technical experience in laboratory testing, electronics, and/or computer science. It also provides that educational content specific to pulmonary function testing should include 12 components, ranging from equipment operation and maintenance, to normal values; statistical methodology, to risks of testing and response to adverse reaction.

The paper categorizes the practice of pulmonary function personnel and related testing into three levels, each with recommended training, experience, and/or credentials. Briefly, they are as follows:

1. Senior/Supervising Pulmonary Technologist: Advanced Testing *(Percutaneous arterial catheterization, exercise testing, bronchial challenge, hypercapnic/hypoxic ventilatory response, lung compliance, tonometry)* The CTS recommends advanced credentials (i.e. Registered Pulmonary Function Technologist or Registered Cardiopulmonary Technologist).

2. Pulmonary Technologist: Simple Tests *(Diffusing capacity, body plethysmography, blood sampling and gas analysis)* The CTS recommends the Certified Pulmonary Function Technologist credential.

3. Pulmonary Technician/Trainee: Basic and Limited Tests (***Spirometry and lung volumes***) The CTS recommends that personnel meet the minimum education noted above.

American Thoracic Society (ATS) - Standards

The ATS has 7 various statements, guidelines and reports related to the clinical aspects of pulmonary function testing which are available on their website (http://www.thoracic.org/statements/) and have been published in the *American Journal of Respiratory and Critical Care Medicine*. The following standards are recognized nationally:

- ATS Statement: Cardiopulmonary Exercise Testing
- Guidelines for the Six-Minute Walk Test
- Guidelines for Methacholine and Exercise Challenge Testing
- Recommendations for Standardized Procedures for the Online and Offline Measurement of Exhaled Lower Respiratory Nitric Oxide and Nasal Nitric Oxide in Adults and Children
- Single Breath Carbon Monoxide Diffusing Capacity
- Standardization of Spirometry **(Attachment 2)**
- Lung Function Testing: Selection of Reference Values & Interpretive Strategies

COPD AWARENESS/OFFICE SPIROMETRY

The Board believes the active promotion of COPD testing through "office spirometry," has contributed to the growing increase in unlicensed personnel performing “basic and limited” PFTs.

In 2000, the National Lung Health Education Program (NLHEP) published a consensus statement on Office Spirometry for Lung Health Assessment in Adults with recommendations to support prevention and early intervention of Chronic Obstructive Pulmonary Disease (COPD) (**Attachment 3)**. Recommendations include:

* Primary-care physicians should perform an office spirometry test in patients with respiratory symptoms such as chronic cough, sputum production, wheezing, or dyspnea on exertion in order to detect asthma or COPD.
* Primary-care physicians may perform an office spirometry test for patients who desire a global health assessment (risk assessment).

* A new category of spirometers, office spirometers, should be available for use in the primary-care setting. Each new model must successfully pass a validation study. (The "rationale" for this recommendation states, "Traditionally, spirometry has been used as a diagnostic test, with the usefulness and accuracy of spirometry measurements depending on both the equipment and proper test performance. Although simple to learn, spirometry is an effort-dependent test that requires a cooperative patient and a ***trained person*** capable of administering the test. Specific recommendations have been developed by the American Thoracic society and other professional organizations to ensure accurate and reproducible measurements when using diagnostic spirometers. In many cases, a diagnostic spirometer that meets ATS standards will be the preferred choice...).
* The current ATS recommendations regarding measures to avoid cross-contamination should be followed by those using office spirometers.
* A new billing code should be created for office spirometry tests.

The statement also provides the need for further research. "There is insufficient published evidence related to many of the technical and procedural issues associated with the above recommendations for office spirometry. More detailed information is needed about the following issues: levels of training required to obtain results of acceptable quality; levels of inaccuracy and imprecision; reliability; durability; and the necessary frequency and type of calibration checks....Research in these areas is strongly encouraged in order to validate and improve the above recommendations."

An article published in the Summer 2004 issue of the ATS *Pulmonary Function Laboratory Registry Newsletter* titled, “Primary Care Office Spirometry,” **(Attachment 4**) responds to the NLHEP's promotion to create a global educational campaign to raise awareness about COPD and encourage spirometry in the primary care setting. The article discusses the mission of the National Lung Health Education Program with support from other organizations including the American Thoracic Society and goes on to note several concerns in relation to this mission including:

- a new type of spirometer, the "office" spirometer and its ability to really replace experienced technicians in evaluating spirometric tracings in terms of assuring test acceptability and repeatability.

- "the NLHEP recommendations for training of spirometric technicians is not well defined. This is a marked distinction from the specific ATS recommendation of at least a year of post high school in formal training and the AARC clinical practice guideline recommendations for certification as a registered pulmonary function technologist...Sub-optimally trained technicians can have significant impact on the quality of the test. ***A large study from New Zealand assessing office spirometry involved only on the job trainees... and this was associated with large numbers of unacceptable tests. This study also found that interpreters of pulmonary function tests, if not properly trained, can misdiagnose tests up to 50% of the time."***

- "a dramatic increase in spirometry billing will not go unnoticed by payers such as Medicare. This could prompt a whole review of spirometry (and perhaps other PFTs) reimbursement. If we find ourselves advocating office spirometry performed by minimally trained office workers and interpreted by primary care physicians, a review by payers could have detrimental effects on both technical and professional payments."

WORKFORCE

Many physician offices and some pulmonary laboratories are under the false presumption that licenses are not required to perform PFT and some also neglect to recognize national standards which also recommend staff possess private credentials.

Great technological advancements have been made with pulmonary function equipment which is a major contributor to the trend of unlicensed personnel performing PFT. A number can be produced from the equipment with minimal instruction to the operator. The trend today with many pulmonary function instruments and tests performed by unlicensed personnel is to produce a number...never minding its source. What results, in many cases where tests are performed by unqualified personnel that lack education in physiology, are erroneous numbers. Many unlicensed personnel (often referred to as medical assistants) have little, if any, understanding that test results, even for the most basic and limited PFT, are effort-dependent as well as technically-dependent upon instruction and coaching patients for reliable results. Because PFT requires “assessment” medical assistants are not legally authorized to perform this testing. Furthermore, there are concerns that infection control guidelines are not being followed.

PFT Credentials

The National Board for Respiratory Care, Inc. **(NBRC)** is a voluntary health certifying board which was created in

1960 to evaluate the professional competence of respiratory therapists. The NBRC is a member of the National Organization for Competency Assurance (NOCA), and its examination programs are accredited by the National Commission for Certifying Agencies (NCCA). Accreditation by the NCCA signifies unconditional compliance with stringent testing and measurement standards among national health testing organizations.

The NBRC provides nationally recognized exams, the most notable being the entry-level respiratory examination used by 48 states as a prerequisite for licensure. The NBRC also offers two credentials in pulmonary function testing upon completion of their exams titled, the Certified Pulmonary Function Technologist (**CPFT**) and the Registered Pulmonary Function Technologist (**RPFT**). There are a number of ways to qualify for the CPFT examination ranging from as little as 2 years of clinical experience in the field of pulmonary technology, to as much as 2 years of postsecondary education (**Attachment 5**). The only requirement to qualify for the advanced RPFT examination is the possession of a CPFT credential.

As of August 2004, there were 679 "credentialed" pulmonary technologists in California; 372 CPFTs and 307 RPFTs (credentialed RPFTs also hold CPFT credentials though this count is not reflected in the 372 CPFT figure in order to avoid duplication of the number of technologists). Of the 679 "credentialed" pulmonary technologists:

74% are also licensed RCPs;
10% previously held licensure as a RCP, and
16% never held licensure as a RCP.

Interestingly, 2 of the current credential holders had their RCP licenses revoked by the Board; one as a result of a criminal conviction, and the other for walking off the job [as an RCP] on two separate occasions without any notification. [The Board notified the NBRC of this discipline and the NBRC is currently proceeding with disciplinary hearings].

Prior to July 2002, the CPFT and RPFT credentials were issued indefinitely with no expiration date. Credentials issued on or after July 1, 2002 are required to "renew" every five years, thus the first renewal period will be July 2007. Therefore, it is believed that of the 679 credentials issued since July 1984, only 2/3 (or 450) of the credential holders are actively practicing.

Estimated Number of Licensed and Unlicensed Personnel

In Pulmonary Function Laboratories

A search of yellow pages on the Internet identified just over 200 independent pulmonary labs and/or pulmonary medical groups with the word "pulmonary" in their business name. It is estimated there are an additional 250 labs within hospitals throughout California. Results from the Board's survey issued in 2004 (discussed later), indicates an average of 1.5 staff are employed (on any given day) at these sites (ref: question 10). Based on this vague data, it is estimated that there are **675 individuals performing pulmonary function testing (at all three levels)** in pulmonary function laboratories. Following are rough estimates on how this figure is broken down by personnel-type:

185 licensed RCPs with a CPFT credential
152 licensed RCPs with the RPFT credential
150 licensed RCPs with no pulmonary credentials
25 other licensed professionals (i.e. registered nurse)
63 unlicensed personnel with a CPFT credential
50 unlicensed personnel with a RPFT credential
50 unlicensed personnel with no credentials

Total: 675 (512 or 76% licensed; 163 or 24% unlicensed)

In Physician Offices

The national promotion of "office spirometry" by primary care physicians (and their staff) has also dramatically increased the performance of PFTs in physician offices (discussed below under "COPD AWARENESS"). The American Board of Medical Specialties reports as of June 2004, that there are 6,574 physicians certified in Family Practice in California. "Basic and limited" PFT performed in physician offices is often performed by unlicensed personnel. However, the Board is unaware of how many physicians are actually providing these services and cannot begin to estimate the number of unlicensed personnel in physician offices who are performing PFT.

RCP Shortage

Currently, the demand for respiratory therapists is greater than the supply. The National Bureau for Labor Statistics reports in its *2004-05 Occupation Outlook Handbook* that "Employment of respiratory therapists is expected to increase faster than the average for all occupations through the year 2012, because of substantial growth in numbers of the middle-aged and elderly population—a development that will heighten the incidence of cardiopulmonary disease."

In the late 90s, employers and educational programs noted a sharp decline in the number of respiratory care practitioners and students entering respiratory care programs. While as recent as in 2003, education programs have seen improvements in enrollment, employers continue to report difficulty in finding respiratory therapists to fill jobs. Some employers have reported that after failed attempts to find respiratory therapists, they have turned to other licensed and unlicensed personnel to fill positions.

The Board has received equal reports citing that pulmonary function laboratories are fully staffed as well as reports that it is difficult to find RCPs to fill PFT positions.

Unregulated Personnel

The Board estimates there are 163 unlicensed personnel performing all levels of PFT (50 of which, also do not hold any type of credential) in laboratories plus hundreds, possibly thousands of unlicensed personnel performing basic and limited PFT in physician offices. These personnel have no regulatory oversight. There are no requirements for minimum education, training, experience, or continuing education and there is no standard or uniform standard for competency. Most unlicensed personnel, predominantly in independent facilities and physician offices, are not fingerprinted to identify criminal history. Moreover, there is no mechanism for unlicensed personnel, in which to rescind practice privileges in the event of incompetency, negligence, etc...

While the CTS has "standards" for training and education of pulmonary personnel as well as oversight by medical directors **(Attachment 6)**, standards are not enforceable and not all physicians follow such standards. "Supervision" is often referred to in both regulations and standards, but rarely, if ever, enforced. Generally, supervision consists of a physician's overall direction and physical presence at the site is not required. Physician responsibility or liability is virtually non existent if challenged; the error of an unlicensed person who is not properly supervised rarely, if ever, results in physician discipline (though cases of severe patient harm may be tried in the civil arena).

Medical Assistants

Many, if not all, of the "unlicensed and non-credentialed personnel" are referred to as medical assistants. A medical assistant is defined by Business and Professions Code, section 2069, as a person who may be unlicensed, who performs basic administrative, clerical, and technical supportive services as authorized and under the supervision of specific licensed professionals. The regulatory oversight of medical assistants is limited to approving formal training and certifying programs and defining their scope of practice. The training required to use the title "medical assistant" may be as simple as training provided in a medical office or through a 1-2 year formal program. In a medical office, training is provided under a licensed physician or podiatrist who shall ascertain the proficiency OR under a RN, LVN, PA, or *qualified medical assistant* acting under the direction of a licensed physician or podiatrist.

The most common "basic/limited" type of PFT performed by unlicensed personnel is spirometry testing which requires quality ***assessment*** of maneuvers to obtain results as well as ***assessment*** of the results (the latter which may be interpreted by the technician or the physician) as outlined in the ATS' *Standardization of Spirometry* 1994 guidelines (Attachment 2).

Another ATS position paper titled, *"Quality Assurance in Pulmonary Function Laboratories"* provides recommendations for quality control of common pulmonary function tests including spirometry. The paper discusses the difficulty in developing proficient testing for spirometry, lung volumes and diffusing capacity, because PFT "utilizes the 'whole' person as part of the testing process, not quantifiable 'products' such as serum or pleural fluid." Recommendations for proficiency testing include keeping a log of PFT results, testing health subjects annually and ***assessing*** "the reference value equations that have been selected for each laboratory test."

An article published in the Medical Board of California's October 2001 *Action Report* titled, "Is Your Medical Assistant Practicing Beyond His or Her Scope of Training?" **(Attachment 7)** states,

"**An unlicensed person may not** diagnose or treat or **perform any task that** is invasive or ***requires assessment*** [emphasis added]....

In summary, medical assistants are not licensed, and it is not legal to use them to replace highly trained, licensed processionals. The medical assistant is present to assist and perform support services in the physician's office.

Those duties must be appropriate with the medical assistant's required training, which cannot be compared with licensed nurses or other health professionals who meet rigorous educational and examination requirements."

Therefore, holding the title “medical assistant” does not qualify or provide the legal authority to perform PFT.

PATIENT HARM

Over the years there has been a marked increase in unlicensed and unqualified personnel performing pulmonary function testing as well as complaints of inaccurate and unreliable PFT results and infection control guidelines not being followed. ***Inaccurate and unreliable PFT results has been the primary concern among the respiratory medical community.*** Another concern is the technician's inability to recognize hazards and properly intervene if necessary. Though it is an extremely rare occurrence, failure to react and react properly could lead to permanent patient injury or even death.

In 1989, the California Thoracic Society **(CTS)** implemented an educational program for hospital-based pulmonary function laboratories in California. The goal of the program was to enhance patient care through quality control for measurements of spirometry, flow-volume loops, and diffusing capacity. The program was short-lived due to limited CTS resources. Currently, however, hospital-based pulmonary laboratories appear to be of least concern as some control measures do exist (i.e. accrediting bodies, Department of Health Services). Whereas, independent laboratories and physician offices have no facility oversight.

Inaccurate test results can lead to the improper diagnosis and treatment of a patient if not detected, as well as add to health care costs. Unreliable test results lead to additional testing which results in additional costs. In the September 2001 issue of the American College of Chest Physicians's quarterly scientific publication, *Pulmonary Perspectives*, an article entitled, "Is This Pulmonary Function Test Interpretable?" notes that while the ATS has made it easier to verify tests are of enough quality to interpret, there is still "a tendency to neglect the details of quality assurance and just 'eyeball' the tests" leading to misinterpretation and potentially misdiagnosis. The article notes that while criteria for performing a test is very helpful, it is important to recognize they "are not a substitute for checking the internal consistency among tests, ***good technical expertise on the part of the person performing the test***, visually examining the graphical results, ***and clinical judgement***. The article also notes that "most pulmonologists are not present at the time of the testing..."

AARC Clinical Guidelines

In various "clinical guidelines" issued by the American Association for Respiratory Care **(AARC)**, several risks and/or hazards are associated with various types of PFT (http://www.rcjournal.com/online_resources/cpgs/cpg_index.asp):

- Infant/Toddler Pulmonary Function Tests (ITPFTs) (1995): vomiting with aspiration with consequent apnea and laryngospasm and/or bronchospasm (the forced deflation technique requires tracheal intubation); pneumothorax (collapse of the lung); increased intracranial pressure; loss of airway patency; transmission of contagion via improperly cleaned equipment or as a consequence of the inadvertent spread of droplet nuclei or body fluids (patient-to-patient or patient-to-technologist); oxygen desaturation due to a worsening of ventilation-to-perfusion mismatch and hypoventilation as a consequence of sedation and/or positioning or interruption of oxygen therapy or failure to preoxygenate the patient prior to performing the forced deflation technique; temporary loss of distending pressure.

- Pulmonary Rehabilitation (2002): During exercise the cardiovascular and ventilatory systems must be able to respond to increased demands. Exercise can lead to muscle or ligament injuries.

- Body Plethysmography (2001): Improper panting technique may result in excessive intrathoraxic (inner-chest) pressures; prolonged confinement in the plethysmograph chamber could result in hypercapnia or hypoxia; transmission of infection through improperly cleaned equipment.

- Exercise Testing for Evaluation of Hypoxemia and/or Desaturation (2001): electrocardiographic abnormalities, severe desaturation, angina (a heart condition marked by uncontrollable attacks of chest pain due to reduced oxygen to the heart), hypotensive responses drop in blood pressure, lightheadedness, rise in blood pressure, mental confusion or headache, cyanosis, nausea or vomiting, muscle cramping; hazards associated with arterial puncture, arterial cannulation, and pulse oximetry; tissue injury as a result of probe misuse.

- Assessing Response to Bronchodilator Therapy at Point of Care (1995): bronchoconstriction; airway collapse; paroxysmal (uncontrollable attack) coughing with or without syncope (loss of consciousness caused by insufficient blood to the brain); inherent hazards or complications of specific assessment procedures (i.e. arterial puncture, esophageal balloons, forced exhalations).

- Methacholine Challenge Testing (2001): bronchoconstriction, hyperinflation, severe coughing; hazards associated with spirometry, such as dizziness, light-headedness, chest pain; possible exposure of testing personnel to provocative substance.

- Static Lung Volumes (2001): Infection may be contracted from improperly cleaned tubing, mouthpieces, manifolds, valves, and pneumotachometers; hypoxemia may result from interruption of oxygen therapy in the body box; ventilatory drive may be depressed in susceptible subjects as a consequence of breathing 100% oxygen during the nitrogen washout; hypercapnia (abnormally high level of carbon dioxide in circulating blood) and/or hypoxemia (below normal oxygen content in arterial blood) may occur during helium-dilution FRC determinations as a consequence of failure to adequately remove carbon dioxide or oxygen to the rebreathed gas.

- Incentive Spirometry (1991) : also referred to as sustained maximal inspiration (SMI), is a component of bronchial hygiene therapy. Ineffective unless closely supervised or performed as ordered; hyperventilation; barotrauma (emphysematous lungs); discomfort secondary to inadequate pain control; hypoxia secondary to interruption of prescribed oxygen therapy if face mask or shield is being used; exacerbation of bronchospasm; fatigue.

- Spirometry (1996): pneumothorax (collapse of the lung); increased intracranial pressure; syncope, dizziness, light-headedness; chest pain; paroxysmal coughing; contraction of nosocomial infections; oxygen desaturation due to interruption of oxygen therapy; bronchospasm.

- Pulse Oximetry (1991): Pulse oximetry is considered a safe procedure, but because of device limitations, false-negative results for hypoxemia (below normal oxygen content in arterial blood) and/or false-positive results for normoxemia or hyperoxemia may lead to inappropriate treatment of the patient. In addition, tissue injury may occur at the measuring site as a result of probe misuse (i.e. pressures sores, electrical shock and burns).

ATS Standards

Other concerns associated with PFT is infection control. Infection control is discussed in the ATS' "Standardization of Spirometry" paper (Attachment 2) and provides that there are two major types of infection control:

> "Direct contact: There is potential for transmission of upper respiratory disease, enteric infections, and blood-borne infections through direct contact. Although hepatitis and HIV contagion are unlikely via saliva, this is a possibility when there are open sores on the oral mucosa, bleeding gums, or hemoptysis. The most likely surfaces for contact are mouthpieces and the immediate proximal surfaces of valves or tubing.
>
> Indirect contact: There is potential for transmission of tuberculosis, various viral infections, and, possibly, opportunistic infections and nosocomial pneumonia through aerosol droplets. The most likely surfaces for possible contamination by this route are mouthpieces and proximal valves and tubing."

The paper details how certain pieces of equipment should be sterilized or discarded after each use.

FDA MAUDE Database

The U.S. Food and Drug Administration compiles reports of events associated with medical equipment into their MAUDE database. Examining a few reports associated with PFT equipment provides some insight to events taking place.

Patient Ingests Filter/Infection Control Questioned

This report provides that at a hospital the patient was inhaling and exhaling as part of a PFT, when the "filter" of the device became dislodged and was ingested by the patient. While the device company's instruction for use included changing the filter for each new patient, the hospital worker stated that the hospital was not doing so and the filter became overused and dislodged. When the hospital worker was questioned on the possibility of health hazard to patients on the use of the same filter and germs propagation from one patient to the other, he replied that only patients with TB and other diseases could have cause to spread infections.

Device Operation Effected Care of Patients

This report describes how a physician became aware that his spirometer equipment was providing incorrect results intermittently and cites that "the device has effected the care of [the Doctor's] patients." It provides that if "the malfunction is not recognized or is ignored by the user, it might lead to an erroneous diagnosis."

Device Usefulness Found by Comparing Hospital Readings

This report provides that the "spirometer used in the office gives much different readings than the spirometer hospitals use." The report implies that the device failure is based solely on the fact that patients seen at the hospital "minutes later" received different results and that no daily equipment checks were being performed.

Respiratory Therapy Called to Assess Problem

This report notes that there was a serious problem with the source for oxygen while performing a PFT. "Respiratory Therapy was notified; with their help, it was concluded that system was letting diffusion gas back into the wall system."

Litigation

Following is a civil suit that emerged as a result of negligence associated with PFT:

Osmun v. Pavonia Medical Association: A thirty-eight year old woman underwent a pulmonary function test by the defendant medical group, which included drawing an arterial blood sample. The technician drew blood from the single mother's brachial artery rather than from her radial artery, because it had a stronger pulse. The needle puncture in the crook of her arm injured a nerve, causing chronic pain. The technician said that she generally chose the brachial nerve for drawing specimens, but the plaintiff contended that this showed that she deviated from accepted standards of care on a widespread basis. According to published accounts, the verdict for the plaintiff was $1.15 million [source: Healthcare Providers Service Organization, May 1998 Legal Case Study, http://www.hpso.com/case/cases_prof_index.php3?id=21&prof=Phlebotomist].

REIMBURSEMENT

Medicare/Medicaid define respiratory care practitioner services to include (but not limited to), direct and indirect pulmonary care services; direct and indirect respiratory care procedures, including the administration of diagnostic and therapeutic agents necessary to implement treatment, disease prevention, pulmonary rehabilitation or diagnostic regimens prescribed by a physician; observation and monitoring of signs and symptoms, general behavior and physiological responses to respiratory care treatment and diagnostic testing.

In another report published by the NLHEP in June 2003 titled, *"Simple Office Spirometry for Primary Care Practitioners"* provides:

> Spirometry testing is reimbursed by many third-party insurance companies for the following ICD-9 codes: COPD 491-495 and 496; shortness of breath 786.09; cough 786.2; and bronchitis due to chemical fumes or vapor 506.x. When performing spirometry for tobacco abuse (V15.82 code) or preoperative respiratory examinations (V72.82 code), these should not be reported as a principal diagnosis, otherwise reimbursement will be denied. Codes should always be assigned to the highest level of specificity. Reimbursement requires a printed copy of the volume-time curves or flow-volume curves.

CPT Codes and Typical Reimbursement Rates for Spirometry in the United States

94010	Spirometry, FEV1 and FVC (other measurements optional)	$30
94060	Spirometry before and after bronchodilator	$57
94375	Flow-volume loops, including forced inspiratory flows	$37
94620	Exercise-induced bronchospasm (EIB) test	$98
94014	Patient-initiated spirometry, done at home for 30 days	$43

Medicare only requires "general supervision" by a physician in order to qualify for reimbursement of those tests identified above as well as several others. "General supervision" is defined by Medicare as "the procedure is furnished under the physicians's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the non-physician personnel who actually performs the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician."

REIMBURSEMENT FRAUD

Following are "Medicare Fraud Alerts" and litigation surrounding fraud as it relates to PFT.

Medicare Fraud Alerts

Medicare Fraud Alert - June 1996 (http://www.cms.hhs.gov/providers/fraud/9603a.asp)

"The individual franchises utilize the services of independent physiological labs that are supposedly not connected to the supplier. These independent labs submitted claims to Medicare for pulse oximetry tests and other respiratory tests which were either not ordered by the referring physician of record or were not performed at all. Tests results were altered in order to meet Medicare criteria for payments. Beneficiary[ies] were apparently requested to perform physical exercise prior to oxygen testing. These tests are usually performed in 3 phases, one at rest, another during exercise and one after the use of inhalation aids. The results of the test after having exercised, was listed as at rest, thereby making the beneficiary appear to satisfy Medicare criteria for oxygen and payment.

The following CPT codes were being billed:

94760 -- Ear or pulse oximetry for oxygen saturation: single determination
94761 -- Multiple determinations (e.g., during exercise)
94762 -- By continuous overnight monitoring (separate procedure)
94010 -- Spirometry, including graphic record total and timed vital capacity, expiratory flow rate measurement, and/or maximal voluntary ventilation
94060 -- Bronchospasm evaluation: spirometry as in 94010, before and after bronchodilator (aerosol or parenteral) or exercise
94375 -- Respiratory flow volume loop"

Medicare Fraud Alert - January 1997 (http://www.cms.hhs.gov/providers/fraud/9702a.asp)

Sleep studies (95807) were billed but not furnished. In addition to sleep studies, most claims reported the same battery of pulmonary tests. Medical records did not document the tests. Pulmonary tests included:
94060 - Bronchospasm Evaluation,
94375 - Respiratory Flow volume Loop,
94200 - Maximum Breathing Capacity,
94664 - Aerosol or Vapor Inhalations,
94762 - Pulse Oximetry, overnight Monitoring, and
94620 - Pulmonary Stress Testing.

Litigation

Mikes vs. Straus (2001)

An article titled, *"Second Circuit Rejects 'Federalization' of Medical Malpractice Cases,"* found in the March 25, 2002 issue of the *New York Law Journal,* cites the *Mikes v. Straus* litigation as an example of medical malpractice cases attempting to be tried in federal courts. The article states in part:

> "The core of Dr. Mikes's malpractice allegations concerned the defendants' supposed failure to follow generally accepted standards for spirometry testing as promulgated by the American Thoracic Society, a division of the American Lung Association. These guidelines, which Dr. Mikes noted are incorporated by reference in various federal statutes and regulations, require among other things, the daily calibration of spirometry equipment, the performance of three successive trials during the course of a test and the performance of testing by spirometry technicians with appropriate training. Dr. Mikes accused the

physicians of departing from these guidelines by failing to ensure proper calibration of the testing equipment, failing to perform the recommended three successive tests, and allowing medical assistants who were not properly trained to perform these tests. As a result, she alleged, the spirometry testing that was performed yielded inherently unreliable data, and therefore charging the Medicare program for poor quality tests violated the False Claims Act. The defendant physicians countered that when Dr. Mikes raised these concerns, they told her to review the test results for any inaccuracies and to train the medical assistants in properly administering the spirometry testing. They further claimed that she never apprized them of any false readings and that she herself failed to supervise the medical assistants."

"Dr. Mikes had also alleged that Medicare's payments for the spirometry testing constituted reimbursement for worthless services, since the defendants knew that they were seeking federal reimbursement for a procedure with no medical value, and thereby were violating the False Claims Act. Judge Cardamone agreed that the Act encompasses a worthless service claim, which would arise when "the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all." Nevertheless, he found that Dr. Mikes had not shown that the defendants knowingly submitted reimbursement claims for worthless services; instead he found that the defendants had proffered ample evidence of their good faith belief that their spirometry tests were of medical value."

SPIROMETRY TRAINING/CERTIFICATION

National Institute for Occupational Safety and Health (NIOSH)

The National Institute for Occupational Safety and Health (NIOSH), an affiliate of the Centers for Disease Control and Prevention (CDC), promulgated the "Cotton Dust Standard" to protect employees who are exposed to cotton dust. Part of the "Cotton Dust Standard" provides, "persons other than licensed physicians, who administer the pulmonary function testing required by this section shall have completed a NIOSH-approved training course in spirometry." Up until October 2004, NIOSH approved courses were the only type of recognized spirometry training courses, even though training concentrated on the Cotton Dust Standard.

The NIOSH website states, "The Cotton Dust Standard does not require any prerequisite or supplemental courses be taken in order to successfully complete a course approved by NIOSH. Currently, there is no requirement for continuing education or refresher courses after completion of a NIOSH-approved spirometry course, though occupational and respiratory professional organizations recommend periodic refreshers. NIOSH is considering whether to recommend periodic retraining at some point in the future. If and when NIOSH determines that re-training is appropriate, the new recommendations will be posted on this website."

NIOSH provides the following design and content criteria for consideration as an approved course:

"The course design must include at least 16 hours of instruction with the following components:
- At least four hours of formal lectures and/or audio visual material.
- At least eight hours of small group practical instruction.
- At least two hours per student devoted to evaluation and testing of the student's spirometry testing skills.

Evaluation consists of a written and a practical examination.

The course content should include:
- Basic physiology of the forced vital capacity maneuver and the determinants of airflow limitation with emphasis on the relation to reproducibility of results.
- Instrumentation requirements including calibration procedures, sources of error, and their correction.
- Performance of testing including subject coaching, recognition of improperly performed maneuvers, and corrective actions.
- Data quality with emphasis on reproducibility.
- Actual use of the equipment under supervised conditions.
- Measurement of tracings and calculation of results.

Information may be presented during a course that is not required by the Cotton Dust Standard. However, this must be in addition to the minimum 16 hours of instruction required by the Standard. Though all NIOSH-approved courses must have the minimal required content in common, the courses vary somewhat in the additional topics that are covered, and some courses are more than 16 hours in length."

American Association for Respiratory Care

In October 2004, the Board learned that the American Association for Respiratory Care is working with the NLHEP who is responsible for the promotion of "office spirometry" discussed earlier. The AARC has begun developing a course to establish minimum competency as it relates to spirometry training to be available in the near future.

SURVEY RESPONSES

In the Summer of 2004, the Board developed three surveys related to the practices of polysomnography, pulmonary function testing and hyperbaric oxygen therapy. At the latter part of August 2004, the Board issued notices to some 1,545 organizations and persons holding in interest in one or more of these professions, encouraging input into these practices via surveys available on its website. Hard copies were also mailed to 200 of these various organizations/persons.

Approximately 917 of these organizations/persons are directly associated with the practice of pulmonary function testing and include: accredited cardio and pulmonary laboratories; CPFTs and RPFTs (credentialed technologists); pulmonary labs found on the Internet; pulmonary associations, and patient advocacy groups. Hard copies of the survey were sent to approximately 100 organizations/persons affiliated with pulmonary function testing. 26 surveys were returned to the Board. **Attachment 8** is a tabulation of all of the received responses.

Respondents indicated overall that:

- The existing demand for PFT is being met
- Reimbursement for services is inadequate, though this is not preventing patients from receiving services
- The average amount reimbursed for various PFT by Medicare is $222; Medi-Cal $75
- State regulation of “pulmonary function technicians” would not increase the cost of services
- The majority of PFTs are done in labs within a hospital followed by physician offices and stand-alone facilities, respectively
- Facilities providing PFTs are open from 4 to 5 days per week
- PFTs are primarily performed for patients ranging in age from 60 - 79 years of age followed by the 40 to 59 year old age group
- The estimated waiting time, from the date a patient is referred or requests service to the date service is provided is most often 1-2 weeks
- Most respondents estimated between 500 and 1000 personnel are performing PFTs in California [one respondent noted that it would be impossible to estimate if including physician offices]
- Nearly 2/3 of respondents were aware of cases where patients had to be retested as a result of personnel failing to perform a test or treatment correctly or ensuring equipment was calibrated properly.
- PFT performed by untrained and uneducated personnel could result in serious patient harm or death
- The potential for patient harm is somewhat possible should a technician have a criminal background
- Most laboratories within an acute care hospital perform criminal background checks on personnel whereas most stand-alone facilities and physician offices do not
- Between 1 and 2 years of education and between 100 and 300 hours of clinical experience is necessary to practice with minimum competency at the entry level
- 2 years of education and over 300 hours of clinical experience is necessary to practice with minimum competency at the advance level of practice

Most believe regulation of PFT technicians would bring about more confidence in these services and would provide physicians more viable resources. However, many noted that it would limit access to care, and make it difficult to find qualified personnel. Some noted that “physician offices” use “secretaries” to perform PFT, would not be willing to pay for a “regulated” technician and such regulation would provide them less options. There were also several comments that cited tests performed in physician offices were done by personnel with minimal or no training producing unreliable results and poor calibration of equipment.

Three respondents stated they were aware of incidents where the patient alleged or was found to be the victim of fraud/theft, battery, and sexual misconduct. Verbal abuse or inappropriate talking to patients was cited for “sexual misconduct” and was the most reported problem. Four respondents were aware of technicians who were impaired while at work as a result of being under the influence of drugs or alcohol.

The most significant potential harm noted by respondents was treatment including medication provided or withheld based on unreliable results.

In response to the final survey question which asks, "Which of the following components of regulation (if employed

to certify 'PFT technologists') do you believe would protect a patient's rights and prevent patient harm (check all that apply)?" 22 total respondents to this question marked:

Regulatory Component	Number of Respondents Marking Each Category (they believe would protect a patient's rights and prevent patient harm)
Competency Testing	20
Criminal Background Check	20
Formal Education	19
Formal Training	18
Continuing Education/Training	19
None	1

OTHER STATES

Of the following seven states, five provide an exemption from their respiratory care practice acts, for credentialed pulmonary function technologists. New Jersey requires licensure as a RCP to perform PFT with the exception of "basic and limited" PFT and Washington requires licensure as a RCP to perform all levels of PFT. The issue of "office spirometry" performed in physician offices, however, is a nation-wide concern that many states, including most of those below, have just recently begun to address.

***New Jersey* - Exemption for "Limited and Basic" PFT Only**

The State of New Jersey faced a similar situation the California Board is now facing in that the practice of PFT required a RCP license, yet there were several unlicensed individuals providing such services. In June 2002, New Jersey's Department of Law and Public Safety issued a notice **(Attachment 9**) advising people that it would begin taking enforcement action after September 1, 2005 against any person practicing pulmonary function testing that was not licensed to practice respiratory care or did not possess another license where the standards of that profession included pulmonary function testing. The notice included one exception, that properly trained unlicensed personnel could continue to perform "basic screening spirometry," limited to peak flow, forced vital capacity, slow vital capacity and maximum voluntary ventilation measurements.

This notice issued by the State of New Jersey has caused great concern for those people that acquired ample experience, generally possess national credentials, and in many cases have more than two years of education. You would also have to surmise that the State is having shortages or difficulty finding qualified people to perform pulmonary function testing and this movement is only aggravating that situation.

***Florida* - Limited Exemption Provided to CPFT/RPFT**

PFT is included in Florida's RCP scope of practice. However, a limited exemption is provided for "any individual certified or registered as a pulmonary function technologist who is credentialed by the National Board for Respiratory Care *for performing cardiopulmonary diagnostic studies*."

***Idaho* - Exemption Provided to CPFT or RPFT**

Idaho's respiratory scope of practice provides and exemption: "Certified or registered pulmonary function technologists who carry out only those professional duties and functions for which they have been specifically trained."

***New Hampshire* - Limited Exemption Provided to CPFT/RPFT**

Legislative amendments to New Hampshire's Respiratory Care Practice Act, made in 2003, provide the following limited exemption: "Respiratory care performed as part of a limited scope of practice, as defined by the board, by certified pulmonary function technicians (CPFT), registered pulmonary function technologists (RPFT) or registered polysomnographic technologists (RPSGT) in a *diagnostic laboratory or research setting."*

***South Carolina* - Exemption for Trained Personnel**

South Carolina's respiratory scope of practice includes pulmonary function testing. An exemption from the Practice

Act is provided as follows: "This article does not affect...(3) an individual or other health care professional who is licensed by the State or who has proven competency in one or more of the functions included in the definition of the practice of respiratory care as long as the person does not represent himself as a respiratory care practitioner. As it relates to respiratory care, individuals exempt pursuant to this section must provide proof of formal training for these functions which includes an evaluation of competence through a mechanism that is determined by the board and the committee to be both valid and reliable. The clinical assessment of artificial pressure adjuncts to the respiratory system may not be performed by any other person without proof of formal training and exemption by the board...."

***Wyoming* - Exemption Provided for CPFT/RPFT**
Legislation enacted in 2003 created Wyoming's "Respiratory Care Board." The respiratory care scope of practice includes pulmonary function testing. The Act provides the following exemption: "An individual who, by passing an examination which includes content in one (1) or more of the functions included in this act, offered by a testing body certified by the national commission for health certifying agencies or its equivalent, shall not be prohibited from performing procedures for which they were tested."

***Washington* - RCP License Required**
Washington's respiratory care scope of practices includes pulmonary function testing and does not provide an exemption.

ASSOCIATION POSITIONS

American Association for Respiratory Care (AARC)
The AARC does not believe that formal state regulation is required for this occupation. However, the AARC does believe that unlicensed personnel should hold either the CPFT or RPFT credential and should only provide services for which the individual was tested. The AARC supports unlicensed and uncredentialed personnel performing pulmonary function testing for the purposes of qualifying for the CPFT examination, provided it is under the direct supervision of a physician who assumes the responsibility and liability of the individual. The AARC also supports unlicensed and uncredential personnel in performing "physician office based spirometry" provided the individual completes a training course and provided such practice is under the direct supervision of a physician who assumes the responsibility and liability of the individual.

***California Thoracic Society* (CTS)**
The CTS has expressed opposition to regulating pulmonary function testing as it pertains to "physician office based spirometry" and is opposed to requiring a training course for unlicensed and uncredentialed personnel. The CTS has conveyed that the supervising physician or medical director should have direct responsibility of personnel. **Attachment 5** is a position paper the CTS provided the Board on November 24, 2004.

ALTERNATIVE RESOLUTIONS

Following are alternatives considered in making a final recommendation.

Alternative 1: Enforce Existing Law

This alternative would require all personnel performing any type of pulmonary function test to be licensed as an RCP. This alternative would prevent the promotion of early detection of COPD and would unemploy approximately 163 people. Because PFT is only a limited component of the respiratory care scope of practice, a grandfather provision would not be a viable option. This would jeopardize the health and welfare of consumers in delaying a COPD diagnosis detected in a physician office as well as potentially delaying treatment for other illnesses due to PFT staffing shortages in laboratories.

Alternative 2: Establish New Licensure Categories for Credentialed Pulmonary Function Technologists

This alternative would create two new licensure categories, one at the entry level (CPFT) and one at an advanced level (RPFT) for those estimated 113 people who hold credentials without licensure. The new licensure categories could be modeled after standards established for this profession which would provide the estimated 50 people (working in laboratories) the "clinical experience" pathway to qualify for the CPFT examination and licensure. This alternative would ensure competency and provide for criminal background checks and a mechanism to rescind privileges for incompetence, negligence, etc.... However, this alternative would still prevent the promotion of early detection of COPD as it would be too burdensome and costly for physician offices to continue such practices.

Alternative 3: Establish New Licensure Categories for Credentialed Pulmonary Function Technologists and Non Credentialed Personnel Performing "Basic and Limited" PFT

This alternative would be the same as "Alternative 2" with the exception that non credentialed personnel would be required to obtain licensure. The minimum requirements for performing "Basic and Limited" PFT would be the completion of an approved training course. However, this alternative would also thwart the promotion of early detection of COPD as it would be too burdensome and costly for physician offices to support.

Alternative 4: Establish New Licensure Categories and Provide and Exemption for the Performance of "Basic and Limited" PFT

This alternative is the same as alternative 2 with the exception that unlicensed personnel could perform "basic and limited" PFT, thereby allowing the promotion of COPD awareness. However, this alternative fails to address the most significant problem which is the lack of competency among unlicensed personnel.

Alternative 5: Provide Exemptions from The RCPA to Allow Credentialed Personnel to Perform PFT and Non Credentialed Personnel with Required Training and Supervision, to Perform "Limited and Basic" PFT

This alternative would include legislative amendments to the RCPA as follows:

A. Exemptions

1. For the purposes of performing pulmonary function testing, any individual who has been issued and maintains a current Certified Pulmonary Function Technologist (CPFT) or a Registered Pulmonary Function Technologist (RPFT) credential issued by the National Board for Respiratory Care, shall not be prohibited from performing procedures included in the examination for which he/she was tested, while under the supervision of a medical director as defined in section 3704, and in accordance with the American Thoracic Society standards.

2. Any individual in a health care clinic or health care facility as defined in the California Health and Safety Code sections 1204 and 1250, for the purposes of obtaining the clinical experience required to obtain a CPFT credential, who has met all other admission requirements for the CPFT examination, shall not be prohibited from performing procedures included in the CPFT examination, while under direct supervision as defined in section 3765a and in accordance with the American Thoracic Society standards.

3. Any individual who has successfully completed a board-approved course, specific to spirometry testing, provided through or approved by the American Association for Respiratory Care, the National Institute for Occupational Safety and Health (NIOSH) or any other board-approved course, may perform for a period of 5 years, "basic screening spirometry" limited to peak expiratory flow rate (PEFR), forced vital capacity (FVC), slow vital capacity (SVC), maximum voluntary ventilation (MVV) measurements and timed forced expiratory volume/1 second (FEV_1), while under direct supervision as defined in section

3765a and in accordance with the American Thoracic Society standards. Individuals shall maintain and demonstrate current competency at least annually with the physician providing "direct supervision" and retain records accordingly.

B. Direct Supervision Defined

3765a. Direct Supervision Defined
For purposes of the exemptions provided in sections xxx and xxx, the term "direct supervision" means supervision and control by a physician who is licensed pursuant to the California Business and Professions Code, Chapter 5 [California physician] and who assumes the legal liability for the services rendered by the personnel he/she supervises and ensures records demonstrating continuing competency of the personnel he/she supervises are maintained. Except in a case of emergency, direct supervision requires the easy availability of the physician within the office, or the physical presence of the physician, for consultation and direction of the actions of the personnel who deliver respiratory care services.

C. Other Provisions Applied to Exemptions

1. Add a section that requires any individual practicing respiratory care through one of these exemptions to provide documentation supporting an exemption upon request of the Board or any representative acting on behalf of the Board within a reasonable amount of time. Failure to do so shall constitute the unlicensed practice of respiratory care.

2. Add a section citing existing enforcement authority against a person or an employer of a person [3763. Misdemeanor; criminal prosecution, 3766 and 3767. Citation and Fines] as it pertains to the unlicensed practice of respiratory care that is not specifically exempted.

RECOMMENDATION
The Professional Licensing Committee recommends Alternative 5. This alternative is the least burdensome method in addressing the issue of greatest concern, competency. This alternative supports the early detection and intervention of COPD and prevents unemployment of competent persons. This alternative will increase accurate diagnoses which will provide greater protection for California consumers and reduce health care costs.

The Board recognizes that by not regulating the field it may be more difficult to enforce these exemptions and ascertain criminal backgrounds. However, consideration must be given to the fact that physician offices would be thwarted in promoting early detection and intervention of COPD and that "limited and basic" PFT does not require extensive education. Patients undergoing "limited and basic" PFT in a physician office are alert and coherent at all times (with the exception of an extremely rare adverse reaction to PFT generally caused by inappropriate testing techniques) . A greater risk for consumers would be the delay of a diagnosis for COPD, than the likelihood of being a victim of a criminal act.

If approved by the Legislature, the Board further recommends that it review the effectiveness of the exemptions, within 4 years from the date they take effect, to determine if amendments are needed or regulation of this specific practice is warranted.

ATTACHMENTS

1) CTS Statement: "Pulmonary Physiology Laboratory Personnel Qualifications"
2) ATS Statement: "Standardization of Spirometry"
3) NLHEP consensus statement on Office Spirometry for Lung Health Assessment in Adults
4) Article titled, "Primary Care Office Spirometry" published in the Summer 2004 issue of the ATS *Pulmonary Function Laboratory Registry Newsletter*
5) NBRC's CPFT Admission Requirements
6) CTS Statement: "Responsibilities of the Medical Director of Respiratory Care Services and Pulmonary Physiology Laboratories"
7) Article titled, "Is Your Medical Assistant Practicing Beyond His or Her Scope of Training?" published in the Medical Board of California's October 2001 *Action Report*
8) 2004 Board survey responses
9) State of New Jersey's Notice Regarding Pulmonary Function Testing
10) CTS Position Statement

POSITION PAPER

Pulmonary Physiology Laboratory Personnel Qualifications

The availability of reliable testing in an office or hospital Pulmonary Laboratory is essential in the diagnosis and management of lung disorders. High quality testing provided in a safe manner requires properly functioning and standardized equipment operated by qualified personnel, who perform under the medical direction of a physician who is knowledgeable in pulmonary physiology and its testing procedures. Such personnel might include pulmonary technologists, respiratory care practitioners, registered nurses or others with similar training. Technical personnel in such a laboratory must meet minimum standards of competence, and should achieve this through standardized education and training, followed by appropriately supervised clinical experience. Continued proficiency is assured by continuing education and ongoing assessment of skills by the Medical Director of the laboratory. (The methodology for this assessment may vary from laboratory to laboratory and is not specially described in this document.)

PULMONARY TECHNICIAN/TRAINEE

Definition: An individual who is acquiring or has acquired knowledge and experience in simple or limited pulmonary function testing, e.g., spirometry and lung volumes. *The technician will, therefore, lack education and experience in the full scope of pulmonary function testing*.

Educational Prerequisites: High school graduate; one or more years of college in math, science and/or health preferred; technical experience in laboratory testing, electronics, computer science preferred.

Training: Each testing procedure requires test-specific training in the physiologic background and clinical application of the test along with the appropriate technical methodology. The duration of the training is not fixed, and is dependent on the trainee's prior education and technical experience. The training should include the following:

a. Educational content:
   1) Equipment operation and maintenance
   2) Clinical application of testing
   3) Pertinent anatomy and physiology
   4) Indications and contraindications for testing
   5) Risks of testing and response to adverse reaction
   6) Normal values; statistical methodology
   7) Safety and infection control procedures
   8) Communication skills; patient privacy requirements
   9) Hospital policies and procedures
   10) Pertinent local, state and federal regulations, Joint Commission of Allied Health Organizations (JCAHO) requirements and professional (California Thoracic Society, American Thoracic Society) standards

11) Cardiopulmonary Resuscitation (CPR)
12) Pertinent pharmacology, where appropriate

b. Skills training (2):

1) Preparation and calibration of equipment
2) Preparation and instruction of patient
3) Performance of testing procedure
4) Assessment of validity and reliability of test results
5) Trouble-shooting of equipment
6) Calculation of test data
7) Preparation of report
8) Performance of maintenance and quality control procedures

Clinical Experience: Technical personnel must perform each test that they have been trained to do under supervision a sufficient number of times until it is determined that they perform the test in a satisfactory manner. For noninvasive tests, this can be done by a Senior or Supervising Technologist. For invasive tests, the Medical Director must be involved. These should be in a variety of circumstances, proceeding along the following sequence:

a. Mannequin or test model, when appropriate
b. Self-testing, when appropriate
c. Normal volunteers, when appropriate
d. Routine patient testing
e. Patients in different clinical circumstances
f. Pediatric patients, when appropriate

At the conclusion of training, appropriate proficiency testing of personnel should be performed by the Medical Director and documented.

Continuing Education: In order to maintain proficiency, the technician is responsible for remaining current in the clinical applications of the procedure, as well as maintaining his/her performance skills. He/she is encouraged to:

a. Attend pertinent lectures and seminars
b. Participate in manufacturer updates on equipment
c. Read pertinent scientific and trade journals
d. Investigate new equipment
e. Take additional college courses (math, science, physiology, health)

Credentials: Seek professional credentials, e.g., Certified Pulmonary Function Technologist (CPFT) (via National Board for Respiratory Care (NBRC)).

PULMONARY TECHNOLOGIST

Definition: An individual who has completed the above training, has become experienced in simple pulmonary function tests and has then been trained in a wide range of pulmonary

function training including:

a. Diffusing capacity
b. Body plethysmography, where available
c. Blood sampling and gas analysis: arterial, capillary, venous.

The methodology for training would be as described above under *Training* and *Clinical Experience* for the Technician/Trainee.

The Technologist would also be expected to pursue *Continuing Education* goals and *Credentials* as described above for the Technician/Trainee.

SENIOR/SUPERVISING PULMONARY TECHNOLOGIST

Definition: A Pulmonary Technologist who has accumulated sufficient laboratory experience (preferably >two years) to be responsible for the training and supervision of Pulmonary Technicians/ Trainees and Technologists; advanced professional credential preferred, e.g., Registered Pulmonary Function Technologist (RPFT), Registered Cardiopulmonary Technologist (RCPT).

Special Studies: A Senior Technologist can perform special pulmonary diagnostic tests after appropriate training and supervised experience, following and educational pattern similar to the Pulmonary Technician/Trainee above, i.e., *Training* and *Clinical Experience*.
These special tests include:

a. Percutaneous arterial catheterization (radial, brachial)
b. Exercise testing
c. Bronchial challenge
d. Hypercapnic/hypoxic ventilatory response
e. Lung compliance
f. Tonometry (e.g., blood oxygen partial pressure at 50% saturation (P_{50}))

Others as determined by the Medical Director, e.g., sleep studies.
Documented training and certification by the Medical Director should be required.

The Senior/Supervising Technologist would also be expected to pursue *Continuing Education* goals and *Credentials* as described above for the Technician/Trainee.

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DEVELOPED FOR THE CTS CLINICAL PRACTICE ASSEMBLY (CPA) STEERING COMMITTEE

Prepared by Paul A. Selecky, MD

Approved by CTS Executive Committee and ©CTS 1987, revised 2004

CTS guidelines are developed to enhance a physician's ability to practice evidence-based medicine, but these should not be considered a substitute for the experience and judgment of a health care provider.

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American Thoracic Society
MEDICAL SECTION .OF THE AMERICAN LUNG ASSOCIATION

Standardization of Spirometry

1994 Update

THIS OFFICIAL STATEMENT OF THE AMERICAN THORACIC SOCIETY WAS ADOPTED BY THE ATS BOARD OF DIRECTORS, NOVEMBER 11, 1994

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The first American Thoracic Society (ATS) Statement on the Standardization of Spirometry'was published 15 yr ago and was based on the Snowbird Workshop held in 1979 (1). This initial statement was updated in March 1987 (2) after 8 yr of practical experience with the initial recommendations. The state of the art of spirometry has continued to advance as a result of scientific studies that have provided additional data relating to performance of spirometry. The use of computers for spirometry measurement has become even more commonplace. New statements by the ATS (3) and the European Respiratory Society (4) also underscore the need to update the ATS statement on spirometry. This revision of the standards for spirometry reflects the changes in clinical emphasis and in available technology since the 1987 ATS spirometry update (2) was published. The changes in clinical emphasis and equipment include:

- The strong emphasis on the use of portable peak flow meters to monitor lung function in asthmatics by the National Heart, Lung, and Blood Institute's Asthma Education Program (5), the International Asthma Management Project (6), the British Thoracic Society (7), and others.
- The corresponding development of many new model peak flow monitoring devices, some purely mechanical and some electronic
- A better understanding of the complexities of correcting spirometric values to BTPS conditions.

This statement was prepared by the Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories. Members *of the committee:* Robert 0. Crapo, M.D., Chairman, John L Hankinson, Ph.D., Charles Irvin, Ph.D., Neil R. MacIntyre, M.D., Karen Z. Voter, M.D., and Robert A. Wise, M.D. *Spirometry Subcommittee:* John L Hankinson, Ph.D., Subcommittee Chairman, Charles Irvin, Ph.D., Robert A. Wise, M.D. *Invited Spirometry and DLCO Workshop participants:* Brian Graham, Ph.D., Carl O'Donnell, Sc.D., Paolo Paoletti, M.D., Josep Roca, M.D., and Giovanni Viegi, M.D. *Corresponding members:* Margaret R. Becklake, M.D., A. Sonia Buist, M.D., Gary duMoulin, Ph.D., Robert L Jensen, Ph.D., Albert Miller, M.D., and Andrea Rossi, M.D.

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- A greater appreciation of the importance of the technicians and procedures in achieving good spirometric results.
- An increased concern about the risk of transmission of infectious diseases during pulmonary function testing.

We have responded to these changes by:

- Separating the standards for laboratory or diagnostic spirometers from those of devices designed to be used primarily as monitors.
- Adding BTPS testing to the testing of spirometers.
- Adding a section on performance of slow vital capacity.
- Strengthening and updating the procedural aspects of quality control, including an appendix with sample spirograms.
- Adding a section on hygiene and infection control.

A central goal of any guideline or standardization document is to improve performance and thus decrease the variability of laboratory testing. In 1979 (1), and again in 1987 (2), the perception was that the major source of variability was instrumentation. More recently, instrumentation has improved to a point where other sources of variability can be identified, in particular, procedural problems. In 1991, the ATS Statement on Lung Function Testing: Selection of Reference Values and Interpretation Strategies (3) stated: "The largest single source of within-subject variability is improper performance of the test." More recently, Enright and coworkers (8) have shown a positive impact of an extensive quality control program on spirometric results. As a consequence, there is an effort in the present statement to address issues of test performance and quality control.

The ATS statements on standardization of spirometry have had far-reaching effects on manufacturers and users of spirometers. In some cases, manufacturers have used the document as a minimum performance requirement document. We continue to be concerned with this approach and encourage manufacturers to seek excellence in design so that the state of the art for spirometers will *exceed* ATS recommendations. Some research protocols. will necessitate even more stringent requirements than stated here

Spirometry is a medical test that measures the volume of air an individual inhales or exhales as a function of time Flow, or the rate at which the volume is changing as a function of time, may also be measured with spirometry. Spirometry, like the measurement of blood pressure, is a useful screen of general health. Like the simple measurement of blood pressure, it does not suffice in certain situations where more extensive testing is warranted. Spirometric results correlate well with morbidity and life expectancy. Spirometry is used to affect decisions about individual patients, including the nature of the defect, its severity, and the response to therapy. Table 1 lists some of the potential indications for spirometry.

Results from tests based on spirometric maneuvers can have an important effect on a person's lifestyle, standard of living, and future treatment (10). Similarly, accurate and precise spirometers are required for epidemiologic studies. Rates of improvement or deterioration of pulmonary function measured in relation to environmental exposures and/or personal characteristics may be erroneous if inaccurate spirometers are used or less sensitive if imprecise spirometers are used (11).

Maximizing the clinical usefulness of spirometry depends on a number of steps, ranging from equipment selection to interpretation, and ultimately involves clinical assessment. Figure 1 is a flow diagram of these steps.

The first step is establishing equipment performance criteria. The Snowbird Workshop (1), 1987 Update (2), and this update give recommendations for equipment used for spirometry.

The second step in the process involves validation that the spirometer design meets the minimum recommendations through the testing of a representative device. Detailed methods for performing the validation testing are outlined later in this statement. The ATS makes equipment recommendations but does not act as a certifying agency to verify compliance with these standards. Spirometer users should carefully select equipment that meets the ATS recommendations to assure that spirometry testing can be done accurately. Before purchasing a spirometer, it is wise to: (1) ask the manufacturer to provide summary data that demonstrates that the device being considered meets or exceeds ATS recommendations, or (2) review results of spirometry testing from independent testing laboratories. This statement does not mandate testing by an independent laboratory. There are many calibrated computer-driven syringes available. When an independent laboratory is not used, manufacturers should make the testing protocol, the raw data, and the summary data available to potential customers for their review..

Even after spirometers have been found to meet ATS recommendations, they (like other mechanical, electrical, or computer equipment) must be routinely checked for performance quality.

TABLE 1

INDICATIONS FOR SPIROMETRY*

Diagnostic
To evaluate symptoms, signs, or abnormal laboratory tests
-Symptoms: dyspnea, wheezing, orthopnea, cough, phlegm production, chest pain
-Signs: diminished breath sounds, overinflation, expiratory slowing, cyanosis, chest deformity, unexplained crackles
-Abnormal laboratory tests: hypoxemia, hypercapnia, polycythemia, abnormal chest radiographs
To measure the effect of disease on pulmonary function
To screen individuals at risk of having pulmonary diseases
-Smokers
-Individuals in occupations with exposures to injurious substances
-Some routine physical examinations
To assess preoperative risk
To assess prognosis (lung transplant, etc.)
To assess health status before enrollment in strenuous physical activity programs
Monitoring
To assess therapeutic interventions
—Bronchodilator therapy
-Steroid treatment for asthma, interstitial lung disease, etc.
-Management of congestive heart failure
-Other (antibiotics in cystic fibrosis, etc.)
To describe the course of diseases affecting lung function
-Pulmonary diseases
Obstructive airways diseases
Interstitial lung diseases
-Cardiac diseases
Congestive heart failure
-Neuromuscular diseases
Cuillain-Barre Syndrome
To monitor persons in occupations with exposure to injurious agents
To monitor for adverse reactions to drugs with known pulmonary toxicity
Disability/Impairment Evaluations
To assess patients as part of a rehabilitation program
-Medical
-Industrial
-Vocational
To assess risks as part of an insurance evaluation
To assess individuals for legal reasons
-Social Security or other government compensation programs
-Personal injury lawsuits
-Others
Public Health
Epidemiologic surveys
-Comparison of health status of populations living in different environments
-Validation of subjective complaints in occupational/environmental settings
Derivation of reference equations

* Adapted from reference 9.

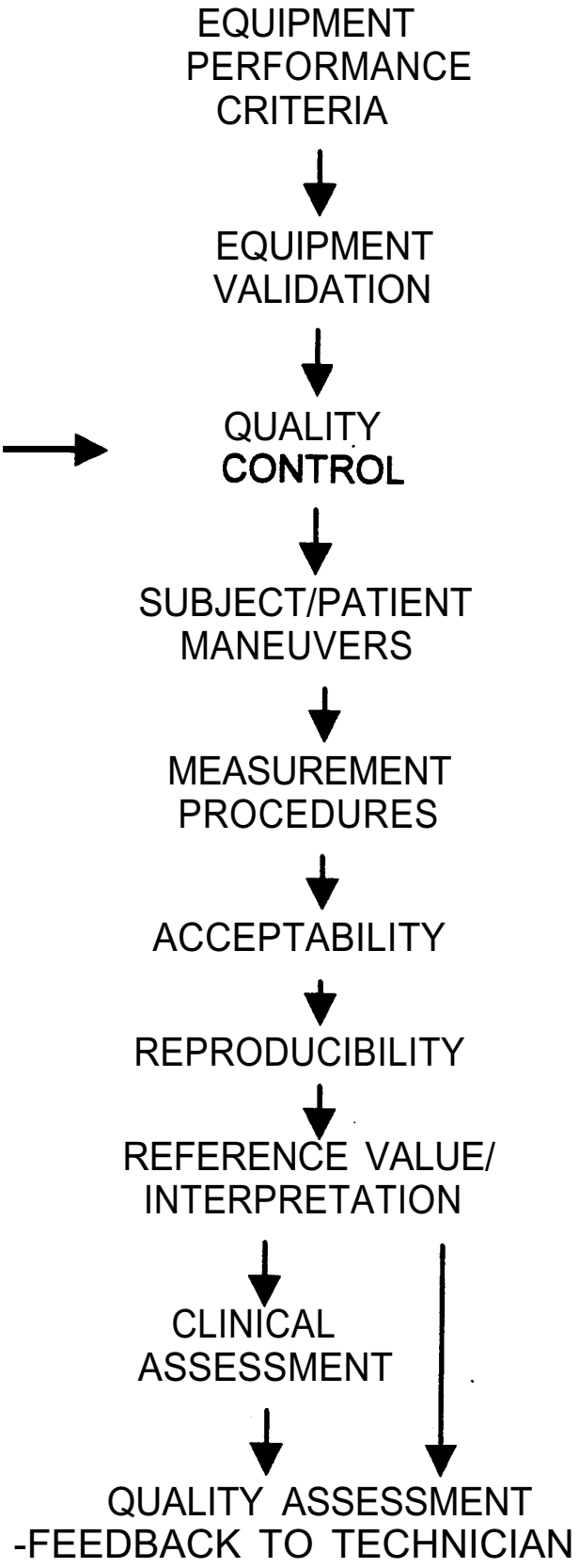


Figure 1. Spirometry standardization steps.

Recommendations for spirometer quality control have been developed by the ATS and are summarized in this statement.

Spirometry is an effort-dependent maneuver that requires understanding, coordination, and cooperation by the patient-subject, who must be carefully instructed. Thus, procedural recommendations are important components of testing. Part of the recommendation is to obtain a sufficient number of maneuvers of adequate quality and then determine if these acceptable maneuvers are reproducible, implying that maximal effort has been achieved. Once spirometry maneuvers have been performed, data are either measured by hand or computer. Measurement procedures are included in this article to help assure that uniform methods are used and comparable results are obtained. These recommendations include considerations such as using "back extrapolation" for determining the "start-of-test" time (zero point) for measures such as FEV_1 and the criteria to determine the end of the expiratory maneuver. Instruments that provide feedback to the technician in the form of checks on the adequacy of the data are clearly desirable.

The interactions between technicians and subjects are crucial to obtaining adequate spirometry, since it is such an effort-dependent maneuver. Technicians must be trained and must maintain a high level of proficiency to assure optimal results.

The spirogram tracing must be carefully scrutinized for quality. Recommendations about quality, acceptability, and reproducibility of test results are presented, as well as examples of unacceptable maneuvers (see APPENDIX A). After adequate results are obtained, they are usually compared with reference values to make an assessment (interpretation) of the results. The ATS 1991 Statement on Lung Function Testing: Selection of Reference Values and Interpretative Strategies provides guidelines for selecting reference values and interpreting the results. Clinical assessment should be an integral part of spirometry. Results obtained from spirometry are only one part of the much more complex patient-care relationship or research study analysis. It is the responsibility of the laboratory director to provide adequate quality control procedures to assure that an attempt to meet these recommendations and criteria has been made

In both the original ATS statement on spirometry and the 1987 update, a rationale was provided for each recommendation. Since many of these recommendations and their rationales have not changed since the original statements, the reader is referred to the 1987 update (2) for the rationales concerning less controversial recommendations.

DEFINITIONS

All terms and abbreviations used here are based on a report of the American College of Chest Physicians (ACCP)-ATS Joint Committee on Pulmonary Nomenclature (12).

Accuracy and precision are important terms in equipment recommendations and warrant some definition. Accuracy error is the systematic difference between the "true" and the measured value The accuracy of a spirometer system depends on a number of factors, including linearity and frequency response of the system or processor, sensitivity to environmental conditions, calibration, and adequacy of correction factors. Its precision depends on the signal/noise ratio and on the resolution (i.e., the minimal detectable volume or flow). Precision error, usually denoted reproducibility, is the numerical difference between successive measurements (4). For example, if a volume spirometer's pen is not on zero but at 1. L, all volumes read directly from the graph would be overread by 1 L. The accuracy error would be 1 L, since the measured volume would read 3 L when the true volume is 2 L. However, the precision of the spirometer would remain unchanged, as the spirometer would consistently read 3 L each time 2 L is injected into the spirometer. For some applications, eg., peak expiratory flow (PEF) monitoring, precision is more important than accuracy.

In several sections of this document, the terms "open circuit" and "closed circuit" technique are used. The term "open circuit" spirometry refers to the method of conducting spirometry where the subject takes a full inspiration before inserting the mouthpiece to perform the test. In this approach, the subject does not inhale from the spirometer or potentially contaminated flow sensor. The term "closed circuit" spirometry refers to the method of conducting spirometry where the subject is attached to the mouthpiece before the inspiration is begun, and often several tidal breaths are obtained. In this approach, the subject does inhale from the spirometer. There are advantages and disadvantages to both of these approaches and both are recommended procedures. For example, an advantage of the closed circuit technique is that it allows measurement of expiratory reserve volume (ERV), tidal volume (TV), and inspiratory flows.

Previous recommendations (1, 2) treated all spirometers alike whether used for clinical, diagnostic, or epidemiologic purposes. However, a new class of device has been added for monitoring purposes. Monitoring devices (portable peak flow meters, etc.) have separate recommendations from diagnostic spirometers for the recorder/display requirements as well as the accuracy requirements. In addition, precision requirements have been added for monitoring devices. Recommendations concerning monitoring devices are identified in this statement by the notation, 'Monitoring." We do *not* recommend the use of monitoring devices for diagnostic purposes in the traditional diagnostic setting where one is comparing a measured value with a reference value. In this setting, monitoring instruments are likely to be inadequate because: (1) they may be less accurate than diagnostic instruments; (2) they usually cannot be calibrated or checked to assure their performance; (3) their graphical displays may be missing or inadequate to allow proper evaluation of the subject's effort and overall test quality; and (4) current PEF standards of ± 10% allow models of instruments to vary by up to 20%, adding variability to reference values derived when a monitoring instrument is used. However, monitoring instruments may be useful in diagnosing excessive variability in spirometric parameters because they tend to have excellent precision.

EQUIPMENT RECOMMENDATIONS

Accurate results require accurate equipment. Spirometer equipment recommendations apply to all diagnostic spirometers whether used for clinical or epidemiologic purposes. Instrumentation recommendations should be followed to provide accurate spirometric data and information that are comparable from laboratory to laboratory and from one time period to another (1). The accuracy of a spirometry system depends on the resolution (i.e., the minimal detectable volume or flow) and linearity of the entire system, from volume or flow transducer to recorder, display, or processor. Errors at any step in the process can affect the accuracy of the results. For example, if the BTPS correction factor is in error, an accurate, uncorrected FVC will be corrupted when the factor is applied.

Recommendations are first provided for diagnostic spirometers, followed by recommendations for monitoring devices under the subheading, "Monitoring." For example, the equipment recommendations for diagnostic spirometry are summarized in Table 2 and for monitoring devices in Table 3. Spirometers are not required to measure all the following parameters but must meet the recommendations for those parameters that are measured. Accuracy and precision recommendations apply over the entire volume range of the instrument.

TABLE 2

MINIMAL RECOMMENDATIONS FOR DIAGNOSTIC SPIROMETRY*

Test	Range/Accuracy (BTPS)	Flow Range (L/s)	Time (s)	Resistance and Back Pressure	Test Signal
VC	0.5 to 8 L ± 3% of reading or ± 0.050 L, whichever is greater	zero to 14	30		3-L Cal Syringe
FVC	0.5 to 8 L ± 3% of reading or ± 0.050 L, whichever is greater	zero to 14	15	Less than 1.5 cm H_2O/L/s	24 standard waveforms 3-L Cal Syringe
FEV_1	0.5 to 8 L ± 3% of reading or ± 0.050 L, whichever is greater	zero to 14	1	Less than 1.5 cm H_2O/L/s	24 standard waveforms
Time zero	The time point from which all FEV_t measurements are taken			Back extrapolation	
PEF	Accuracy: ± 10% of reading or ± 0.400 Us, whichever is greater Precision: ± 5% of reading or ± 0.200 Us, whichever is greater	zero to 14		Same as FEV_1	26 flow standard waveforms
$FEF_{25-75\%}$	7.0 L/s ± 5% of reading or ± 0.200 Us, whichever is greater	± 14	15	Same as FEV_1	24 standard waveforms
$\dot{V}$	± 14 Us ± 5% of reading or ± 0.200 Us, whichever is greater	zero to 14	15	Same as FEV_1	Proof from manufacturer
MVV	250 Umin at TV of 2 L within ± 10% of reading or ±15 Umin, whichever is greater	± 14 ± 3%	12 to 15	Pressure less than ± 10 cm H_2O at 2-L TV at 2.0 Hz	Sine wave pump

* Unless specifically stated, precision requirements are the same as the accuracy requirements.

Recommendation: Vital Capacity (VC)

vc = The maximal volume of air exhaled from the point of maximal inhalation or the maximal volume of air inhaled from a point of maximal exhalation can be measured with a slow exhalation or inhalation, respectively. This was previously called the "slow" vital capacity and has been better described as the "relaxed vital capacity" (13). The VC is expressed in liters **(BTPS).** BTPS is body conditions: normal body temperature (37" C), ambient pressure, saturated with water vapor. When the **rebreathing** technique is used, an oxygen supply may be provided and carbon dioxide absorbed to account for oxygen consumption and the production of carbon dioxide In this case, the oxygen supply must account for the total oxygen consumed, maintaining the volume constant at functional residual capacity. If this is not done properly, an incorrect VC could be obtained. Because of this potential error, the rebreathing technique with the absorption of carbon dioxide is discouraged as a technique when only VC is to be measured.

Rationale. In some subjects, a slow or relaxed vital capacity provides a more accurate determination of the vital capacity than those obtained with a forced exhalation. Forced expiratory volumes are usually lower than those obtained with a slow exhalation in subjects with airways obstruction and in older subjects. With severe airways obstruction, VC values may be larger than FVC values by as much as 1 L.

TABLE 3

MINIMAL RECOMMENDATIONS FOR MONITORING DEVICES

Requirement	FVC & FEV_t (BTPS)	PEF (BTPS)
Range	High: 0.50 to 8 L Low: 0.5 to 6 L	High: 100 Umin to ≥ 700 Umin but ≤ 850 Umin Low: 60 Umin to ≥ 275 Umin but ≤ 400 Umin
Accuracy	± 5% of reading or ± 0.100 L, whichever is greater	± 10% of reading or ± 20 L/min, whichever is greater
Precision	± 3% of reading or ± 0.050 L, whichever is greater	Intradevice: ≤ 5% of reading or ≤ 10 Umin, whichever is greater Interdevice: ≤ 10% of reading or ≤ 20 Umin, whichever is greater
Linearity	Within 3% over range	Within 5% over range
Graduations	Constant over entire range High: 0.100 L Low: 0.050 L	Constant over entire range High: 20 Umin Low: 10 Umin
Resolution	High: 0.050 L Low: 0.025 L	High: 10 Umin Low: 5 Umin
Resistance	Less than 2.5 cm H_2O/L/s, from zero to 14 Us	Less than 2.5 cm H_2O/L/s, from zero to 14 Us
Minimal detectable volume	0.030, L	
Test Signal	24 standard volume-time. waveforms	M-standard flow-time waveforms

High = high range and low = low range devices.

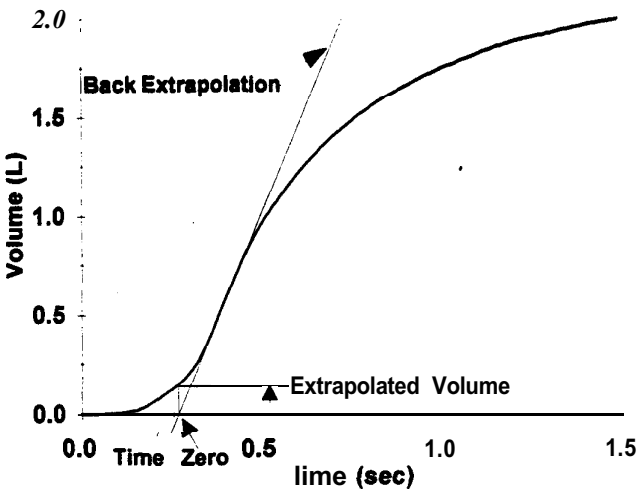


Figure 2. Typical subject waveform of a volume-time spirogram illustrating back extrapolation to determine "time zero." Extrapolated volume = Vext.

For measurements of VC, the spirometer must be capable of accumulating volume for *at feast* 30 s. Spirometers must be capable of measuring volumes of *at least 8* L (BTPS) with flows between zero and 14 L/s with a volume accuracy of *at least* ± 3% of reading or ± 0.050 L, whichever is greater.

Recommendation: Forced Vital Capacity (WC)

FVC = Maximal volume of air exhaled with maximally forced effort from a position of maximal inspiration, i.e., vital capacity performed with a maximally forced expiratory effort, expressed in liters (BTPS).

The diagnostic spirometer must be capable of measuring volumes up to *a? feast 8* L (BTPS) with an accuracy of *a? least* ± 3% of reading or ± 0.050 L, whichever is greater, with flows between zero and 14 L/s. The 8-L range requirement applies to newly manufactured instruments; existing spirometers with a 7-L range may continue to be used. The spirometer must be capable of accumulating volume for *at least* 15 s, although longer times are recommended.

Monitoring. Monitoring devices must be capable of measuring volumes up to *at least 8* L (BTPS) with an accuracy of *at least ± 5%* of reading or ± 0.100 L, whichever is greater, with flows between zero and 14 L/s. The precision of the monitoring devices must be *at least ± 3%* of reading or ± 0.050 L, whichever is greater. The device must be capable of accumulating volume for *at least* 15 s.

Recommendation: Timed Forced Expiratory Volume (FEV_t)

FEV, = The volume of air exhaled in the specified time during the performance of the FVC, e.g., FEV_1 for the volume of air exhaled during the first second of FVC, expressed in liters (BTPS).

Measuring FEV_t requires a spirometer capable of measuring volumes of at *feast* 8 L. The spirometer must measure FEV_t within an accuracy of *at least* ± 3% of reading or ± 0.050 L, whichever is greater, with flows between zero and 14 L/s. The start-of-test for purposes of timing must be determined by the back extrapolation method (1, 14, 15) or a method shown to be equivalent (Figure 2). For manual measurements, the back extrapolation method traces back from the steepest slope on the volume-time curve (Figure 2) (15, 16). For computer methods of back extrapolation, we recommend using the largest slope averaged over an 80-ms period (17). The total resistance to airflow at 14.0 L/s must be less than 1.5 cm H_2O/L/s. The total resistance must be measured including any tubing, valves, pre-filter, etc., that may be inserted between the subject and the spirometer. Since some devices may exhibit changes in resistance due to water vapor condensation, resistance requirements must be met under BTPS conditions when up to eight successive FVC maneuvers are performed in a IO-min period.

Monitoring. The monitoring device must be capable of measuring FEV_t up to at *feast 8* L (BTPS) with an accuracy of at least ± 5% of reading or ± 0.100 L, whichever is greater, with flows between zero and 14 L/s. The precision of the monitoring devices for FEV_t must be at *least* ± 3% of reading or ± 0.050 L, whichever is greater. Resistance should be less than 2.5 cm H_2O/L/s and the start-of-test requirement is the same as for diagnostic spirometry.

Recommendation: PEF

PEF = Largest expiratory flow achieved with a maximally forced effort from a position of maximal inspiration, expressed in liters/second (BTPS).

Measuring PEF requires an instrument that has a frequency response that is flat (± 5%) up to 12 Hz. The instrument must measure PEF within an accuracy of ± 10% of reading or ± 0.300 L/s, whichever is greater. Intra-instrument precision must be less than 5% of reading or 0.150 L/s, whichever is greater. Inrerdevice precision must be less than 10% or 0.300 L/s, whichever is greater.

The following or an equivalent method can be used in the determination of FEF, or PEF for volume-time curvés. However, the method used to derive PEF may depend on the measuring instrument (18), and the final determination of compliance should be determined through testing using the standard waveforms (26 flow-time waveforms, APPENDIX D), with PEF derived from the flow-time waveform (Table Dl, column 2).

Determination of PEF can be performed from the volume-time data by using a parabolic curve-fitting algorithm, which smooths the data using a least squares parabolic fit to a 40- or 80-ms segment (np = 2 or 4) of the volume-time curve, or:

$$\text{flow}(n) = \frac{\sum_{j=-np}^{np} j \cdot \text{vol}(n+j)}{2.h. \sum_{j=1}^{np} j \cdot j} \qquad \text{PEF} = \text{Max (flow)}$$

where flow = an array of flow values from start to end of test; n = index of current flow data point (n = [np + 1] to index value of end of test); vol = an array of volume values; j = an index value as indicated in the equation; h = the time between samples (0.01 s in this example); np = the number of data points (for a 40-ms segment, np = 2 and for an 80-ms segment, np = 4); and PEF is the maximum value observed in the array flow.

Rationale. Using the 26 flow-time waveforms to define PEF is a change from the ATS 1987 Update. The PEFs for the 24 standard volume-time waveforms and the FEF_{max} described in the 1987 ATS Spirometry Update used the above algorithm with an 80-ms interval. Manufacturers, through the use of mechanical simulators and the 24 standard volume-time waveforms, have been implementing this or equivalent methods through their attempts to derive PEFs similar to those defined by the 24 standard volume-time waveforms.

In addition, the National Asthma Education Program (NAEP) (5) has adopted ATS standard volume-time waveform number 24 as their standard for portable PEF meters. Hankinson and Crapo (18) have shown that reducing the time interval in the above equation from 80 to 40 ms results in as much as an 8% higher PEF for two of the 24 standard volume-time waveforms and a

5% higher PEF value for waveform number 24. Regardless of this apparent change, PEF is a flow parameter and therefore should be defined based on a flow-time waveform rather than a volume-time waveform (i.e., waveform number 24). The final determination of compliance should be determined through testing using the standard 26 flow-time waveforms (APPENDIX D) and the PEF derived from the flow-time curve (Table D1, column 2). This approach allows all of an instrument's characteristics to be considered, rather than only the PEF computational algorithm. Because PEF is more variable than FVC and FEV, and because of the confusion surrounding PEF definition, a relatively large ± 10% accuracy requirement was allowed.

Recommendation (Monitoring): PEF

PEF = Largest expiratory flow achieved with a maximally forced effort from a position of maximal inspiration, expressed in liters/minute (BTPS).

Monitoring PEF also requires an instrument that has a frequency response that is flat (± 5%) up to 12 Hz and a resistance less than 2.5 cm H_2O/L/s with flows up to 14 L/s. The instrument must measure PEF within an accuracy of ± 10% of reading or ± 20 L/min, whichever is greater, with PEFs between 60 to 400 L/min for children and from 100 to 850 L/min for adults. The lower limit range of the instrument must be less than or equal to 60 L/min for children and 100 L/min for adults. The upper limit range must be greater than or equal to 275 L/min but less than 400/L min for children and greater than'or equal to 700 L/min but less than 850 L/min for adults. If manual reading of the instrument is used, the reader must be able to resolve at least 5 L/min for low range (children) and 10 L/min for high range (adults) (marked PEF intervals [graduations] no greater than 10 L/min for low range and 20 L/min for high range). Intra-instrument precision must be less than or equal to 5% of reading or 10 L/min, whichever is greater. Interdevice precision must be less than 10% or 20 L/min, whichever is greater. Data on the instrument's life span and durability must be provided by the manufacturer, specified as the typical life span over which the instrument will satisfy the requirements of this section.

In addition to the above requirements, PEF measuring devices must also provide a method of reporting values at BTPS. For portable PEF meters, BTPS correction may be accomplished by limiting the environmental operational range for the instrument in terms of barometric pressure (altitude) and ambient temperature. Portable PEF meters must meet the accuracy and precision requirements above, given the range of environmental conditions encountered with typical use. A 10% accuracy requirement, higher than the 5% for other flows, is recommended to allow for potential BTPS correction complications associated with PEF measurements. Besides providing a method of correcting PEF values to BTPS, the instrument's manufacturer must also provide a correction for the effects of altitude or other environmental conditions as appropriate.

A package insert must be provided with each portable PEF meter containing *at feast: (1) clear* instructions (with illustrations) for use of the instrument in simple terms that are understood by the general public; (2) instructions concerning maintenance of the instrument and methods to recognize when it is malfunctioning; and (3) appropriate actions to be taken when PEF readings change appreciably (i.e., whom to contact).

Rationale. Concerning the requirement of a flat frequency response up to 12 Hz, Lemen and coworkers (19) have shown that the mean highest frequency (HF) with significant amplitude content was 5.06 Hz in healthy individuals and 6.4 Hz in patients and smokers. They concluded that flow measuring devices should have a frequency response that is flat up to 12 Hz. Peslin and coworkers (20) found a slightly higher HF of about 10 Hz in healthy males and 7.5 Hz in female subjects. In addition, current mechanical waveform-generating equipment generally cannot accurately produce waveforms with frequency content above 12 Hz. The accuracy recommendation is less stringent for PEF than for the FVC and FEV, (10% versus 5%) because of the higher within- and between-subject variabilities associated with PEF measurements and because of testing instrument limitations. The PEF instrument precision and intra-instrument variability recommendations are lower (5%) than the accuracy and inter-instrument variability requirements (10%) because of the need for low instrument variability in the routine use of PEF meters for serial measurements. In addition, several studies have shown PEF meters to be much more precise than accurate (21-23). These recommendations are also similar to those of the NAEP (5). The range recommendations are made with the understanding that PEF measurements are often made using portable PEF meters. With these meters, reading resolution (number of graduations) must be balanced against the range of the meter (upper and lower meter limits). Therefore, different instrument ranges for children and adults are appropriate. The range recommendations for children are not intended to preclude the use of an instrument with adult ranges if the instrument meets the resolution requirements (ease of reading) for children.

An instrument's life span and durability are difficult to determine and will be specific to an instrument. However, portable peak flowmeters are often used for extended periods of time. Therefore, the instrument manufacturer must provide information on the typical life span of their instrument as well as cleaning and other maintenance instructions. The package insert requirements recommended by the NAEP (5) are similar to those recommended in this statement.

Recommendation: $FEF_{25-75\%}$

$FEF_{25-75\%}$ = Mean forced expiratory flow during the middle half of the FVC. Formerly called the maximal mid-expiratory flow (MMEF), expressed in liters/second (BTPS).

The $FEF_{25-75\%}$ must be measured with an accuracy of *at feast* ± 5% of reading or ± 0.200 L/s, whichever is greater, over a range of up to 7 L/s. The $FEF_{25-75\%}$ must be measured on a system that meets diagnostic FVC recommendations.

Recommendation: Flow ($\dot{V}$)

$\dot{V}$ = Instantaneous forced expiratory flow (except for PEF), expressed in liters/second (BTPS).

Flow may be measured electronically or manually from a flow-volume display with adequate size for hand measuring. Where flow-volume loops or other uses of flow are made, with flow in the range of -14 to 14 L/s, the flow must be measurable to within ± 5% of reading or ± 0.200 L/s, whichever is greater.

Recommendation: Forced Expiratory Time (FET%)

FET% = Time from the back-extrapolated "time zero" until a specified percentage of a maneuver's FVC is exhaled, expressed in seconds. For example, FET95% would be the time required to reach 95% of a maneuver's FVC. See APPENDIX A for FET% examples. FET100% would be defined as the time required to reach the FVC or the time at which the volume was observed to be at its highest level. For maneuver quality assessment purposes, the reporting of the FET99% (24) or FET100% is encouraged but not mandated. Also, the FET25-75% (mid-expiratory time) may be a useful indicator of diminished flow when VC is decreased and may be less dependent on body or lung size than other flow parameters (25).

Recommendation: Forced Inspiratory Vital Capacity Maneuvers

These maneuvers are inspiratory vital capacity maneuvers per-

formed with maximally forced effort from a position of maximal expiration to a position of maximal inspiration. Roth volume and flow parameters are measured, which roughly correspond (except for direction) to those from the FVC maneuver. Volume measurements are expressed in liters (BTPS), flow measurements in liters/second (BTPS).

Rationale. Forced inspiratory maneuvers are useful in diagnosing and monitoring upper airway obstruction. They are usually performed either preceding or following the FVC maneuver but may be performed separately. Elderly or ill patients often have difficulty performing forced inspiratory and expiratory maneuvers as part of the same effort. Forced inspiratory maneuvers require the use of one of the closed circuit techniques.

For measurements of forced inspiratory spirometric parameters diagnostic spirometers must meet the corresponding range, accuracy, and precision recommendations specified for diagnostic spirometry systems (Table 2).

Recommendation: Maximal Voluntary Ventilation (MW)

MVV = The volume of air exhaled in a specified period during repetitive maximal respiratory efforts, expressed in liters/minute (BTPS).

When a spirometer is used for measuring MVV, it must have an amplitude-frequency response that is flat within ± 10% from zero to 4 Hz at flow rates of up to 12 L/s over the volume range. The time for exhaled volume integration or recording must be no less than 12 s nor more than 15 s (26). The indicated time must be accurate to within ± 3%. The MVV must be measured with an accuracy of ± 10% of reading or ± 15 L/min, whichever is greater.

General Background: Spirometry Recorders/Displays

Paper records or graphic displays of spirometry signals are required and are used for:

1. Diagnostic function-when waveforms are to be used for quality control or review of the forced expiratory maneuver to determine if the maneuver was performed properly, so that unacceptable maneuvers can be eliminated.
2. Validation function-when waveforms are to be used to validate the spirometer system hardware and software for accuracy and reliability through the use of manual measurements (for example, measurement of FEV, using back extrapolation by comparing computer- and manually determined FEV,).
3. Manual measurement function-when waveforms are to be manually measured for spirometric parameters (FVC, FEV_1, etc) in the absence or failure of a computer.

With the continued advances in computer technology, there are many different ways to display and record spirometric waveforms. The committee continues to encourage use of computer technology.

Paper recorder requirements are the same regardless of the purpose, diagnostic, validation, or manual measurement. If no paper recorder or printer is available, then proof of validation of the accuracy and stability of the spirometer by an independent laboratory *must* be provided by the manufacturer. For these computer methods, any new software releases *must* also be validated.

Recommendation: Display of VC Maneuver

Either "open" or "closed" circuit technique may be used to measure the VC maneuver. Although the open circuit technique may be preferred because of hygiene concerns, this technique does not allow the monitoring (display) of the inhalation to TLC and therefore is less than optimum. Regardless of whether the open or closed circuit technique is used, a display of the entire VC maneuver must be provided. The maximal expiratory volume must be assessed to determine whether the subject has obtained a plateau in the expiratory effort. Subjects with airways obstruction usually exhibit different shaped curves at the end of their expiratory maneuver-a slope showing the nonhomogeneous emptying of lung units. Some patients with severe airways obstruction are not able to return to the level of FRC due to gas trapping (see APPENDIX A, VC maneuvers). In addition, important differences between inspiratory (IVC) and expiratory (EVC) maneuvers may be observed in patients with airways obstruction (27). For systems using a closed circuit with carbon dioxide absorption, a'volume-time display is needed to verify baseline end-expiratory level (functional residual capacity or FRC). The graph should indicate the starting volume to evaluate the correct positioning of FRC.

Recommendation: Display of NC Maneuver

Displays using flow versus volume instead of volume versus time expand the initial portions (first l-2 s) of the forced vital capacity maneuver. Since this portion of the maneuver, particularly the peak expiratory flow, is correlated with the pleural pressure during the maneuver, the flow-volume display is useful to assess the magnitude of effort during the initial portions of the maneuver. Overlaying a series of flow-volume curves registered at apparent TLC (maximal inhalation, which may not be true TLC) is helpful in detecting a submaximal effort that may result in a large though nonreproducible FEV, as a consequence of negative effort dependence (28).

Unlike the flow-volume curve display, display of the FVC maneuver as a volume-time graph expands the terminal portions of the maneuver. Therefore, the volume-time display is useful in assessing the duration of effort and whether a plateau is achieved. Where spirometry may need to be reviewed by independent agencies, a volume-time tracing of sufficient size allows independent measurement and calculation of parameters from the FVC maneuvers. Overlaying a series of volume-time curves aligned at back-extrapolated time zero or flow-volume curves aligned at TLC is useful in evaluating reproducibility and submaximal efforts. For optimal quality control, both flow-volume and volume-time displays are useful and strongly encouraged. See APPENDIX A for illustrations of volume-time and flow-volume displays.

Recommendation: VC and NC Maneuver Volume and Time Scales

Volume scale: When a volume-time curve is plotted or displayed, the volume scale must be *at least:* 10 mm/L (BTPS).

Time scale: *at least* 2 cm/s; larger time scales are preferred (at least 3 cm/s) when manual measurements are to be made (1, 29, 30). When the volume-time plot is used in conjunction with a flow-volume curve (both display methods are provided for interpretations and no hand-measurements are performed), the time scale requirement is reduced to 1 cm/s from the usually required minimum of 2 cm/s. This exception is allowed because, in these circumstances, the flow-volume curve can provide the means for quality assessment during the initial portion of the FVC maneuver. The volume-time curve can be used to evaluate the terminal portion of the FVC maneuver, and the time scale is less critical. For display of the slow VC, the volume scale may also be reduced to 1 cm/L and the time scale to 0.5 cm/s.

Recommendation: Flow-Volume Curves

When a flow-volume curve is plotted or displayed, exhaled flow must be plotted upwards and exhaled volume towards the right.

TABLE 4

MINIMUM REQUIRED SCALE FACTORS FOR TIME, VOLUME, AND FLOW GRAPHICS

Parameter	Resolution Required	Scale Factor
Volume	0.025 L	10 mm/L
Flow	0.100 us	5 mm/Us
Time	0.20 s	2 cm/s

A 2:1 ratio must be maintained between the flow and volume scales, e.g., 2 L/s of flow and 1 L of exhaled volume must be the same distance on their respective axes. The flow and volume scales must be at *least* as shown in Table 4.

Rationale. It was the committee's unanimous opinion that the previous diagnostic recorder requirements of 5 mm/L and 1 cm/s have proven inadequate for judging the quality of an expiratory effort, eg., terminal events are not detectable (APPENDIX A). For certain applications (for example, for disability determination and legal cases), diagnostic size displays are clearly not adequate (26, 30). The U.S. Cotton Dust standard requires "... tracings must be stored and available. for recall and must be of sufficient size that manual measurements may be made ..." (31). Also, users will customarily not be able to verify accuracy and stability of spirometers by themselves in the absence of an adequate paper recording.

Recommendation: Correction to BTPS

This statement recommends that diagnostic spirometric studies not be conducted with ambient temperatures less than 17" C or more than 40" C. In part, the rationale for this recommendation is based on problems with finite cooling times of gases in volume-type spirometers (32-34) and the problems of estimating BTPS correction factors for flow devices (35-37). When a subject performs.an FVC maneuver, the air leaving the lungs and entering the spirometer is at approximately 33 to 35" C (38, 39) and is saturated with water vapor. Most volume-type spirometers assume instantaneous cooling of the air as it enters the spirometer. However, this is not always the case, and an error in FEV, can occur due to the incorrect assumption of instantaneous cooling of the air. For capillary and screen pneumotachometers, the gain is dependent on gas viscosity and increases with increasing temperature. Therefore, a different correction factor is needed between patients and a calibrating syringe and between inspiratory and expiratory maneuvers. In addition, the assumption is usually made that no cooling of the air occurs as the air passes through the flow sensor. This may not be the case, particularly with unheated flow sensors (35). If the expired gas is assumed to be BTPS, an error of about 1% will result. The error will increase if the flow sensor is located further from the mouth and more cooling occurs. In addition, water condensation within or on the surface of a flow sensor may alter its calibration. Depending on environmental temperature, the BTPS correction factor may be as large as 10%. Therefore, the method used to calculate or estimate the BTPS factor can potentially introduce significant errors by the application of an erroneous BTPS correction factor.

Changes in spirometer temperature can be a source of variability; therefore, spirometer temperature should be measured and not assumed to be constant, even over the course of one testing session. Johnson and colleagues (40) found that if ambient temperature was used in BTPS correction and applied to all maneuvers, FEV, and FVC measurement errors of up to 6% may occur. When using volume spirometers, they recommend that the temperature of air inside the spirometer should be measured accurately during each breathing maneuver.

Recommendation (Monitoring): Correction to BTPS

For operating simplicity, monitoring devices may use one BTPS correction factor for a range of barometric pressures (altitude) and environmental temperatures. However, the use of a single BTPS correction factor or direct readings at BTPS does not eliminate the requirement to meet the accuracy specifications under BTPS conditions. Therefore, manufacturers must provide appropriate labeling concerning the environmental conditions (ambient temperature and pressure) under which their device will meet the accuracy requirements. If necessary or appropriate, the manufacturer may provide several BTPS correction factors to meet the accuracy requirements over a range of environmental conditions (altitude and temperature).

EQUIPMENT VALIDATION

Recommendation: FVC Validation

The diversity of FVC maneuvers encountered in clinical practice are currently best simulated by the use of the 24 standard waveforms developed by Hankinson and Gardner (17, 41). These waveforms can be used to drive a computer-controlled mechanical syringe or its equivalent for testing actual hardware and software (42, 43) or they can be put into a system in digital form to evaluate *only* the software. It is strongly recommended that spirometry systems be evaluated using a computer-driven mechanical syringe or its equivalent and that the digital forms only be used for evaluating changes in software. APPENDIX C shows the measured values for each of the 24 standard waveforms. The American Thoracic Society also provides these waveforms on floppy disks for an IBM-PC.* Appropriate corrections for using gas at ambient temperature and humidity instead of BTPS may need to be made for some mechanical syringe-spirometer combinations. In addition, precision criteria have been added, and testing of spirometry systems using heated and humidified test gas is recommended.

The accuracy validation limits (tolerance for simulator systems is included in these limits) for volume are: volume (FVC, FEV,) ± 3.5% of reading or ± 0.070 L, whichever is greater; and average flow ($FEF_{25-75\%}$) ± 5.5% of reading or ± 0.250 L/s, whichever is greater. The error range is expanded from the earlier ATS spirometry recommendation to allow for errors associated with mechanical syringes (42). The precision validation limits are: volume (FVC and FEV_1) 3.5% (range percent) or 0.100 L, whichever is greater; and flow ($FEF_{25-75\%}$) 5.5% or 0.250 L/s, whichever is greater. Mechanical syringes used for validation must be accurate within ± 0.025 L for FVC and FEV, and ± 0.100 L/s for $FEF_{25-75\%}$.

Rationale. Testing of spirometry systems using heated and humidified test gas has been added to the validation criteria because of potential problems associated with BTPS correction (32-37). See APPENDIX B for further details.

Recommendation: PEF Validation

PEF instrument designs must be validated using a mechanically driven syringe or its equivalent, using the flow-time waveforms described in APPENDIX D. These waveforms are available on digital media from the ATS. In addition, the mechanically driven syringe must be validated (APPENDIX B) to ensure that it accurately produces these waveforms and corresponding PEFs within ± 2% of reading. The flow-time waveforms in APPENDIX D were chosen to represent a range of peak flows and flow-time signals with various times-to-PEF (time required to go from 0.200 L/s to PEF). The accuracy validation limit for PEF is ± 12% of reading or ± 25 L/min, whichever is greater.

* Available from the American Thoracic Society.

The precision (range deviation) validation limit for PEF is 6% or 15 L/min, whichever is greater.

Rationale. The NAEP (5) recommended the use of a mechanically driven syringe to test and validate the accuracy of peak flow measuring instruments and to assess intra- and interdevice precision. Their recommendations included the use of ATS waveform 24 with various multipliers to achieve different PEFs. One problem with using only waveform 24 is a lack of variability in the shape or rise-time in the waveforms used to test PEF meters. Therefore, the use of several waveforms in the testing and validation of PEF meters to provide a range of PEFs and times-to-PEF (rise-times) is recommended. The waveforms in APPENDIX D are flow-time waveforms and, therefore, the definition of peak flow obtained from these waveforms is simple to derive. In addition, a volume-time curve for use by the mechanically driven syringe can be obtained from a flow-time curve by simply summing the flow-time values (integrating the flow signal).

The accuracy of the mechanically driven syringe for PEE ± 2% of reading, was chosen based on current technical feasibility. Current technology of mechanically driven syringes is not sufficient to provide greater accuracies. This is due to the dynamic aspect of peak flow – high frequency content and PEF occurs at a point in the flow-time signal where the acceleration is changing, resulting in potential "overshoot" by a mechanical syringe. In addition, insufficient data are available concerning the accuracy of PEF meters using waveforms with higher frequency content (shorter times-to-PEF). Additional detailed information concerning spirometer testing procedures is contained in APPENDICES B, C, and D.

Recommendation: MW Validation

When tested with a pump producing a sinusoidal waveform, the accuracy validation limits of the spirometer used for MVV for flows up to 250 L/min, produced with stroke volumes up to 2 L, are ± 10.5% of reading or ± 20 L/min, whichever is greater. During the testing, the pressure at the mouthpiece must not exceed ± 10 cm H_2O. For volume spirometers, these requirements apply throughout their volume range.

QUALITY CONTROL

Routine equipment preventive maintenance – cleaning, calibration checks, verification, and quality control- is essential to assure accurate spirometry results (44). A spirometry procedure manual is an important base for a quality assurance program. The manual should contain a quality control plan, guidelines for ordering spirometry, guidelines for performing spirometry, and guidelines for reporting spirometry results. See the document, "ATS Quality Assurance for Pulmonary Laboratories," for more details (44).

Recommendation: Technician's Role in Quality Control

Quality control is important to ensure that the laboratory is consistently meeting appropriate standards. In any quality control program, an important element is a procedures manual containing: calibration procedures, test performance procedures, calculations, criteria, reference values source, and action to be taken when "panic" values are observed. A notebook should be maintained that documents daily instrument calibration as well as problems encountered with the system, corrective action required, and system hardware and software upgrades. Records of anomalous events involving either patients/subjects or the technician should be documented, with the results of subsequent evaluation and responses to the event. The technician should also maintain records of continuing education and the results of evaluation and feedback provided by the medical director. Perhaps the most important component in successful spirometry is a well-motivated, enthusiastic technician. A recent study has clearly demonstrated the importance of a quality control program with feedback to technicians in obtaining adequate spirometry results (8). A quality control program that continuously monitors technician performance is critical to the collection of high-quality spirometry data. Feedback to the technicians concerning their performance should be provided on a routine basis. This feedback should include, at a minimum: (1) information concerning the nature and extent of unacceptable FVC maneuvers and nonreproducible tests; (2) corrective action the technician can take to improve the quality and number of acceptable maneuvers; and (3) recognition for superior performance by the technician in obtaining good maneuvers from challenging patients/subjects.

Manufacturers are encouraged to include quality control aids in their software packages for spirometers. For example, a calibration logging program may be provided that stores the time and results of routine daily calibration checks. Additionally, the program could issue a warning if an acceptable daily calibration check has not been performed.

Recommendation: Hygiene and Infection Control

This section has been reviewed by the Microbiology Assembly.

The major goal of infection control is to prevent infection transmission to patients/subjects and staff during pulmonary function testing. Two major types of infection transmission are:

1. Direct contact: There is potential for transmission of upper respiratory disease, enteric infections, and blood-borne infections through direct contact. Although hepatitis and HIV contagion are unlikely via saliva, this is a possibility when there are open sores on the oral mucosa, bleeding gums, or hemoptysis. The most likely surfaces for contact are mouthpieces and the immediate proximal surfaces of valves or tubing.
2. Indirect contact: There is potential for transmission of tuberculosis, various viral infections, and, possibly, opportunistic infections and nosocomial pneumonia through aerosol droplets. The most likely surfaces for possible contamination by this route are mouthpieces and proximal valves and tubing.

Prevention:

1. Prevention of infection transmission to technicians exposed to contaminated spirometer surfaces can be accomplished through proper hand washing or use of barrier devices (latex gloves). To avoid technician exposure and cross-contamination, hands should be washed immediately after direct handling of mouthpieces, tubing, breathing valves, or interior spirometer surfaces. Gloves should be worn when handling potentially contaminated equipment if there are any open cuts or sores on technicians' hands. Hand washing should always be performed between patients. Indications and techniques for hand washing during pulmonary function testing have been reviewed by Tablan and coworkers (45).
2. To avoid cross-contamination, reusable mouthpieces, breathing tubes, valves, and manifolds should be disinfected or sterilized regularly. Mouthpieces, nose clips, and any other equipment coming into direct contact with mucosal surfaces should be disinfected, sterilized, or discarded (i.e., disposable mouthpieces, nose clips, etc) after each use. The optimal frequency for disinfection or sterilization of tubing, valves, or manifolds has not been established. However, any equipment surface with visible condensation from expired air should be disinfected or sterilized before reuse Since the use of cold sterilizing agents is not without risk, laboratory staff should take care to follow all manufacturer's recommendations regarding proper handling of these products.
3. Between subjects, spirometers using the closed circuit tech-

nique should be flushed at least five times over the entire volume range to facilitate clearance of droplet nuclei. Also, the breathing tube and mouthpiece should be decontaminated between patients. When the open circuit technique is used, only that portion of the circuit through which rebreathing occurs needs to be decontaminated between patients. For example, when a pneumotachometer system is used, either inspiration from the device should be avoided or the resistive element and tubing should be decontaminated between subjects. A disposable sensor is another alternative. When an open circuit technique is used for measurement of only the forced exhalation, without inspiration from the measuring system (either volume- or flow-type spirometers), only the mouthpiece needs to be changed or decontaminated between subjects.

It should be noted that disassembling, cleaning, and/or sensor replacement requires recalibration. If patients do not inspire through the device, there is the disadvantage that test acceptability may be more difficult to assess in the absence of an inspiratory tracing. On the other hand, disassembly, cleaning, or sensor replacement has the disadvantage that recalibration is required. Alternatively, in-line filters may be effective in preventing equipment contamination (46). However, if an in-line filter is used, the measuring system should meet the minimal recommendations for range, accuracy, flow resistance, and back pressure with the filter installed. The influence of commercially available in-line filters on forced expiratory measures, such as the FVC and FEV,, has not been well characterized.

4. In settings where tuberculosis or other diseases spread by droplet nuclei are likely to be encountered, proper attention to environmental engineering controls, such as ventilation, air filtration, or ultraviolet decontamination of air, should be used to prevent disease transmission.
5. Special precautions should be taken when testing patients with hemoptysis, open sores on the oral mucosa, or bleeding gums. Tubing and breathing valves should be decontaminated before reuse and internal spirometer surfaces should be decontaminated with accepted disinfectants for blood-transmissible agents.
6. Extra precautions may be undertaken for patients with known transmissible infectious diseases. Possible precautions include: (a) Reserving equipment for the sole purpose of testing infected patients; (b) testing patients at the end of the day to allow time for spirometer disassembly and disinfection; and (c) testing patients in their own room or in rooms with adequate ventilation and easily cleaned surfaces.
7. In the absence of evidence for infection transmission during pulmonary function testing, the regular use of in-line filters is not mandated when the precautions described above are followed. However, some spirometric equipment, particularly those incorporated in multi-purpose testing systems, employ valve manifolds that are situated proximal to breathing tubes. These valving arrangements provide internal surfaces on which deposition of expired aerosol nuclei is likely. Given their complexity, they may be difficult to disassemble and disinfect between subjects. To the extent that in-line filters have been shown to remove microorganisms from the expiratory air stream and thus prevent their deposition, presumably as aerosol nuclei on spirometer surfaces (46), their use may be indicated in this setting. The economy of using in-line filters compared with tubing and valve changes depends on the PFT equipment in use. The extent to which measures such as maximum expiratory flow or other instantaneous flows are influenced by the use of in-line filters is undocumented. One study has shown that a low impedance barrier device did not have a significant impact on spirometric indices, such as the forced vital capacity and the FEV, (47). If an in-line filter is used during spirometry, interpretation of spirometric indices other than FVC and FEV, (eg., PEF) should allow for the possibility that the filter might affect spirometer performance The mechanical characteristics of the combined measuring device and filter should meet the minimal recommendations outlined in Table 2. Furthermore, if in-line filters are used, it is recommended that equipment be calibrated with the filter installed. The use of in-line filters does not eliminate the need for regular cleaning and decontamination of spirometric equipment.
8. Manufacturers of spirometric equipment are encouraged to design instrumentation that can be easily disassembled for disinfection.

Rationale. Spirometric equipment has not been directly implicated in the transmission of infections, although there is indirect evidence of infection transmission during pulmonary function testing (PFT). Organisms from the respiratory tract of test subjects can be recovered from PFT mouthpieces and from the proximal surfaces of tubing through which the subjects breathe (48, 49). There is one case report of a tuberculosis skin-test conversion after exposure to a spirometer used to test a patient with documented tuberculosis (50). Likewise, there is circumstantial evidence that contaminated PFT equipment may be implicated in the increasing prevalence of *Pseudomonas* infections among cystic fibrosis patients at one center (51). There is some evidence that pneumotachometer-based systems are less susceptible to bacterial contamination than water-sealed spirometers (52). Finally, it is well documented that community hospital water supplies can be contaminated with Mycobacteria and *Pseudomonas aeruginosa* organisms (53-55). Thus, the potential exists for both patients/subjects and health care workers to deposit microorganisms onto spirometer surfaces (including mouthpieces, nose clips, tubing, and any internal or external machine surface), which could subsequently come into direct or indirect contact with other patients. This does not seem to pose an appreciable threat to patients/subjects with competent immune systems.

It has been argued that immunocompromised patients may require only a relatively small infective dose of either opportunistic organisms or common pathogens. Concerns for the protection of immunocompromised hosts, along with increased public and provider awareness of hospital infection control issues over the past decade, has led many laboratory directors to use in-line filters routinely as a means of reassuring patients and laboratory personnel that adequate consideration has been given to protection. There is no direct evidence that routine spirometry testing poses an increased risk of infection to immunocompromised patients.

Recommendation: Equipment Quality Control

The recommendations that follow are primarily aimed at diagnostic devices.

Attention to good equipment quality control and calibration is an important part of good laboratory practice. Log books of calibration results must be maintained. Documentation of repairs or other alterations that return the equipment to acceptable operation need to be maintained. Dates of computer software and hardware updates or changes must also be maintained.

Volume. The spirometer's ability to accurately measure volume must be checked *at least* daily with a calibrated syringe with a volume of at least 3 L. During industrial surveys or other studies in which a large number of subject maneuvers are done, the equipment's calibration must be checked daily, before testing, and every 4 h during use (44). In circumstances where the temperature is changing (e.g., field studies), more frequent temperature corrections may be needed. Although there is minimal day-to-day variation in volume calibration, daily calibration checking is highly recommended so that the onset of a problem can be de-

termined within 1 day, eliminating needless reporting of false values for several weeks or months and also to help define day-to-day laboratory variability. It is recommended that the calibration syringe be stored and used in such a way as to maintain the exact temperature and humidity of the testing site. This is best accomplished by keeping the syringe in close proximity to the spirometer. In the case of flow-type spirometers where a volume syringe is used to check the instrument, volume calibration checks using different flow rates are recommended. At least three trials where the flow rates are varied between 2 and 12 L/s must be performed (3-L injection times of approximately 1 s, 6 s, and somewhere in between 2 and 6 s).

Syringe Accuracy. The syringe used to check the volume calibration of spirometers must have an accuracy of at least 15 ml or at least 0.5% of full scale (15 ml for a 3-L syringe), and the manufacturer must provide recommendations concerning appropriate syringe calibration intervals. If the syringe has an adjustable variable stop, the syringe may be out of calibration if the stop is reset. Calibration syringes should be leak-tested periodically by trying to empty them with the outlet corked.

Leak Test. Volumetric spirometer systems must be evaluated for leaks on a daily basis (15, 56). The Intermountain Thoracic Society Manual (15) suggests that leaks can be detected by applying a constant positive pressure of 3 cm H_2O or more with the spirometer outlet occluded. Any observed volume change of greater than 10 ml after 1 min is indicative of a leak (15) and needs to be corrected.

Linearity. At least quarterly, volume spirometers must have their calibration checked over their entire volume range (in 1-L increments) using a calibrated syringe (42) or an equivalent volume standard. Flow spirometers must have their linearity determined *at least* weekly and given the current software capabilities, daily linearity checks are reasonable. Plow spirometer linearity can be checked by injecting the volume from a 3-L syringe with several different flows. The linearity check is considered acceptable if the spirometer meets the volume accuracy requirements for all flows and/or volumes tested.

Time. Assessing mechanical recorder time scale accuracy with a stopwatch must be performed *at feast* quarterly. An accuracy of within 1% must be achieved. If equipment is changed or relocated (e.g., industrial surveys), calibration checks and quality control procedures must be repeated before initiating further testing.

PEF Meters. Since it is difficult to perform a calibration check of portable peak flow monitoring meters, it is particularly important that the instructions from the manufacturer include information concerning typical instrument lifetimes and methods of recognizing when an instrument is malfunctioning.

Other Qualify Assurance Procedures. In addition to calibration with physical standards, the practice of using laboratory personnel as "known subjects" and performing intralaboratory and interlaboratory testing is recommended (44). The ATS has published guidelines for quality assurance in pulmonary function laboratories (44), which can be consulted for specific details.

The use of computers to analyze spirometry has accelerated in the past 10 yr, and this trend is advantageous to obtain accurate spirometry (10, 30). However, testing of commercially available spirometers consistently shows that a major source of errors is in computer software (42). Because of the increased use of computers in pulmonary laboratories and the problems associated with them (42, 57), the ATS has published computer guidelines for pulmonary laboratories (58), which should be followed. Computer software must adhere to ATS recommendations, especially procedural recommendations, contained in this statement. Because of the tremendous improvement in the power and speed of computers and their extensive'use in hospitals and clinics, manufacturers should attempt to integrate computers into their spirometry systems. Primary data should be available, allowing independent manipulation of uncorrected values by the user. Listings or descriptions of ATS algorithms should be available (end of test, back-extrapolation, etc.). In addition, some program flexibility should be available to the user, for example, allowing user selection of appropriate reference equations, including the use of user-derived reference equations.

TABLE 5

EQUIPMENT QUALITY CONTROL SUMMARY

Test	Minimum Interval	Action
Volume	Daily	3-L syringe check
Leak	Daily	3 cm H_2O constant pressure for 1 min
Linearity	Quarterly Weekly (flow spirometers)	1-L increments with a calibrating syringe measured over entire volume range (flow spirometers simulate several different flow ranges)
Time	Quarterly	Mechanical recorder check with stopwatch
Software	New versions	Log installation date and perform test using "known" subject

MANEUVER PERFORMANCE RECOMMENDATIONS

Personnel Qualifications

The ATS has made recommendations for laboratory personnel conducting pulmonary function tests (59). High school training was recommended. In addition, the ATS encouraged but did not mandate one or more years of college or equivalent training and a strong background in mathematics. For pulmonary function laboratories, 6 mo of supervised training time is recommended for conducting spirometry. If troubleshooting is to be a part of the laboratory technician's responsibility, a training period of 1 yr is recommended. The ATS recommends that the medical directors must have appropriate training and be responsible for all pulmonary function testing (60).

For industrial/occupational testing, there are training requirements mandated by the National Institute for Occupational Safety and Health (NIOSH), industry, and the ACCP (16, 31, 61). Several excellent *training* manuals have been prepared for performance of spirometry (15, 16, 31, 62, 63). NIOSH approves the content of spirometry training courses under the U.S. Cotton Dust Standard (16).

Recommendation: K-Subject Instruction and Maneuver Performance

The VC maneuver may be considered either as an inspiratory vital capacity (IVC), where the subject inhales completely from a position of full expiration, or as an expiratory vital capacity (EVC), where the subject exhales completely from a position of full inspiration. In addition, several spirometer setups are possible using either open or closed circuit techniques with or without rebreathing.

1. A closed circuit technique *without CO,* absorption (i.e., using a rolling-sealed or water-sealed spirometer) may be used. Subjects may also rebreathe from the spirometer circuit. Rebreathing is preferable because it allows technicians to better monitor the entire vital capacity maneuver. In the absence of CO, absorption and the addition of supplemental oxygen, the maneuver should be brief – fewer tidal volumes before and after the VC maneuver.
2. A closed circuit technique *with CO,* absorption and the addition of supplemental oxygen may be used. This system allows

the subject to rebreathe for a longer period of time and establish a better FRC baseline. However, it requires precise replacement of oxygen to avoid shifting the baseline.

3. A modified closed circuit technique (i.e., flow-sensor-based systems where the subject can breathe in and out through the sensor without the need for CO_2 absorption) may be used.
4. An open circuit technique where the subjects may inhale completely before inserting the mouthpiece and exhaling into the spirometer may be used. This may be preferable when hygiene concerns are present.

For all systems, it is important to instruct the subject in the VC maneuver and demonstrate the appropriate technique. It is important that subjects understand they must ***completely*** fill and empty their lungs.

Standard Procedure Open Circuit Technique. The subject inhales maximally, inserts the mouthpiece just past his/her front teeth, seals his/her lips around the mouthpiece, and blows slowly and evenly until a clear plateau is seen at maximal exhalation or until end-of-test criteria (see sections on FVC and end-of-test criteria) are met. The technician must observe the subject's inhalation to ensure that it is complete and that air is not exhaled while the mouthpiece is being inserted. During the exhalation, the technician should monitor the spirometer volume-time display to ensure that a relatively constant expiratory flow and an adequate end-expiratory plateau is achieved (see APPENDIX A for examples of the VC maneuver).

Closed Circuit Techniques. The following procedure should be used when testing is conducted ***without CO,*** absorption (limited oxygen reserve available for test performance). A two-way valve may be useful, allowing the initial tidal volumes to be performed with room air before the subject is connected to the spirometer. The test is begun with quiet breathing, preferably with the subject breathing room air. No more than five tidal volumes should be recorded with the subject rebreathing from the spirometer. The subject should then perform the VC maneuver described below. When CO, absorption is not used, returning to FRC after the VC maneuver followed by three tidal volumes may be helpful but is not required.

The following procedure should be used when testing is conducted with CO, absorption and oxygen supplementation. The test is begun with quiet breathing. Several tidal volumes should be recorded (minimum of five or until a stable end-expiratory level is observed). The subject should then perform the VC maneuver described below. The end of test is reached when the subject returns to the level of FRC and performs at least three more tidal volumes.

For both procedures, the maneuver is not forced; it is performed in a relaxed manner with the subject using a mouthpiece and a nose clip. The VC maneuver is composed of the subject exhaling completely to residual volume (RV), and completely inhaling to total lung capacity (TLC), and then exhaling to residual volume again. The technician should encourage the subject to reach maximal inhaled and exhaled volumes with a relatively constant flow. Technicians should observe the subject to be certain his/her lips are sealed, that nothing obstructs the mouthpiece, that no leaks occur, and that TLC and RV are reached. The technician should check the volume display to ensure relatively linear inspiratory and expiratory volume curves and adequate maximal inspiratory and expiratory level plateaus. Oxygen should be added to the circuit to precisely counterbalance the absorption of CO,.

For all techniques, a minimum of two acceptable VC maneuvers should be obtained, with a maximum of four attempts. The largest VC should be reported. Some investigators have reported that the VC is slightly higher than the FVC in normal subjects(64).

TABLE 6

PERFORMANCE OF FVC MANEUVER

Check spirometer calibration
Explain test
Prepare subject
Ask about smoking, recent illness, medication use, etc.
Instruct and demonstrate test to subject
Correct posture with head elevated
Inhale completely
Position mouthpiece (open circuit)
Exhale with maximal force
Perform maneuver
Have subject assume correct posture
Attach nose clip
inhale completely; the inhalation should be rapid but not forced
Place mouthpiece in mouth and close lips around mouthpiece
Exhale maximally as soon as lips are sealed around mouthpiece'
Repeat instructions as necessary, coaching vigorously
Repeat for a minimum of three maneuvers; no more than eight are usually required
Check test reproducibility and perform more maneuvers as necessary

• D'Angelo and coworkers (65) have reported that PEF and FEV_1 for 13 normal subjects measured in a body plethysmograph are reduced (4% and 5%. respectively) when, during the inspiratory maneuver, there is a 4-6-s pause at TLC before beginning exhalation. Therefore, an excessive pause at TLC should be avoided.

Recommendation: **FVC-Subject Instruction and Maneuver Performance**

Instruct the subject in the FVC maneuver. The technician should demonstrate the appropriate technique (Table 6). Have the subject inhale from FRC and then, if using the open circuit method, insert the breathing tube into his/her mouth, making sure his/her lips are sealed around the mouthpiece, and begin the FVC maneuver with minimal hesitation (65). It is ***impemtive*** that the subject have a complete inhalation before beginning the forced exhalation. Prompt the subject to "blast," not just "blow," the air from their lungs, then continue to encourage him/her to fully exhale. Throughout the maneuver, enthusiastically coach the subject by word and body language. It is particularly helpful to observe the subject and the chart recorder or computer display during the test to better ensure maximal effort. Perform a ***minimum*** of three acceptable FVC maneuvers. If a subject shows large variability (FVC and/or FEV_1) between expiratory maneuvers (> 0.2 L), reproducibility criteria may require that up to but usually no more than eight maneuvers be performed. Volume-time or flow-volume curves from the best three FVC maneuvers must be retained. See Figure 3 and the section on acceptability and reproducibility for further clarification.

Recommendation (Monitoring): PEF-Subject Instruction and Test Performance

Since PEF is both effort- and volume-dependent, maximum subject cooperation is essential. Since an optimal peak flow is usually reached in about one-tenth of a second, patients must be encouraged to perform the expiratory maneuver as vigorously as possible. The subject should not cough and a prolonged exhalation is unnecessary (1 to 2 s is adequate).

When implementing unobserved self-administered PEF measurements, it is essential that:

1. The subject should be taught how to use the peak flow meter properly by someone skilled with the procedure. Trained personnel should observe the subject's performance both initially and on repeat visits.
2. The subject should be taught how and when to record PEF measurements, along with other pertinent information, such as symptoms.
3. The subject should be instructed about what action to take if PEF falls.

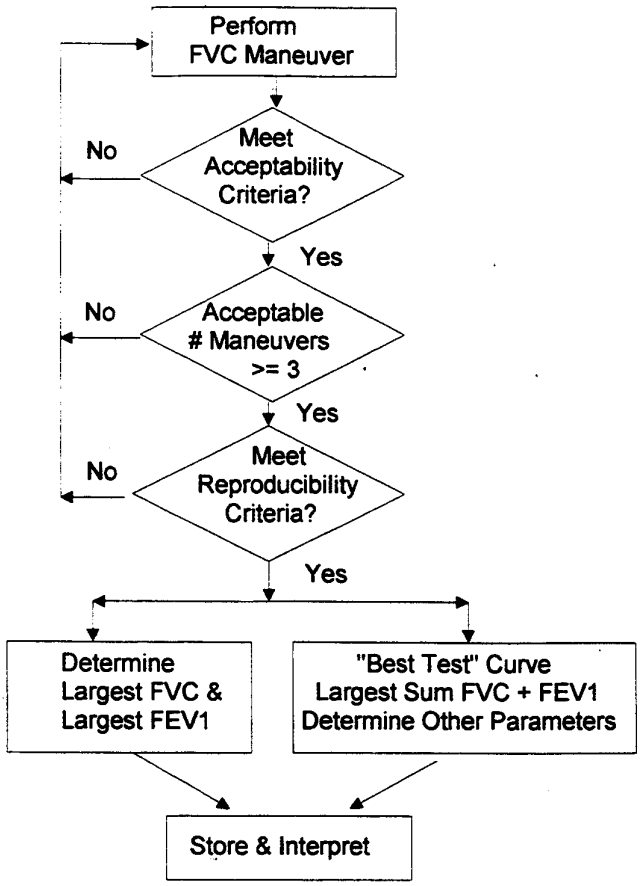


Figure 3. Flow-chart diagram of FVC spirometry testing.

Recommendation: FVC—Satisfactory Start-of-Test Criteria

To achieve accurate "time zero" and ensure that the FEV_1 comes from a maximal effort curve, the extrapolated volume must be less than 5% of the FVC or 0.15 L, whichever is greater. See Figure 2 for an example and explanation of back extrapolation. In the example shown, the extrapolated volume is 0.16 L or 8%. In general, back-extrapolated volume should be measured on any curve with a perceptible extrapolated volume. Provisions for rapid computerized feedback to the technician when these criteria are not met are encouraged.

The committee discussed the possible use of time-to-PEF as a measure of the subject's performance early in the FVC maneuver. However, the committee felt there were insufficient data on which to base a clear recommendation, and additional research is needed. When conducting research on assessment of the subjects' correct performance of FVC maneuvers, investigators are encouraged to measure the time-to-PEF or rise-time of peak flow in addition to other quality assessment parameters. The rise-time of peak flow is defined as the time required for expiratory flow to rise from 10% to 90% of the maneuver's peak flow. Although use of other measures of acceptable efforts have been described and may be useful (8, 66), they are not recommended at this time.

Rationale. A very slow start with a low peak flow will result in a greater than allowable extrapolated volume (Figure 2) (1, 67–69). In addition, the FEV_1 from a submaximal effort can be either smaller than those obtained when a maximal effort is performed because the subject fails to reach a maximal TLC, or larger due to less dynamic compression of airways in subjects where airways are relatively more collapsible. Recent experience in large epidemiologic studies (8) suggests that use of time-to-PEF and PEF reproducibility may minimize most of these problems in the majority of subjects. However, at this time, it is not recommended that maneuvers be eliminated because of a low PEF or PEF rise-time, but only because of an excessively large extrapolated volume.

TABLE 7

PERFORMANCE OF PEAK FLOW MANEUVER

Explain and demonstrate the test*
Zero the PEF monitor, if necessary
Stand up straight
Inhale completely; the inhalation should be rapid but not forced
Place PEF monitor in mouth and close lips around mouthpiece†
Exhale with maximal force‡ as soon as lips are sealed around mouthpiece§
Write down results
Repeat two more times (three total)
Record all three values

* Not necessary if at home.
† Nose clips are not necessary.
‡ Make sure subject understands to make full use of respiratory muscles, not just use the diaphragm as a "toot" or "mouth" maneuver.
§ D'Angelo and coworkers (65) have reported that PEF is reduced when, during the inspiratory maneuver, there is a 4–6-s pause at TLC before beginning exhalation. It is not known if similar changes will be observed with portable peak flow meters.

Recommendation: FVC—Minimum Exhalation Time

A minimum exhalation time of 6 s (length of maximum expiratory effort), unless there is an obvious plateau in the volume–time curve display, is required to obtain maximal FVC results. There are instances (e.g., the testing of children, young adults, and some restricted patients) where shorter exhalation times are acceptable.

Recommendation: FVC—End-of-Test Criteria

To obtain an optimal effort, it is important that subjects be verbally exhorted to continue to exhale air at the end of the maneuver. End-of-test criteria are used to identify a reasonable FVC effort. Recommended end-of-test criteria are:

1. The subject cannot or should not continue further exhalation. Although subjects should be encouraged to achieve their maximal effort, they should be allowed to terminate the maneuver on their own at any time, especially if they are experiencing discomfort. The technician should also be alert to any indication the patient is experiencing discomfort and should terminate the test if a patient is becoming uncomfortable.

OR

2. The volume–time curve shows an obvious plateau. This criterion is based on no change in volume for *at least* 1 s after an exhalation time of *at least* 6 s (10 s is optimal). "No change in volume" is defined as the minimal detectable volume of the spirometer. To meet ATS criteria, the minimal detectable volume for spirometers must be 0.030 L or less.

OR

3. The forced exhalation is of reasonable duration. For patients with airways obstruction or older subjects, exhalation times longer than 6 s are frequently needed to reach a plateau. Many would not reach a plateau even with a 20-s exhalation. However, exhalation times greater than 15 s will rarely change clinical decisions. *Multiple* prolonged exhalations (longer than 6 s) are seldom justified and may cause lightheadedness, syncope, undue fatigue, and unnecessary discomfort. In such patients, a slow or unforced VC maneuver (previously described) may provide a more appropriate denominator for calculation

of the $FEV_t/VC\%$. Manufacturers should note that several of the 24 test waveforms have durations longer than 20 s.

Achieving an end-of-test criterion is one measure of maneuver acceptability. Maneuvers that do not meet an end-of-test criterion should not be used to satisfy the requirement of three acceptable maneuvers. However, early termination is not by itself a reason to eliminate a maneuver from further consideration. Information such as FEV_1 and FEV_3 may be valid (depending on the length of exhalation) and should be reported from these early terminated maneuvers. When the subject does not exhale completely, the volume accumulated over a shorter period of time (e.g., 4 s) may be used as an approximate surrogate for FVC. In such cases, the volume label should reflect the shorter exhalation time (e.g., FEV_4 for a 4-s exhalation).

Recommendation: VC and FVC—Maximum Number of Maneuvers

Although there may be some circumstances in which more than eight consecutive FVC maneuvers may be needed, eight maneuvers is considered a practical upper limit for most subjects. After several forced expiratory maneuvers, fatigue begins to take its toll on subjects, and thus on their spirometric parameters, so additional maneuvers would be of little added value. In addition, some subjects with asthma may exhibit spirometry-induced bronchospasm. Ferris and associates (70) and Kanner and colleagues (71) have reported that for adults and children, eight maneuvers is a practical upper limit. For VC, four is considered a practical upper limit. Because of the potential for muscular fatigue and volume history effects, it is preferable that VC maneuvers be performed before FVC maneuvers.

Recommendation (Monitoring): PEF—Number of Trials

The subject must perform and record a minimum of three trials.

Recommendation: VC and FVC—Environmental Conditions

Spirometric testing with ambient temperatures less than 17° C or more than 40° C may pose problems. Ambient temperature must *always* be recorded and reported to an accuracy of ± 1° C. In situations where the ambient air temperature is changing rapidly (> 5° C in less than 30 min), continuous temperature corrections should be made. Spirometer users should be aware of the problems with testing done at lower temperatures, which in some subjects can cause airflow limitation. Due to other technical reasons, 17° C is judged to be an acceptable and reasonable lower limit (32–38, 72) for ambient temperature. Ranges of barometric pressures that are acceptable for the spirometer must be published by the manufacturer.

Rationale. There is evidence that some subjects may develop airflow limitation with the inhalation of very cold air. Therefore, spirometry should not be conducted when the ambient temperature is cold enough to induce airflow limitation.

Studies also point out the problem of finite cooling times of gases in volume-type spirometers and their associated tubing (32–35) when BTPS correction techniques usually assume instantaneous cooling. In one of these studies, it was found that a 7.7 to 14% error in FEV_1 results if the volume-type spirometer is at an ambient temperature of 3° C and the standard BTPS correction is used. This error is less if the spirometer is warmer (nearer body temperature) (32). As a result, 17° C was judged to be an acceptable and reasonable lower limit.

Complexities related to temperature are also encountered with flow-measuring devices (34–38). Air exhaled from the mouth is estimated to be 33 to 35° C (36, 38, 39). If any connecting tubing is used between the mouthpiece and the flow sensor, the exhaled gas will experience a variable amount of cooling if the room temperature is not at approximately 33° C. Details of the cooling pattern for many types of flow spirometers have not been studied, but they may result in errors similar to those for volume devices (34–38).

Because not all spirometers are used at sea level (blood pressure = 760 mm Hg), the range of barometric pressures allowed by the spirometer and its associated computational equipment must be specified by the manufacturer.

Recommendation: VC and FVC—Use of Nose Clips

In most people, not wearing nose clips does not appreciably influence the FVC when using the open circuit technique. However, some people breathe through the nose and the use of nose clips is encouraged, especially when performing a slow VC maneuver. Nose clips must be used if a closed circuit technique with carbon dioxide absorption is used.

Recommendation: VC and FVC—Sitting Versus Standing

Testing may be done either in the sitting or standing position. Indication of position is necessary on the report (1, 73). The standing position may not be appropriate in some circumstances, such as in hospitals where many patients may not be able to tolerate the standing position, especially when making forced maneuvers. The selection of the position for testing is, therefore, an individual one. If the standing position is used, an appropriately shaped chair should be placed behind the patient/subject so he/she can be quickly and easily eased into a sitting position if he/she becomes light-headed during the maneuver.

Rationale. Studies by Townsend show that for adults there are significantly larger FEVs in the standing position than in the sitting position (73). The earlier ATS recommendation indicates that in children, VC is greater when standing (1).

Recommendation (Monitoring): PEF—Nose Clips and Subject Position

Nose clips are not necessary when using PEF meters. Although the test can be conducted while sitting, the standing position is preferred.

Rationale. Because the PEF is dependent on a complete inhalation and an exhalation with maximal force, the standing position is preferred.

Bronchodilator Testing. Spirometry is often performed before and after inhalation of bronchodilators (or bronchoconstrictors) from a metered dose inhaler (MDI) or nebulizers. Although specific recommendations are beyond the scope of this document, it should be remembered that this is a complex procedure. Factors that can significantly affect a patient's response include: (*1*) activity, dose, and airway deposition of the medication; (*2*) recent prior medication; (*3*) timing of the postmedication maneuver; (*4*) choice and variability of the measurement used to detect a response; and (*5*) the method of calculating the magnitude of change after administering the bronchodilator.

MEASUREMENT PROCEDURES

Measurement

Spirometric variables should be measured from a series of *at least* three acceptable forced expiratory curves.

Recommendation: VC and FVC—Test Result Selection/Reporting of Results

The largest VC should be reported from all acceptable curves, including the forced maneuvers (FVC). The largest FVC and the largest FEV_1 (BTPS) should be recorded after examining the data from all of the acceptable curves, even if they do not come from the same curve. Other measures, such as the $FEF_{25-75\%}$ and the instantaneous expiratory flows, should be obtained from the single curve (1, 2, 15) that meets the acceptability criteria and gives the largest sum of FVC plus FEV_1 (best test).

Recommendation (Monitoring): PEF—Test Result/Reporting of Readings

Although all readings are recorded, the highest reading at any testing session (minimum of three trials) should be used in trend analysis. All readings are recorded to allow the comparison of the trials to evaluate reproducibility and to detect possible maneuver-induced bronchospasm.

Rationale. Since the PEF is effort-dependent, the highest reading should be used. This is consistent with the current recommended selection method for FVC and FEV_1.

ACCEPTABILITY AND REPRODUCIBILITY

Recommendation: VC and FVC—Maneuver Acceptability

For FVC measurements, acceptability must be determined by ascertaining that the recommendations outlined previously in the section on performing the FVC test are met. APPENDIX A contains examples of unacceptable volume-time and corresponding flow-volume curves. In review, these acceptability criteria are: (*1*) satisfactory start-of-test; (*2*) minimum FVC exhalation time of 6 s; and (*3*) end-of-test criteria. In addition, the technician should observe that the subject understood the instructions and performed the maneuver with a maximum inspiration, with a good start, with a smooth continuous exhalation, with maximal effort, and *without*:

1. An unsatisfactory start of expiration, characterized by excessive hesitation, false start, or extrapolated volume of greater than 5% of FVC or 0.15 L, whichever is greater (Figure 2).
2. Coughing during the first second of the maneuver, thereby affecting the measured FEV_1 value, or any other cough that, in the technician's judgment, interferes with measurement of accurate results (APPENDIX A, Figures 2A and 2B).
3. Early termination of expiration. A plateau in the volume-time curve should be observed, as defined by no change in volume for at least 1 s or a reasonable expiratory time. In a *normal* young subject this would be before completion of the breath—*usually* less than a 6-s maneuver. In an obstructed or older healthy subject, a longer expiratory time is required to reach a plateau (2, 74, 75) (APPENDIX A, Figures 3A and 3B). However, *multiple* prolonged exhalations (longer than 6 s) are seldom justified.
4. Valsalva maneuver (glottis closure) or hesitation during the maneuver that causes a cessation of airflow (APPENDIX A, Figures 4A and 4B).
5. A leak (APPENDIX A, Figures 5A and 5B).
6. An obstructed mouthpiece (e.g., obstruction due to the tongue being placed in front of the mouthpiece or false teeth falling in front of the mouthpiece).

For VC measurements, all of the above requirements should be met with the exception of those related to the forced nature of the effort. In addition, plateaus in the volume-time display should be reached at both the maximal inspiratory and expiratory volumes.

Computer-based systems that provide feedback to the technician when the above conditions are not met are desirable. The reporting format should include qualifiers indicating the acceptability of each maneuver. However, it cannot be overemphasized that failure to meet these criteria does not necessarily invalidate the maneuver, since for some subjects this is their best performance. Further, such maneuvers should be retained, since these maneuvers may contain useful information.

A flow chart outlining how acceptability and reproducibility criteria are to be applied is shown in Figure 3.

Recommendation: VC and FVC—Test Result Reproducibility

As a goal during test result performance, the largest FVC (or VC) and second largest FVC (or VC) from acceptable maneuvers must not vary by more than 0.2 L. In addition for forced exhalations, the largest FEV_1 and the second largest FEV_1 must not vary by more than 0.2 L. The 0.2 L reproducibility criteria are a change from the ATS 1987 Spirometry Statement and are intended to provide an equal assessment of test reproducibility independent of lung size. However, these criteria are only goals during data collection; therefore, an immediate change in spirometry data collection software is not warranted.

The reproducibility criteria are used as a guide to whether more than three acceptable FVC maneuvers are needed; these criteria are *not* to be used for excluding results from reports or for excluding subjects from a study. Labeling results as being derived from data that do not conform to the reproducibility criteria stated above is encouraged (especially when the data suggest that bronchospasm was triggered by the FVC maneuver). In addition, the reproducibility criteria are minimum requirements and many subjects should be able to provide FVC and FEV_1 reproducibility well below 0.2 L. The acceptability criteria must be applied before the reproducibility criteria (Figure 3). Unacceptable maneuvers must be discarded before applying the reproducibility criteria.

The only criterion for unacceptable subject performance is fewer than two acceptable curves. No spirogram should be rejected solely on the basis of its poor reproducibility. Reproducibility of results should be considered at the time of interpretation. Use of data from maneuvers with poor reproducibility is left to the discretion of the interpreter. In addition, use of data from unacceptable maneuvers due to failure to meet the end-of-test requirements is left to the discretion of the interpreter.

Rationale. Several epidemiologic studies (67–69) have shown that the elimination of data from subjects who fail to meet the ATS reproducibility criteria may result in a population bias by excluding data from subjects who have abnormal lung function. Pennock and colleagues (76) have reported that subjects with obstruction have greater coefficients of variation than do normal subjects. Therefore, these subjects are more likely to be unable to meet the ATS minimum reproducibility criteria. The reproducibility criteria have been simplified to eliminate confusion. If acceptability criteria are not applied before the reproducibility criteria, a passive exhalation maneuver will often be labeled as the best test maneuver because it may give the largest sum of FVC and FEV_1.

The calculation of the FVC and FEV_1 reproducibility presents no problem for a computer; however, the need for rapid determination of FEV_1 during the testing session presents a recognized logistics problem if results are hand-measured and calculated. Changing to 0.2-L criterion does simplify this calculation.

Changing the reproducibility criteria to a minimum value of 0.2-L is based on evidence that within subject variability of FVC and FEV_1 is not dependent on body size. The use of a 5% or 100-ml criterion has been shown to result in more individuals of short stature being classified as nonreproducible. In contrast, a 0.2-L fixed volume criterion provides a commensurable level of difficulty for all subjects, regardless of age or height (lung volume) (77). Regardless of the reproducibility criterion for FVC or FEV_1, it should be used as a goal during data collection. Therefore, continued use of the previous criteria (5% or 0.1 L, whichever is greater) during an interim period should have little practical impact on spirometry results.

Recommendation: PEF—Maneuver Acceptability and Reproducibility

PEF values for each maneuver must be recorded in the order in which they occur. This information will be useful in detecting possible test (maneuver)-induced bronchospasms.

TABLE 8

ACCEPTABILITY AND REPRODUCIBILITY CRITERIA: SUMMARY

Acceptability criteria
- Individual spirograms are "acceptable" if:
  - They are free from artifacts (*see* APPENDIX A for examples)
    - Cough or glottis closure during the first second of exhalation
    - Early termination or cutoff
    - Variable effort
    - Leak
    - Obstructed mouthpiece
  - Have good starts
    - Extrapolated volume less than 5% of FVC or 0.15 L, whichever is greater; *OR*
    - Time-to-PEF of less than 120 ms (optional until further information is available)
  - Have a satisfactory exhalation
    - 6 s of exhalation and/or a plateau in the volume–time curve; *OR*
    - Reasonable duration or a plateau in the volume–time curve; *OR*
    - If the subject cannot or should not continue to exhale

Reproducibility criteria
- After three acceptable spirograms have been obtained, apply the following tests:
  - Are the two largest FVC within 0.2 L of each other?
  - Are the two largest FEV_1 within 0.2 L of each other?
- If both of these criteria are met, the test session may be concluded.
- If both of these criteria are not met, continue testing until:
  - Both of the criteria are met with analysis of additional acceptable spirograms; *OR*
  - A total of eight tests have been performed; *OR*
  - The patient/subject cannot or should not continue
- Save at a minimum the three best maneuvers

Rationale. Unlike the FEV_1 obtained from routine spirometry, PEF measurements are more variable, and the measurement is often conducted in patients with high variability in their PEF. Although there may be some benefit from using PEF reproducibility to improve a subject effort, no specific reproducibility criterion is recommended at this time.

REFERENCE VALUES, INTERPRETATION STANDARDIZATION, AND CLINICAL ASSESSMENT

Clinical/Epidemiologic Considerations

Whether the spirogram results are to be used for clinical or epidemiologic purposes, the following recommendations apply.

Since the last standards were issued in 1987, a detailed statement on selection of reference values and interpretation of lung function tests has been published (3). The interpretation of spirometry involves two tasks: (*1*) The classification of the derived values with respect to a reference population and assessment of the reliability of the data; and (*2*) The integration of the spirometric values into the diagnosis, therapy, and prognosis for an individual patient. The first task is ordinarily the responsibility of the laboratory director or a designee and serves not only to communicate information to referring health care providers but also is an important aspect of laboratory quality control. The second task is ordinarily the responsibility of the physician requesting the studies and is performed within the context of patient care.

It is the responsibility of the medical director to develop explicit procedures for interpretation of spirometry and to select appropriate reference values. The procedures for interpretation and reference values may legitimately vary from laboratory to laboratory depending upon geographic location and the characteristics of the population being tested. In a setting where large numbers of healthy individuals are being screened for abnormality and the prevalence of disease is low, it is appropriate to set the threshold for abnormality at a higher level than in a setting where most individuals are referred because of symptoms or disease. In the latter case, where the prevalence of disease is high, an appropriate standard would be set to a more sensitive threshold for abnormality. The interpretative strategy should also take into consideration the consequences of false-positive and false-negative errors. Accordingly, no specific guidelines for interpretative procedures are recommended that would be applicable to all laboratories. More important, however, is that there be a consistent approach to the interpretation of lung function tests within a single laboratory. Therefore, referring physicians will not infer a change in the condition of the patient from a change in interpretation when it is the result of a change in the approach of the interpreting physician.

In providing the referring physician with an interpretation of spirometry results, it is also important to comment on deviations of the data from the guidelines for acceptability and reproducibility set forth herein. Although a spirometry session may not meet all of the guidelines, it may provide important clinical information and should be reported with appropriate qualification. Although some individuals display negative effort dependence, submaximal efforts usually lead to underestimation of the maximal effort values (28). Suboptimal efforts may be adequate to assist clinical decisions, where it can be judged that the recorded values underestimate true lung function.

Acknowledgment: The Committee thanks those who have provided input to this update of the Standardization of Spirometry. Special thanks go to the original participants of the Update Workshop, whose valued input was sought and used.

External reviewers: Scott T. Weiss, M.D., M.S., Gary R. Epler, M.D., and James R. Hansen, M.D.

APPENDIX A

Sample Spirograms

The sample spirograms shown in this appendix are from actual individuals and represent a few illustrations of acceptable and unacceptable maneuvers. It is imperative that the technician administering the test be capable of recognizing these anomalies and take appropriate corrective action—proper coaching. During the interpretation process, the reviewer may decide to include a maneuver that may have been considered unacceptable during test performance. As with the reproducibility criteria, some judgment must be made concerning what is an unacceptable maneuver. This decision will be based on the number of curves available, the disease pattern observed or expected for the individual, etc. However, the technician's action taken during the data collection stage of the process should almost always be to obtain additional maneuvers combined with effective coaching of the individual.

Figures A1a and A1b are volume–time and corresponding flow–volume samples that are acceptable spirograms from the draft NIOSH spirometry manual (78). In these spirograms, the individual exhibited a maximal effort for the entire maneuver, exhaling for at least 6 s with a greater than 1 s plateau in the volume–time curve. Figure A1a illustrates the relative expansion of the last portion of the FVC maneuver associated with a volume–time curve display. In contrast, Figure A1b illustrates the relative expansion of the initial portion of the FVC maneuver associated with a flow–volume curve display. Notice in the flow–volume curve (Figure A1b) it is more difficult to determine that the individual produced an acceptable plateau than in the volume–time curve display.

Figures A2a and A2b illustrate an unacceptable spirogram due to a cough during the first second of exhalation. Notice that the cough, which occurs at approximately 3.0 to 3.5 L, is very apparent in the flow–volume curve but is more difficult to detect in the volume–time curve. The anomalies seen in the volume–time curve at approximately 5.0 and 5.5 L could be slight coughs or variable effort, but occurred after the first second of exhalation.

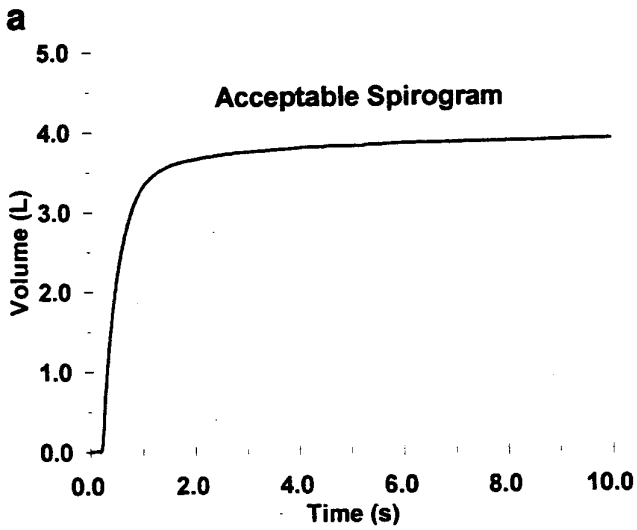


Figure A1a. Acceptable volume–time spirogram.

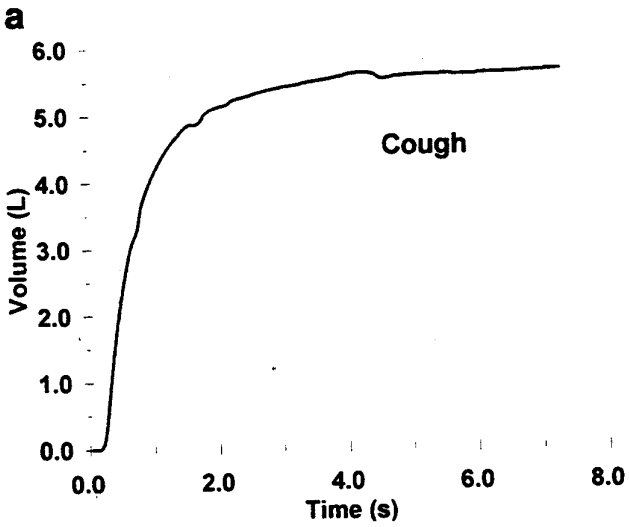


Figure A2a. Volume–time spirogram with a cough during the first second of exhalation.

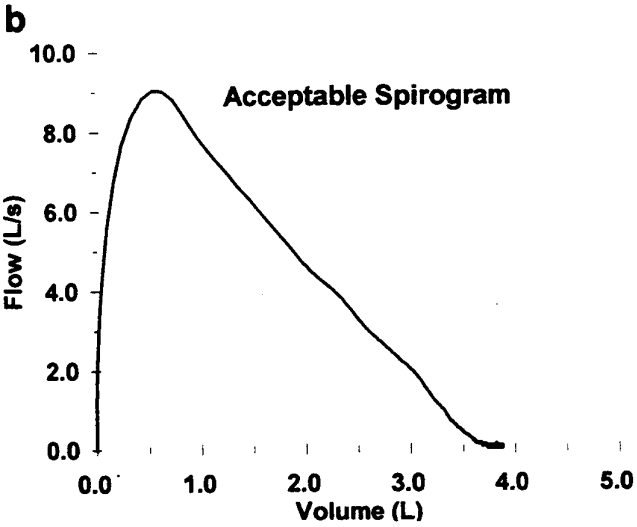


Figure A1b. Acceptable flow–volume spirogram.

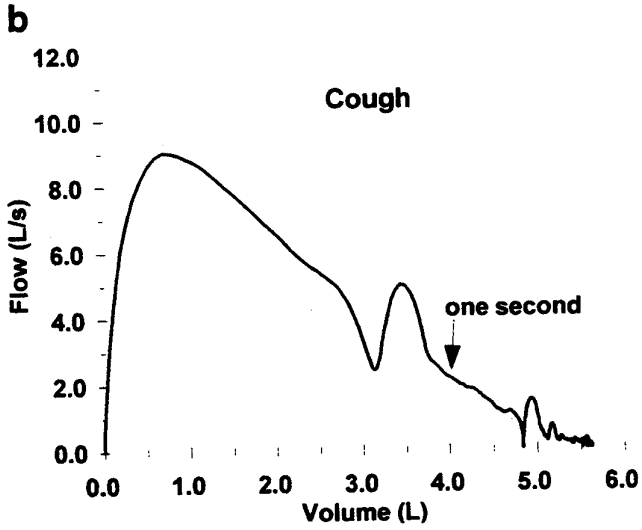


Figure A2b. Flow–volume spirogram with a cough during the first second of exhalation.

Although the fluctuations in flow observed in the flow–volume curve in Figure A2b are reasonably large, they may not result in a significantly different FEV_1. Therefore, the FEV_1 from this curve may be valid, particularly if all other curves are unacceptable. Regardless, when the technician observes the spirograms in Figures A2a and A2b, additional maneuvers should be obtained from the individual.

Figures A3a and A3b illustrate an unacceptable spirogram due to a variable effort or cough during the first second of exhalation and early termination of the maneuver. The anomaly observed at 1 L of exhalation is apparent on both the volume–time and flow–volume curves.

The duration of the anomaly and the fact that the flow immediately following the anomaly does not exceed the expected flow–volume envelope suggest that the anomaly is a variation in effort instead of a cough. The early termination is less apparent on the flow–volume curve. However, on the volume–time curve, it is apparent that the individual failed to exhale for 6 s and there is no 1-s plateau of the volume–time curve.

Figures A4a and A4b illustrate unacceptable sample spirograms due to an abrupt termination of flow at the end of the maneuver, possibly the result of the individual closing his/her glottis. Notice in Figure A4a that the volume–time curve plateau occurs abruptly at approximately 2.2 s where the volume remains constant for the remainder of the maneuver. In Figure A4b, the flow–volume curve exhibits an abrupt decrease in flow at the end of the maneuver.

Figures A5a and A5b illustrate unacceptable sample spirograms due to a leak in the volume-type spirometer or spirometer hose. This leak is approximately 50 ml/s and produces an approximate 300-ml loss in volume over the 6-s exhalation produced by this individual. Notice that the leak is very apparent on the volume–time curve and perhaps less apparent on the flow–volume curve. At the end of the maneuver when the leak is most

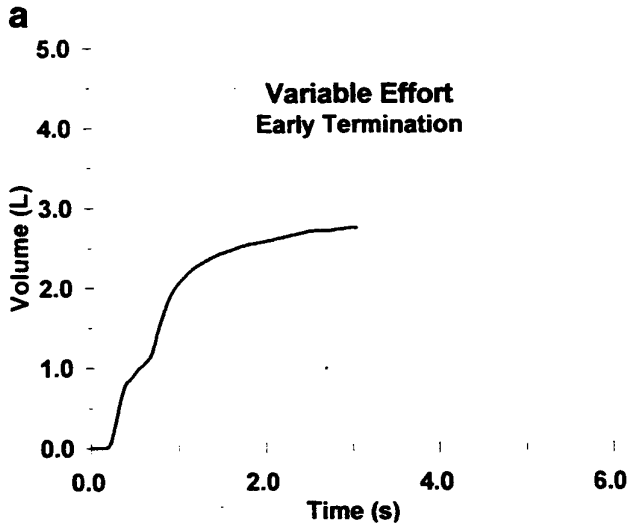


Figure A3a. Unacceptable volume–time spirogram due to variable effort and early termination.

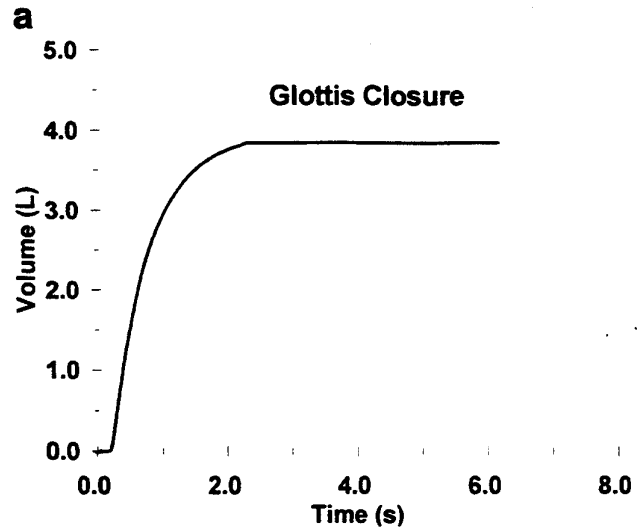


Figure A4a. Unacceptable volume–time spirogram due to possible glottis closure.

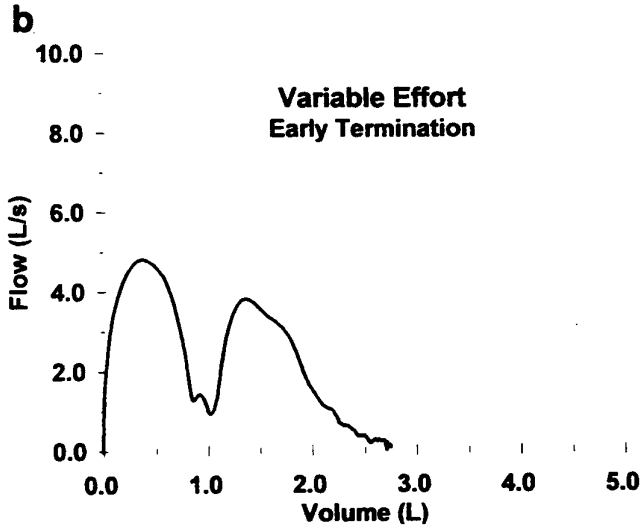


Figure A3b. Unacceptable flow–volume spirogram due to variable effort and early termination.

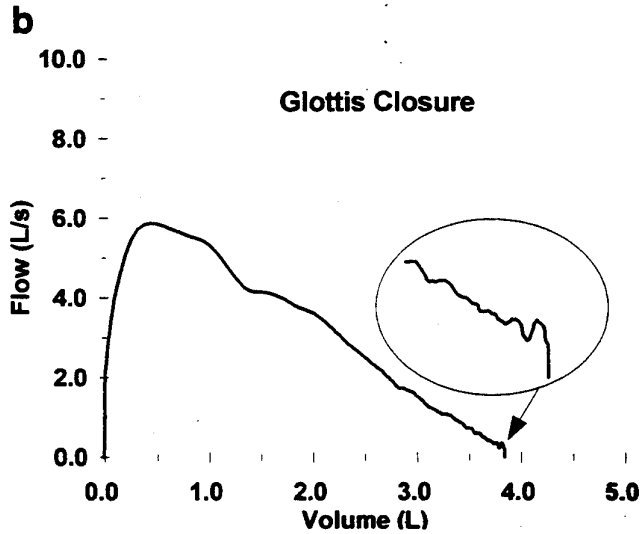


Figure A4b. Unacceptable flow–volume spirogram due to possible glottis closure.

apparent, the flow is slightly negative and volume is decreasing (*see* insert in Figure A5b, short line moving to the left below the zero flow line). If a spirometry system display does not display negative flows, then the leak would be even less apparent on the flow–volume curve.

Figures A6a and A6b illustrate acceptable sample spirograms for an individual with mild airways obstruction ($FEV_1/FVC\%$ = 67%). Notice the relatively small change in volume after 10 s of exhalation (Figure A6a) and the corresponding relative low flow (Figure A6b) at the end of the maneuver.

In addition to requiring three acceptable maneuvers, the reproducibility criteria for FVC and FEV_1 should be met as a goal during test performance. Figure A7a illustrates the volume–time curve and Figure A7b the corresponding flow–volume curve for a 22-yr-old, healthy female. In these figures, the subject did not meet the minimum reproducibility criteria for both the FVC and FEV_1 despite performing three acceptable maneuvers. The second largest FVC was 0.43 L (10%) lower than the largest, and the second largest FEV_1 was 0.37 L (12.1%) lower than the largest FEV_1. Therefore, at least one additional maneuver should be performed by this subject in an attempt to meet the FVC and FEV_1 reproducibility criteria. The most likely cause of this pattern (nonreproducible tracings but good initial effort) is a failure to achieve a maximal inhalation before performing the FVC maneuver.

Figures A8a and A8b illustrate a reproducible test with three acceptable maneuvers. Figure A8a displays the three acceptable volume–time curves, and Figure A8b displays the corresponding flow–volume curves. These maneuvers were obtained from an 80-yr-old male with an $FEV_1/FVC\%$ = 61.7%. Notice that the curves are very reproducible even though the subject required approximately 20 s to reach his final volume or FVC.

Figure A9 shows a sample VC maneuver for a normal subject. This subject starts the test with several tidal volumes through

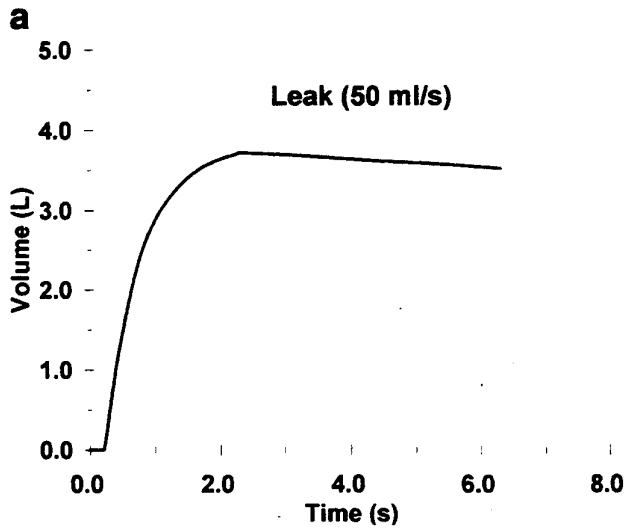


Figure A5a. Unacceptable volume–time spirogram due to a leak.

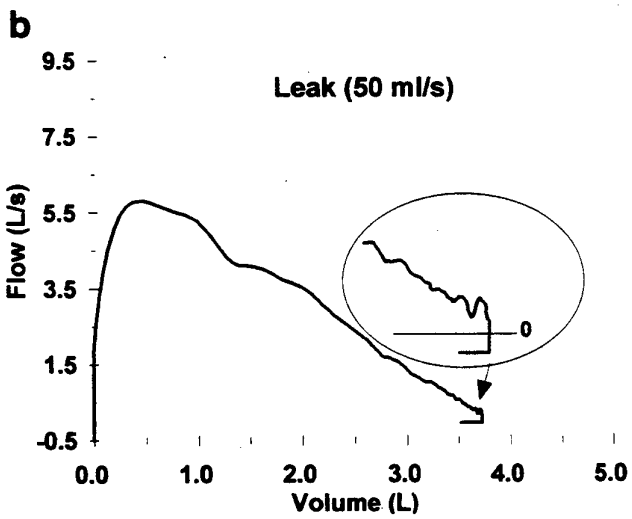


Figure A5b. Unacceptable flow–volume spirogram due to a leak.

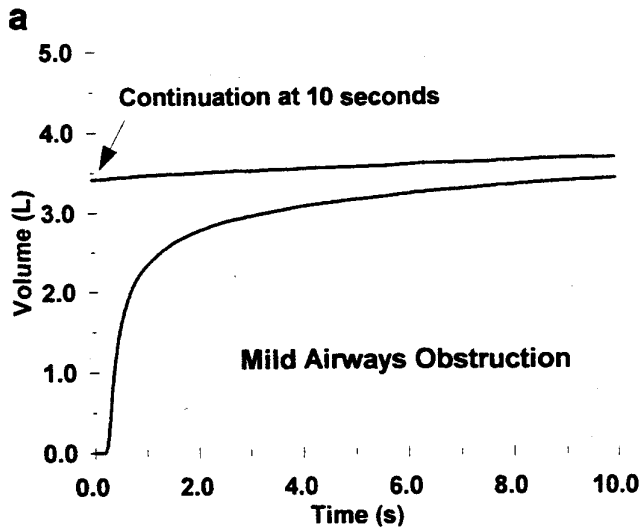


Figure A6a. Acceptable volume–time spirogram for an individual with mild airways obstruction.

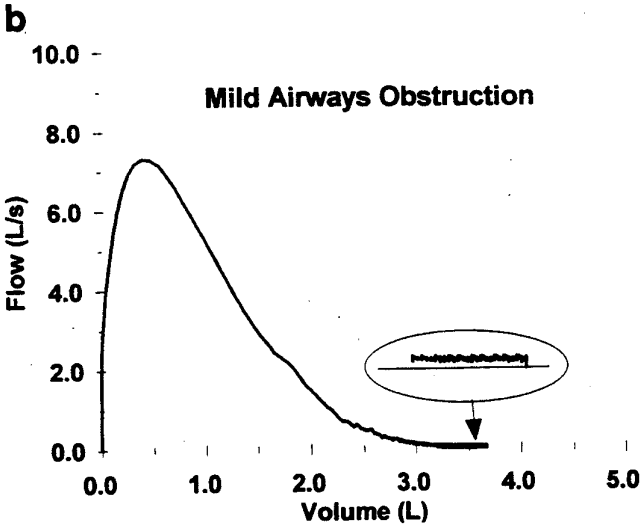


Figure A6b. Acceptable flow–volume spirogram for an individual with mild airways obstruction.

a valve opened to room air to become accustomed to breathing on the mouthpiece. The subject is then connected to the spirometer, where several additional tidal volumes are recorded. The subject then completely inhales to total lung capacity (TLC) and slowly exhales to residual volume (RV), making sure to completely inhale to TLC and exhale to RV. After reaching RV, the subject returns to FRC, where several tidal volumes are again obtained before the subject comes off the mouthpiece. Notice the plateaus at TLC and RV, indicating that the subject has completely inhaled and exhaled.

Figure A10 shows a sample VC maneuver for a subject with severe airways obstruction. The identical maneuver for the normal subject shown in Figure A9 is repeated for this subject with severe airways obstruction. However, the tidal volumes of the subject with severe airways obstruction are much more rapid and the subject requires a longer exhalation time to reach RV, as long as 25 s. Notice that as with the normal subject, a plateau in the volume–time curve is obtained at both TLC and RV. This indicates that the subject has completely inhaled and exhaled. Also notice that the subject has some difficulty in obtaining a stable FRC after the VC maneuver, probably due to gas trapping.

APPENDIX B

Spirometer Testing Guidelines

The following testing guidelines should be used when evaluating new spirometer designs and when changes have been made to spirometer hardware or software. For production testing, the use of a smaller set of test waveforms may be appropriate. The spirometer selected for testing should be a "production" model and not one that was specifically selected because of any extraordinary calibration efforts. Once testing has begun, the device be-

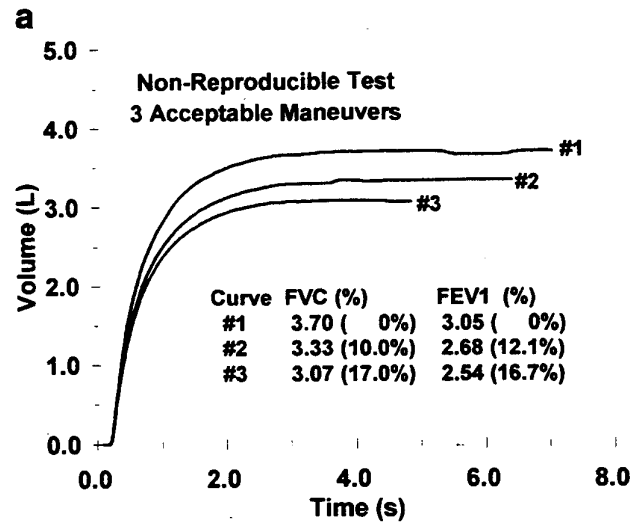


Figure A7a. Nonreproducible test with three acceptable volume–time curves. Percents are difference from largest value.

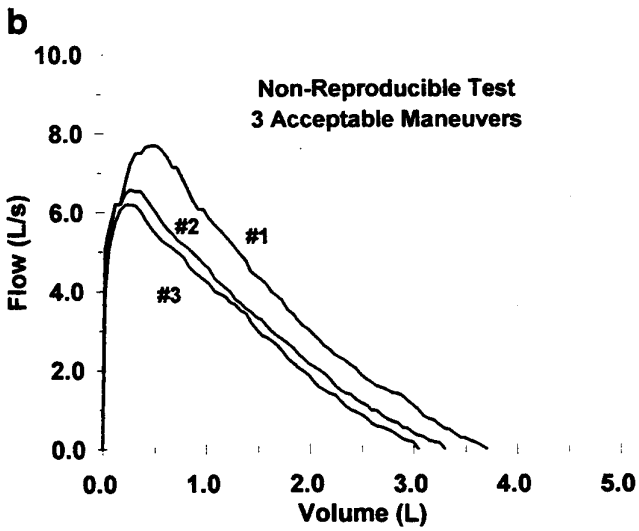


Figure A7b. Nonreproducible test with three acceptable flow–volume curves.

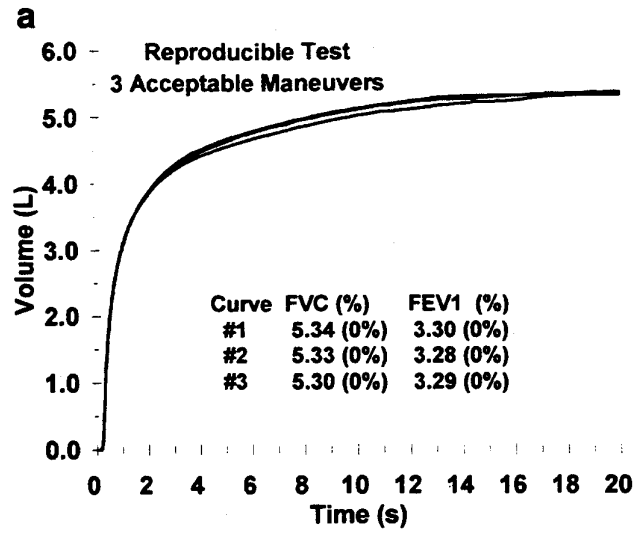


Figure A8a. Reproducible test with three acceptable volume–time curves. Percents are difference from largest value.

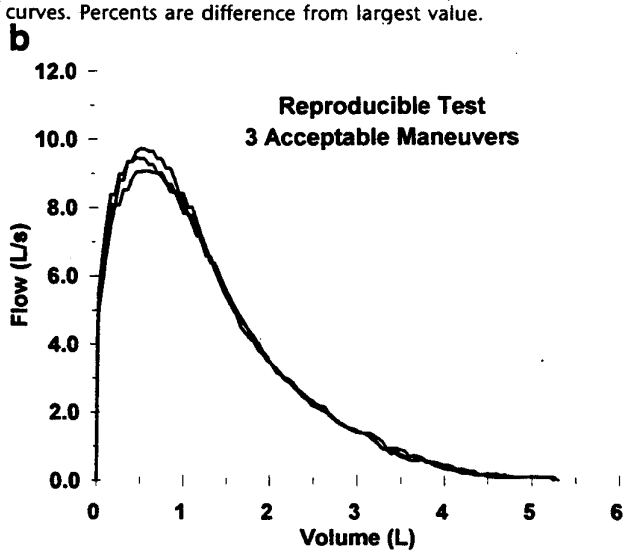


Figure A8b. Reproducible test with three acceptable flow–volume curves.

ing tested should not receive any adjustments or special calibration procedures that are not part of its routine operational procedures.

Volume parameters should be validated using the 24 volume-time standard waveforms described in APPENDIX C. For PEF and other flow parameters *not* based on a percentage of the FVC, the 26 flow-time standard waveforms should be used (APPENDIX D). The validation limits are provided for each parameter in the main sections of this statement. All tests should be conducted using the appropriate waveforms and a computer-controlled mechanical syringe or its equivalent (waveform generator). The accuracy of the waveform generator should be checked at least daily when in use, either using a spirometer for volume waveforms or a pneumotachometer for flow waveforms, or an equivalent method. The desired accuracy of the waveform generator for volume parameters is ± 0.5% (or ± 0.05 L, whichever is greater); ± 2% (or ± 5 L/min, whichever is greater) for flow parameters (e.g., PEF). In comparing results obtained from a particular spirometer, the tolerance limits of the waveform generator are to be considered by adding them to the accuracy requirement for the parameter under test, for example 0.5% (± 0.05 L) for volume parameters and 2% (± 5 L/min) for flow parameters. Therefore, the FVC accuracy requirement for comparisons with observed values would be ± 3.5% (performance accuracy requirement ± 3% plus waveform generator accuracy of ± 0.5%).

The accuracy and precision validation limits contained in this section assume a waveform generator accuracy of 0.5% for volume and 2% for flow parameters. The accuracy of available waveform generators has not been established; therefore, the desired 2% waveform generator accuracy for flow parameters may not be achieved. In this circumstance, the *actual* accuracy limit of the waveform generator should be added to the accuracy require-

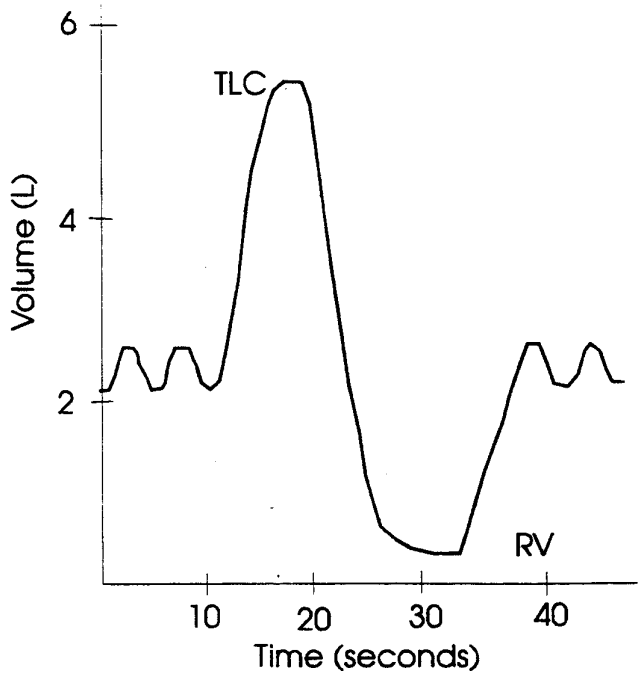


Figure A9. Sample relaxed VC maneuver in a normal subject.

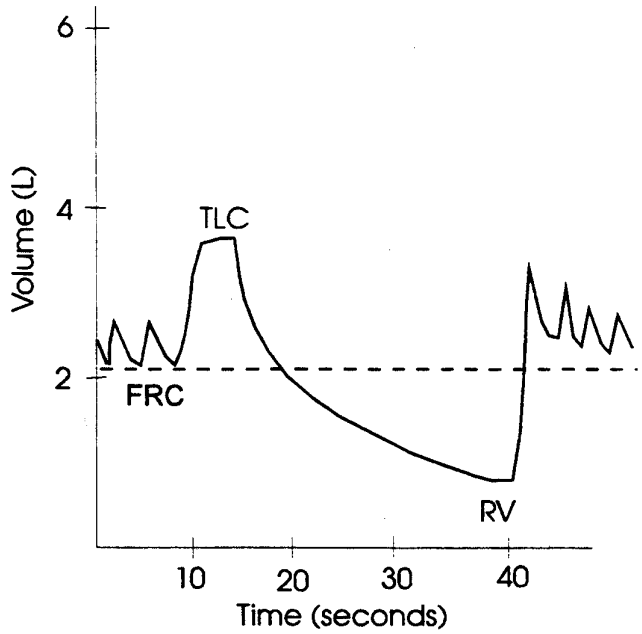


Figure A10. Sample VC maneuver from a subject with severe airways obstruction.

ment of the parameter under test. Every attempt should be made to improve the accuracy of waveform simulators, but in no case should the simulator accuracy limit be considered less than 0.5% for volume and 2% for flow parameters.

Spirometers or peak flow meters should be connected to the waveform generator in the same orientation used in the testing of subjects. Tubing or other connecting material may be used, but the volume associated with the connecting tubing should be less than 300 ml. For handheld devices, full testing should be conducted with the sensor in a horizontal position (the typical position with the patient at TLC about to initiate the maneuver). In addition, handheld devices should be tested with two waveforms (standard volume-time waveforms 1 and 6) at a typical FRC position (instrument at a 30° angle down from horizontal). These devices must meet diagnostic spirometer accuracy criteria for these two waveforms in the 30° down-angle position.

The instruments (diagnostic or monitoring devices) should be tested using the waveform generator under conditions similar to those present when testing human subjects. No special procedures should be followed in testing the instrument. Specifically, each waveform will be injected into the instrument within not less than 5 s or more than 1 min of the instrument being set to the ready condition. In measuring the resistance of the instrument, pressure should be measured in the side of the standard mouthpiece used by the instrument when constant flows are injected into the spirometer. If an in-line filter is to be used as part of routine testing of humans, a filter must be attached during spirometer validation and resistance testing.

Five repeats of each of the 24 waveforms should be injected into the test instrument using room air at ambient temperature. In those circumstances where the flow or volume sensor is changed between subjects (e.g., disposable flow sensor), a different sensor should be used for each of the repeat tests. The average of the five repeat values should be used for comparison with the standard values. The range and percent deviations of values from the five repeated tests should also be computed by:

$$\text{Range} = \text{maximum} - \text{minimum} \quad \text{(B1)}$$

$$\text{Range (\%)} = 100 * \frac{(\text{maximum} - \text{minimum})}{\text{average}} \quad \text{(B2)}$$

$$\text{Deviation} = \text{average} - \text{standard} \quad \text{(B3)}$$

$$\text{Deviation (\%)} = 100 * \frac{(\text{average} - \text{standard})}{\text{standard}} \quad \text{(B4)}$$

Averages are calculated as a simple n weighted average.

The five repeats of 24 waveforms should be considered a rigid testing sequence. The testing of a device should be completed by running all 24 waveforms with five repeated tests. If the device fails to accurately measure a value for a particular waveform, no additional repeats should be conducted for only one waveform.

Diagnostic devices should also be tested by injecting at least four waveforms using heated and humidified air (waveforms 1 through 4) to verify accuracy of volume parameters under BTPS conditions. Using volume-time waveforms 1 through 4, the average FVC and FEV_1 of three trials shall be compared to the standard values. The validation limits for testing under BTPS conditions are ± 4.5% or 200 ml, whichever is greater. Spirometers must meet these accuracy criteria for all four waveforms under BTPS conditions. Using 4.5% allows a 1.5% simulator error, necessary because of the added uncertainty when using heated and humidified air. The time between each of the three trials should be less than 2 min. The temperature of the air injected into the device under test should be within ± 1° C of 37° C and should be measured before the air is injected into the device. Waveform generators are being modified to allow BTPS testing. The BTPS testing requirement will be implemented when BTPS testing services are available.

In addition to testing using the waveform generator, the device should be tested using at least two healthy human subjects.

TABLE B1

STROKE VOLUME, VOLUME IN SPIROMETER AT START OF TEST (FOR VOLUME SPIROMETERS), RATE, AND CORRESPONDING MVV TARGET VALUES

Test Number	Target MVV (L/min)	Stroke Volume (L)	Rate (Strokes/min)	Starting Volume (L)
1	60	1.0	60	2.0
2	100	1.0	100	3.0
3	120	2.0	60	3.0
4	200	2.0	100	3.0

The purpose of the testing using a human subject is to verify that the instrument will function properly under conditions other than those present using a mechanical simulator. To achieve a balanced design, each subject should perform alternating maneuvers between a standard spirometer and the device being tested, performing three maneuvers on each device, for a total of six maneuvers. One subject should be randomly assigned to perform their first maneuver on the standard spirometer while the other subject's first maneuver will be performed on the device being tested, allowing the learning effect to be equally distributed across both instruments. The differences between the largest of the three trials from each device should be within ± 6% or 200 ml, whichever is greater, for FVC and FEV_1, and ± 15% or 30 L/min, whichever is greater, for PEF.

For validating MVV, a mechanical pump should be used with a sinusoidal waveform. The response of the device should be determined using incrementally increased flows up to a maximum of 250 L/min, produced with stroke volumes up to 2 L. The specific minimum patterns and for volume spirometers, the volume in the spirometer, are given in Table B1. The device should read the MVV within ± 10.5% of reading or ± 20 L/min, whichever is greater for all four test patterns specified in Table B1. In addition, the pressure measured at the mouthpiece should not exceed 10 cm H_2O during the entire MVV maneuver. No mechanical pump testing at BTPS is required for MVV.

DIAGNOSTIC DEVICES: TESTING FOR ACCURACY AND PRECISION WITH A WAVEFORM GENERATOR

Accuracy Testing

Accuracy criteria: Deviation ± 3.5% or ± 0.100 L, whichever is greater, for volume measurements; ± 5.5% or ± 0.250 L/s, whichever is greater, for $FEF_{25-75\%}$; ± 12% or ± 25 L/min (± 0.420 L/s), whichever is greater, for PEF. These criteria are increased slightly from those in Table 2 to account for the waveform generator inaccuracy. For MVV testing, deviation must be less than ± 10.5% or 20 L/min, whichever is greater.

Waveforms: Twenty-four standard volume-time waveforms (APPENDIX C) for FVC, FEV_1, and $FEF_{25-75\%}$; 26 standard flow-time waveforms (APPENDIX D) for PEF. For BTPS testing, volume-time waveforms 1 through 4 should be used with heated and humidified air as specified in this appendix. For MVV testing, sinusoidal waveforms should be used with the patterns specified in Table B1.

Spirometer tested: One production spirometer. Spirometers should not be screened or especially calibrated before testing. If an in-line filter is to be used during the testing of humans, it should be attached for this testing. When during clinical testing, if the flow or volume sensor is changed between subjects, the sensors must be changed for each of the five repeat tests described below. The spirometer may not be recalibrated after these sensor changes unless recalibration is required after each sensor change during clinical testing.

Validation: Each spirometric waveform is to be injected into the spirometer five times. MVV patterns will be injected in duplicate. Average values will be calculated for each waveform and, along with individual values, will be used to score the spirometer. See formulas B1–B4.

Acceptable performance: For FVC and FEV_1 in each of the volume-time waveforms: deviation (formula B3) must be less than 0.100 L *or* deviation (%) (formula B4) must be less than 3.5%. For $FEF_{25-75\%}$ in each of the volume-time waveforms: deviation must be less than 0.250 L/s *or* deviation (%) must be less than 5.5%. For PEF in each of the flow-time waveforms: deviation must be less than 25 L/min (0.420 L/s) or deviation (%) must be less than 12%. For BTPS testing using waveforms 1–4: deviation must be less than 0.2 L or deviation (%) must be less than 4.5%. For MVV in each of the patterns: deviation must be less than 20 L/min or deviation (%) must be less than 10.5%.

An error occurs when both deviation (formula B3) and deviation (%) (formula B4) exceed their specified limits. For testing with ambient air, acceptable performance is present if the error rate for each individual parameter (FVC, FEV_1, $FEF_{25-75\%}$, PEF) is less than 5% (one error for each parameter when 24 or 26 waveforms are used). For MVV testing and spirometric testing with BTPS conditions, acceptable performance is present if the error rate is zero.

Precision Testing: Intradevice Testing

Precision criteria: See the acceptable performance criteria listed below.

Waveforms: Use data generated as part of accuracy testing. Acceptable performance: For FVC and FEV_1, for each of the volume-time waveforms: The range (formula B1) must be less than 0.100 L *or* range (%) (formula B2) must be less than 3.5%. For $FEF_{25-75\%}$ using each of the volume-time waveforms: The range (formula B1) must be less than 0.250 L/s or the range (%) (formula B2) must be less than 5.5%. For PEF using each of the flow-time waveforms: The range must be less than 25 L/min (0.420 L/s) or the range (%) must be less than 7%.

An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance is present if the error rate for each individual parameter (FVC, FEV_1 PEF) is less than 5% (one error for each parameter if 24 or 26 waveforms are used).

MONITORING DEVICES (PEF) TESTING CRITERIA

The range and deviations from the standard PEF values should be calculated using formulas B1 through B4.

Accuracy Testing

Accuracy criterion: ± 12% or ± 25 L/min of target values, whichever is larger. The primary criterion is ± 10%; 2% is added to account for the inaccuracy of the waveform generator.

Waveforms: 26 flow-time curves (APPENDIX D).

Meters tested: Two production meters. Meters should be selected routinely from a production run and not be screened before validation testing.

Validation: Each meter will receive five maneuvers for each of the 26 waveforms. An average for each waveform will be calculated and used to score that meter against the accuracy criteria.

Acceptable performance: An error occurs when both deviation (formula B3) and deviation (%) (formula B4) exceed their specified limits. Acceptable performance is less than three errors out of the total 52 tests (26 waveforms, 2 meters).

Precision Testing: Intradevice Testing

Criterion: Less than 6% intradevice variability or 15 L/min, whichever is greater. The primary criterion is less than 5%. One per-

TABLE C1

VALUES FOR STANDARD WAVEFORMS

Curve	FVC (L)	FEV_1 (L)	FEV_1 (%FVC)	Vext (L)	Vext (%FVC)	FEF_{max} (L/s)	$FEV_{25-75\%}$ (L/s)
1	6.000	4.262	71.0	0.052	0.9	6.497	3.410
2	4.999	4.574	91.5	0.068	1.4	9.873	5.683
3	3.498	1.188	33.9	0.014	0.4	1.380	0.644
4	1.498	1.371	91.5	0.019	1.3	2.952	1.704
5	5.132	3.868	75.4	0.087	1.7	7.535	3.209
6	4.011	3.027	75.5	0.317	7.9	5.063	2.572
7	3.169	2.519	79.5	0.354	11.2	4.750	2.368
8	1.993	1.615	81.0	0.151	7.6	3.450	1.857
9	4.854	3.772	77.7	0.203	4.2	7.778	3.365
10	3.843	3.031	78.9	0.244	6.3	4.650	2.899
11	2.735	1.811	66.2	0.022	0.8	3.708	1.272
12	2.002	1.621	81.0	0.094	4.7	3.807	1.780
13	4.896	3.834	78.3	0.460	9.4	5.207	3.677
14	3.786	3.053	80.6	0.338	10.2	4.368	3.122
15	5.937	5.304	89.3	0.080	1.3	12.132	6.092
16	5.458	3.896	71.4	0.215	3.9	7.395	2.892
17	5.833	2.597	44.5	0.035	0.6	5.257	1.153
18	4.343	3.155	72.6	0.042	1.0	7.523	2.335
19	3.935	2.512	63.8	0.044	1.1	5.408	1.137
20	2.881	2.563	89.0	0.041	1.4	5.822	2.695
21	4.477	3.549	79.3	0.102	2.3	9.398	3.368
22	3.857	2.813	72.9	0.036	0.9	5.055	2.204
23	3.419	1.360	39.8	0.013	0.4	2.868	0.531
24	1.237	0.922	74.5	0.037	3.0	2.095	0.709

Definition of abbreviations: Vext = extrapolated volume (*see* Figure 2 for description).

cent or 5 L/min is added to account for the imprecision of the waveform generator.

Waveforms: Four of the 26 standard flow-time waveforms (waveforms 1, 4, 8, and 25).

Meters tested: Ten production meters.

Validation: Three flows for each waveform for each meter. For each waveform and for each meter, calculate range (formula B1) and range (%) (formula B2) for each PEF.

Acceptable performance: An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance is six or fewer errors (error rate ± 5% for 120 trials).

Precision Testing: Interdevice Variability

Criterion: Less than 11% interdevice variability or 25 L/min, whichever is greater. This includes 1% or 5 L/min for the imprecision of the waveform generator.

Waveforms: Same as for intradevice testing.

Meters tested: Same as for intradevice testing.

Validation: Same data as for intradevice testing. Interdevice percentage is calculated as follows: for each meter, calculate an average PEF for each waveform. For each waveform, combine all data from the 10 meters to calculate range (formula B1) and range (%) (formula B2) for each of the four waveforms.

Acceptable performance: An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance is present if there are no errors.

TABLE D1

CALCULATED VALUES FOR 26 STANDARD FLOW-TIME WAVEFORMS (0.002-S SAMPLING INTERVAL)*

Waveform Number	Flow PEF (L/s)	Vol-80 PEF (L/s)	Vol-40 PEF (L/s)	Rise-Time (ms)	Vext Time-to-PEF (ms)	Flow Time-to-PEF (ms)	Extr Vol (L)	%Vext (%FVC)	FEV_1 (L)
1	7.445	7.245	7.337	93.5	86.8	151.7	0.108	2.5	3.373
2	10.860	9.905	10.450	55.7	46.5	86.6	0.093	2.2	3.838
3	4.794	4.372	4.630	68.3	53.0	114.7	0.054	3.3	1.302
4	4.401	4.240	4.321	76.0	65.6	116.3	0.051	2.9	1.468
5	3.630	3.564	3.584	159.5	170.6	241.0	0.081	3.0	2.053
6	3.088	2.728	2.949	44.5	36.8	62.7	0.021	1.3	1.110
7	2.509	2.237	2.403	148.0	67.6	173.6	0.057	3.7	1.046
8	2.328	2.048	2.210	42.4	35.6	57.6	0.015	1.0	0.950
9	5.259	4.923	5.109	57.0	47.2	85.4	0.046	1.8	2.182
10	4.733	4.657	4.666	46.7	93.6	122.2	0.035	1.5	2.029
11	6.870	6.472	6.706	81.1	67.4	125.6	0.085	3.1	2.080
12	10.684	10.528	10.558	115.3	139.9	214.1	0.189	3.4	4.618
13	4.804	4.708	4.739	105.3	121.7	194.9	0.080	2.7	2.304
14	3.821	3.756	3.769	124.7	127.7	201.8	0.074	2.5	2.249
15	7.956	7.814	7.852	174.9	152.6	270.4	0.192	5.0	3.219
16	5.251	5.100	5.165	76.3	80.5	123.7	0.060	2.1	2.246
17	5.842	5.721	5.757	165.1	163.4	265.1	0.151	5.0	2.802
18	8.593	8.404	8.465	132.9	126.2	248.7	0.178	3.6	4.303
19	6.953	6.651	6.807	76.5	63.7	120.2	0.083	2.2	3.007
20	7.430	7.274	7.324	120.9	143.3	268.4	0.141	2.5	4.613
21	3.973	3.745	3.880	130.3	88.4	193.1	0.079	6.0	1.096
22	3.377	3.316	3.334	184.2	157.6	259.6	0.094	5.0	1.559
23	8.132	7.954	8.019	84.8	83.1	152.1	0.107	2.4	3.476
24	4.155	4.028	4.086	50.3	52.3	83.7	0.032	1.2	1.833
25	14.194	13.896	13.964	57.9	53.7	100.3	0.126	1.9	5.944
26	11.595	10.446	11.172	49.6	42.2	79.1	0.088	1.7	4.311

Definition of abbreviations: Flow PEF = peak flow determined by obtained highest observed flow value; Vol-80 PEF = peak flow determined from volume–time curve using an 80-ms segment; Vol-40 PEF = Peak flow determined from volume–time curve using a 40-ms segment; Rise-Time = time required for the flow to rise from 10% of PEF to 90% of PEF; Flow Time-to-PEF = time required for flow to rise from 200 ml/s to maximum flow (PEF); Vext Time-to-PEF = time required for flow to rise from Vext time zero to PEF.

* Units: flow (L/s), volumes (L), and time (milliseconds). These waveforms are available on digital media from the American Thoracic Society.

MONITORING DEVICES (FVC AND FEV_1) TESTING CRITERIA

Accuracy Testing

Criterion: Deviation ± 5.5% *or* deviation (%) ± 0.1 L, whichever is larger.

Waveforms: Twenty-four standard volume–time waveforms (APPENDIX C).

Device testing: Two production devices selected routinely from a production run and not screened before testing.

Validation: Each device will receive five maneuvers for each of the 24 waveforms. An average for each waveform will be calculated and used to score that meter against the accuracy criteria.

Acceptable performance: An error occurs when both deviation (formula B3) and deviation (%) (formula B4) exceed their specified limits. Acceptable performance for each individual parameter is less than three errors out of the total 48 tests (24 waveforms, 2 devices).

Precision Testing: Intradevice Testing

Criterion: Range (%) < 3.5% or range < 0.1 L, whichever is greater.

Waveforms: Four of the 24 standard volume–time waveforms (waveforms 1, 3, 6, and 11).

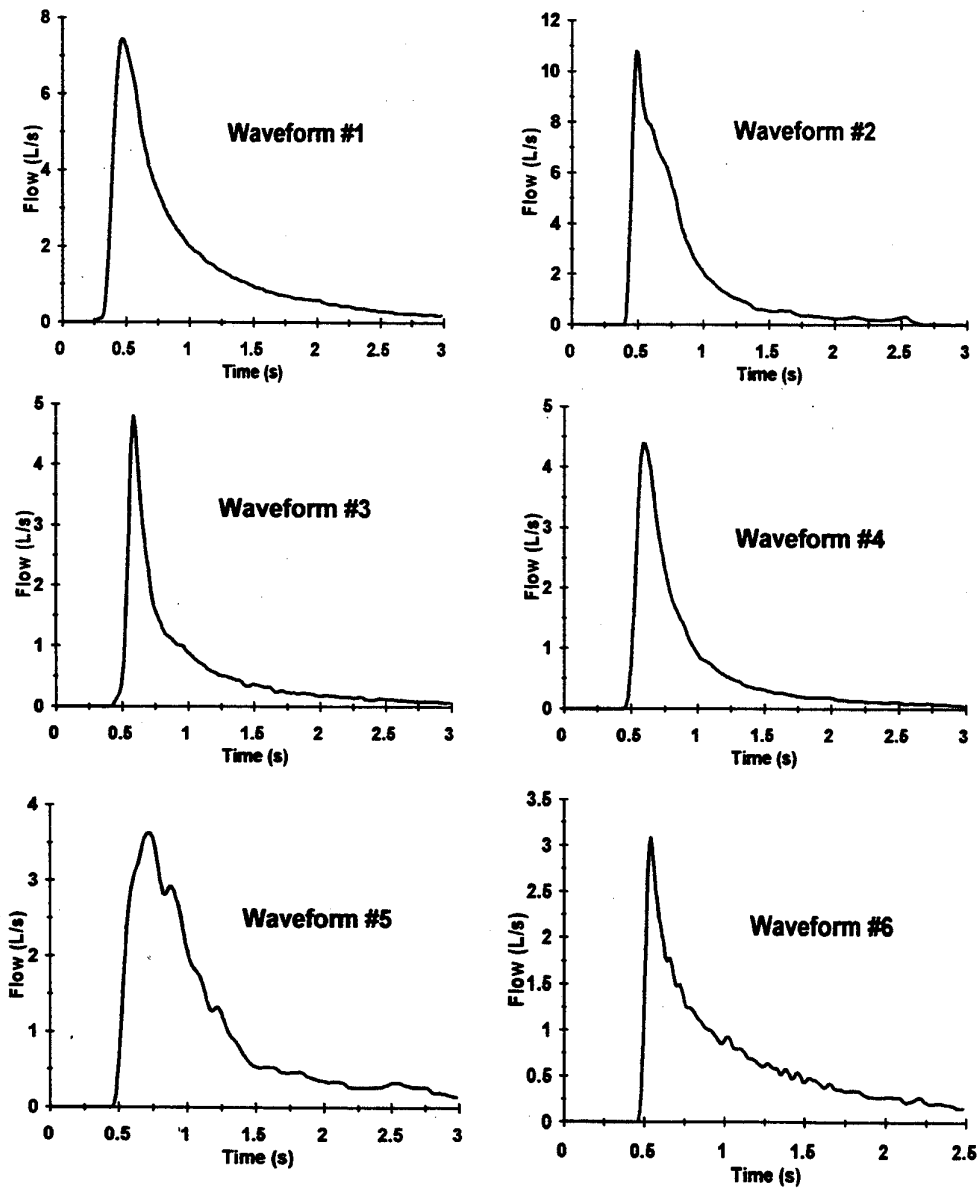
Meters tested: Ten production devices.

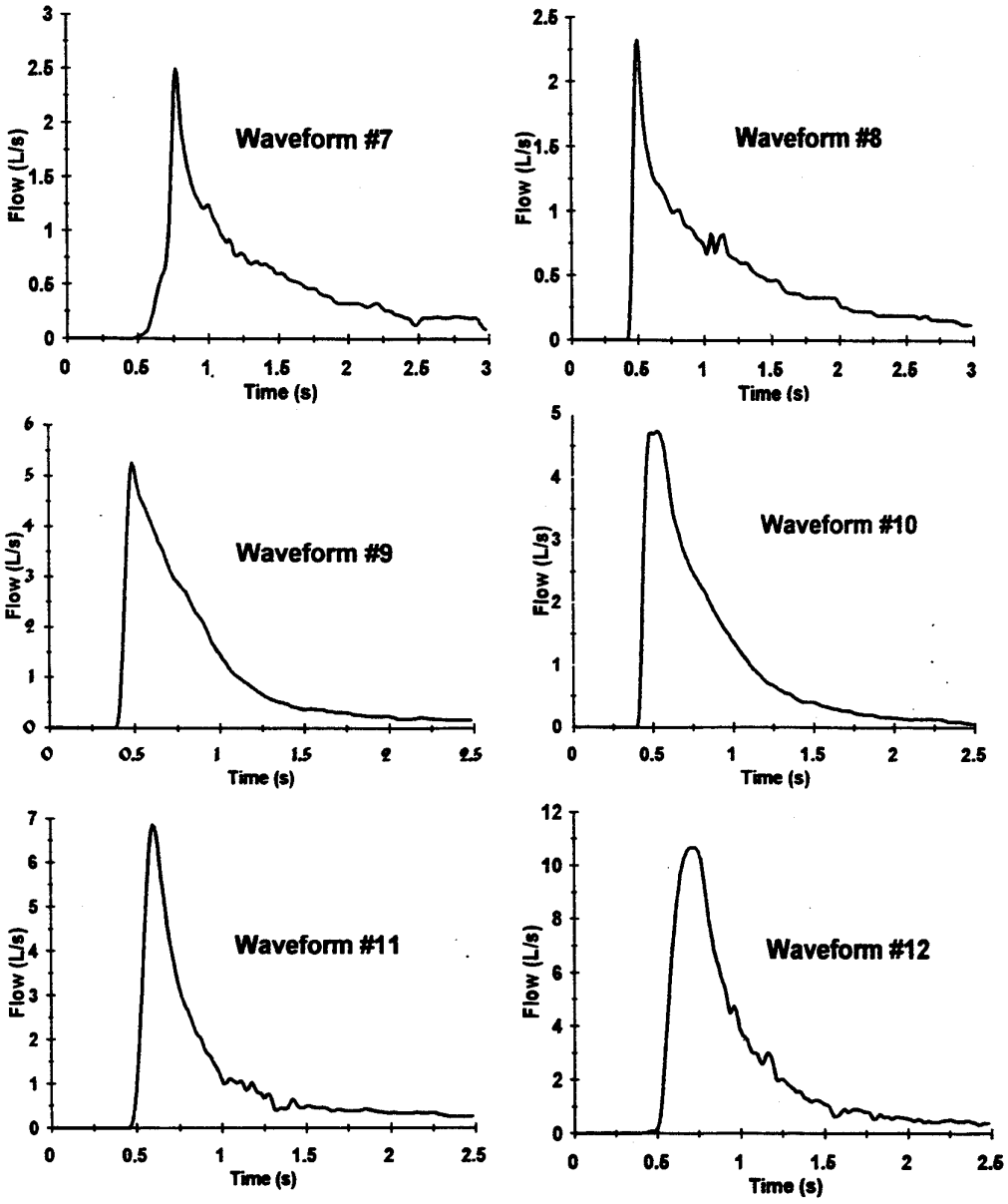
Validation: Three flows for each waveform for each device. For each waveform and for each device, calculate range (formula B1) and range (%) (formula B2) for FVC and FEV_1.

Acceptable performance: An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance for each individual parameter is six or fewer errors (error rate ± 5% for 120 trials).

Precision Testing: Interdevice Variability

Criterion: Less than 11% interdevice variability or 0.2 L, whichever is greater.





Waveforms: Same as for intradevice testing.

Devices tested: Same as for intradevice testing.

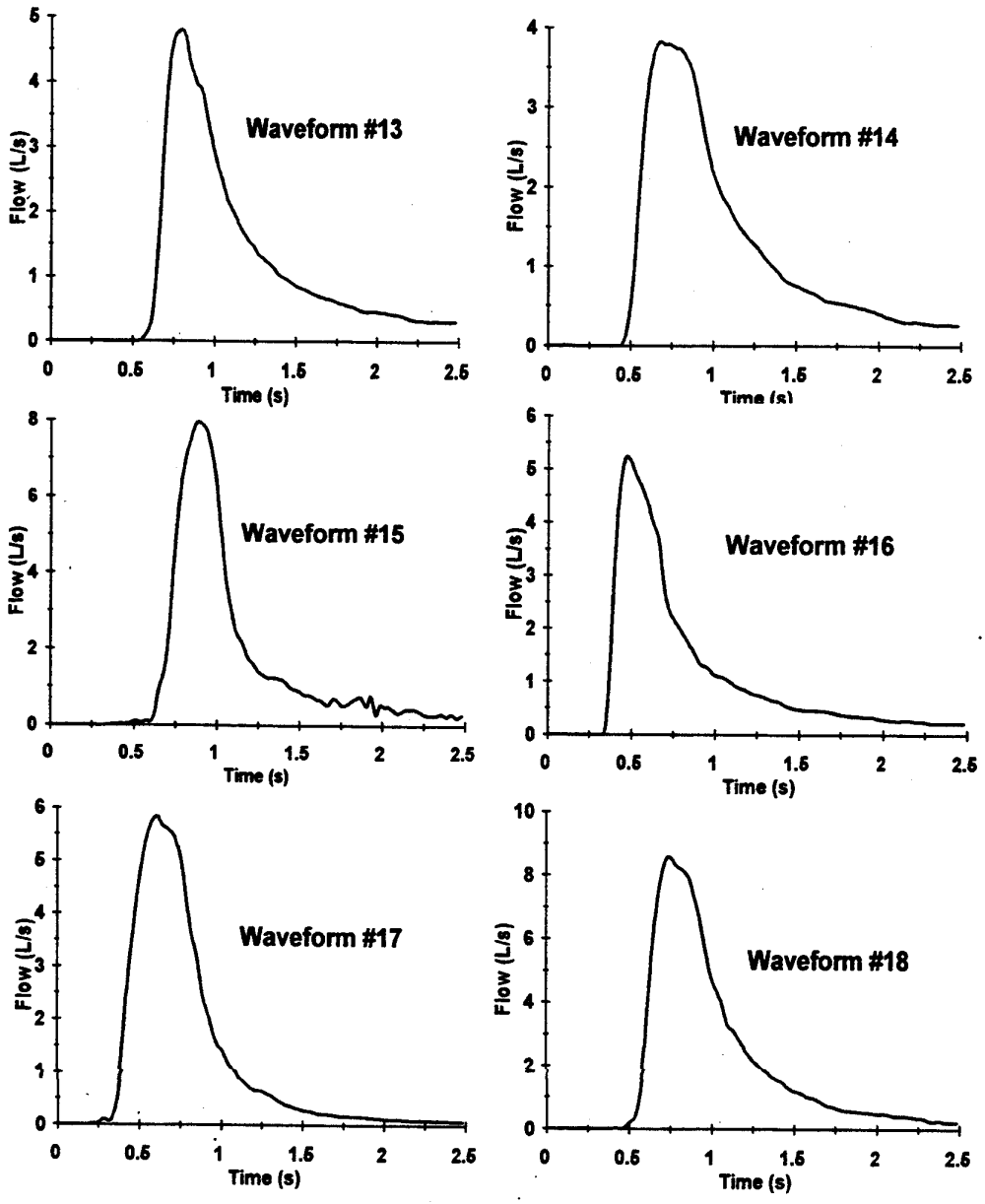
Validation: Same data as for intradevice testing. Interdevice percentage is calculated as follows: for each device, calculate an average FVC and FEV_1 for each waveform. For each waveform and parameter, combine all data from 10 meters to calculate range (formula B1) and range (%) (formula B2) for each of the four waveforms.

Acceptable performance: An error occurs when both range (formula B1) and range (%) (formula B2) exceed their specified limits. Acceptable performance is present if there are no errors.

APPENDIX D

Standard Flow-Time Waveforms for Validating PEF

The following flow-time waveforms are intended primarily for testing portable PEF meters but can be used for testing other types of spirometers, especially those measuring PEF, time-to-peak flow, or rise-time. These waveforms were chosen to represent a range of PEFs and efforts (rise-times). The PEF is derived directly from the flow-time waveform-maximal observed value. To calculate the volume-determined PEF, volume is first obtained by integrating (summing) the flow values. Flow is then calculated from the volume-time waveform using the ATS 8-point smoothing function. The resulting volume PEF is usually lower than the PEF obtained from the flow-time waveform. Rise-time is defined as the time required for the flow to rise from 10% of the PEF to 90% of the PEF and is expressed in milliseconds. Other investigators have used the time-to-PEF, using the back-extrapolated technique to determine the zero time-point. Using back-extrapolation to calculate time-to-peak flow sometimes



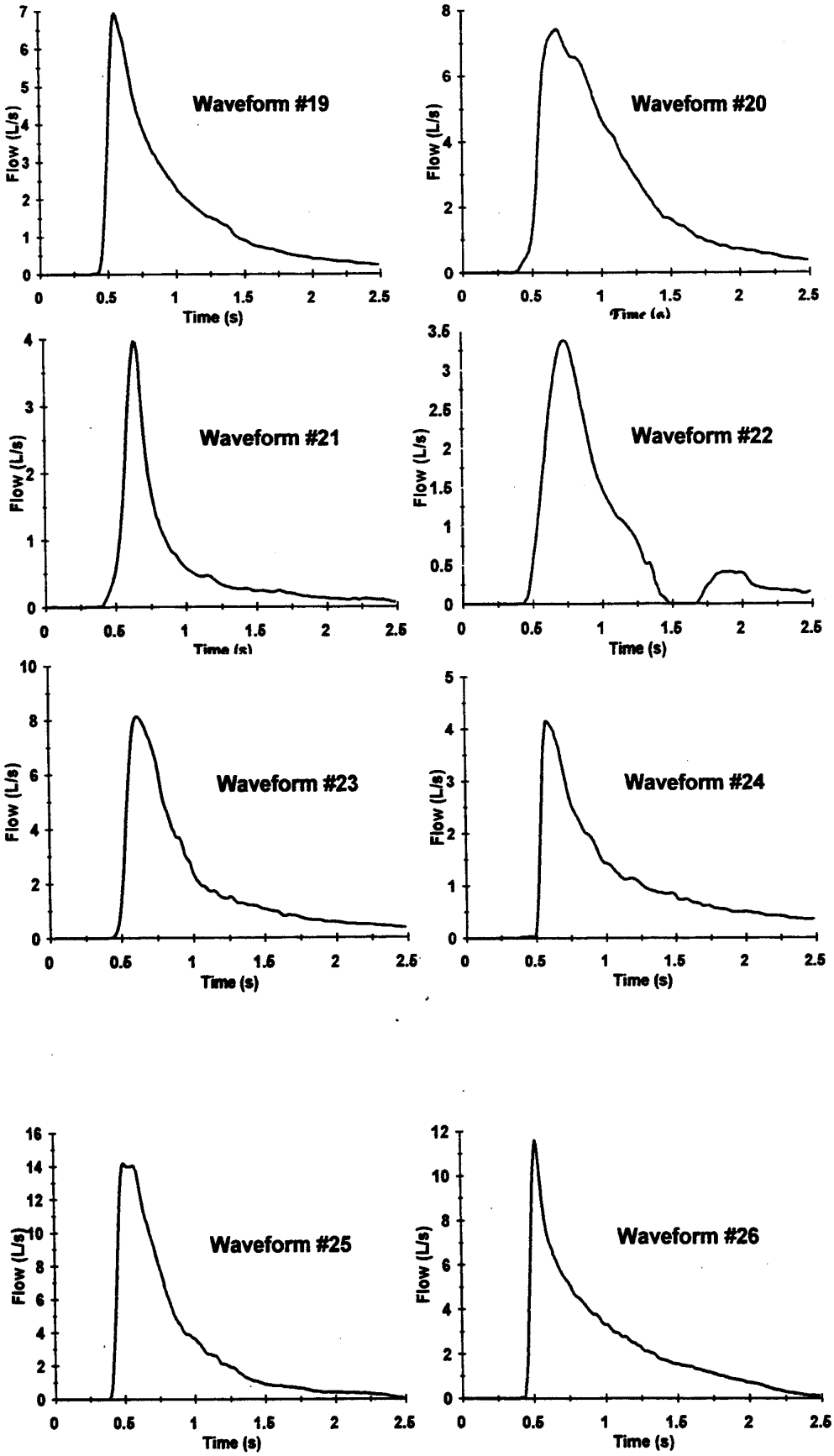
results in artificially lower time-to-PEF, as can be seen in waveform 7.

APPENDIX E

Signal-Processing Tutorial

Since computers have come into such common use in spirometry and since fundamental errors have been detected in recently tested commercially available hardware and software (79), a short tutorial on signal processing is presented (Figure E1).

For volume spirometers, signals are generally derived from electrical voltages from a potentiometer. Some spirometers also use optical shaft or position encoders (80). Flow devices of the Fleisch pneumotachometer variety also have electrical voltage outputs. For the volume spirometer with a potentiometer and the flow device with a flow transducer, the signal is sampled by a computer's analog to digital (A-to-D) converter. The ability of these systems to accurately measure the spirogram depends on the volume or flow transducer's linearity, the accuracy and linearity of the electrical transducer (potentiometer), and the resolution of the A-to-D converter. A resolution of 12 bits (1 part in 4,096, raw resolution from 0.003 to 0.004 L) for the A-to-D converter is recommended, although 10 bits (1 part in 1,024, raw resolution from 0.008 to 0.016 L) may be adequate for sampling volume. The sampling rate of the spirometer volume or flow is very important. Lemen and associates (19) have shown


Waveform #19
Waveform #20
Waveform #21
Waveform #22
Waveform #23
Waveform #24
Waveform #25
Waveform #26
Flow (L/s)
Time (s)

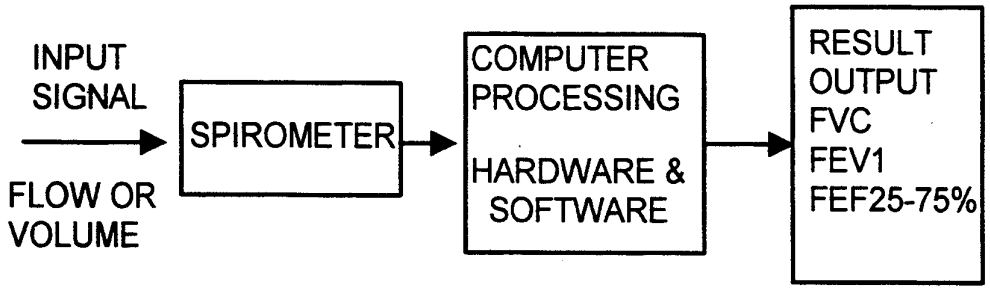


Figure E1. Block diagram of spirometer data acquisition.

that for both infants and adults, 95% of the signal energy in the flow-time spirogram is within a bandwidth of zero to 12 Hz. For the volume-time curve, 95% of the signal energy is contained from zero to 6 Hz. Digital sampling theory requires that samples be taken at least twice the rate of the highest frequency contained in the signal (81). Thus for volume-time spirograms, a 12-Hz sampling rate should be adequate. However, most volume-time spirograms are sampled at a 100-Hz or greater rate to make measurements easier and more accurate. Computer system developers should be aware that even with 100-Hz sampling, it may be necessary to linearly interpolate between sampling points to determine accurate FEV_1, $FEF_{25-75\%}$, and other similar spirometric measures.

Volume sampling techniques with optical and shaft or position encoders of the volume-time signal have been used (80). This approach measures the time interval between uniform volume intervals (for example, 0.010 L). In this case, the resolution of the time interval between measurements during rapid flow becomes a limiting factor. Ostler and associates have recently addressed these issues (80). For example, if a resolution of flow to within ± 5% of reading at 12 L/s for a system with 0.010-L resolution is required, then a clock resolution of at least 40 μs is needed (80).

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special report

Office Spirometry for Lung Health Assessment in Adults*

A Consensus Statement From the National Lung Health Education Program

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COPD is easily detected in its preclinical phase using spirometry, and successful smoking cessation (a cost-effective intervention) prevents further disease progression. This consensus statement recommends the widespread use of office spirometry by primary-care providers for patients ≥ 45 years old who smoke cigarettes. Discussion of the spirometry results with current smokers should be accompanied by strong advice to quit smoking and referral to local smoking cessation resources. Spirometry also is recommended for patients with respiratory symptoms such as chronic cough, episodic wheezing, and exertional dyspnea in order to detect airways obstruction due to asthma or COPD.

Although diagnostic-quality spirometry may be used to detect COPD, we recommend the development, validation, and implementation of a new type of spirometry—office spirometry—for this purpose in the primary-care setting. In order to encourage the widespread use of office spirometers, their specifications differ somewhat from those for diagnostic spirometers, allowing lower instrument cost, smaller size, less effort to perform the test, improved ease of calibration checks, and an improved quality-assurance program. ***(CHEST 2000; 117:1146–1161)***

Key words: COPD; risk assessment; smoking; spirometry

Abbreviations: ACCP = American College of Chest Physicians; ATS = American Thoracic Society; BTPS = body temperature, ambient temperature, and saturation with water vapor; FET = forced expiratory time; FEV_6 = forced expiratory volume in 6 s; HRCT = high-resolution CT; LHS = Lung Health Study; LLN = lower limit of normal; NHANES = National Health and Nutrition Examination Survey; NHLBI = National Heart Lung and Blood Institute; NLHEP = National Lung Health Education Program; PCP = primary-care provider; PEF = peak expiratory flow; PEFT = peak expiratory flow time; PF = pulmonary function; QC = quality control

During the last 40 years, the desire to reduce the morbidity, mortality, and expense of common chronic diseases in the United States has led to successful programs designed to identify and modify risk factors such as hypertension and hypercholesterolemia.[1,2] The primary and secondary prevention of disease through early recognition and intervention has become a key strategy, leading to the preparation of guidelines by various expert panels that recommend specific screening and monitoring programs.[3–5] Despite evidence documenting the very high burden of suffering and the economic cost of chronic respiratory diseases,[6] and despite calls for methods to reduce the impact of COPD,[7,8] recent

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Although representatives from NIOSH participated in the NLHEP conferences and reviewed drafts of this document, official approval from NIOSH was not obtained.

Manuscript received June 7, 1999; revision accepted November 8, 1999.

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consensus statements on the management of COPD have not addressed the early assessment of respiratory function in people at risk for chronic respiratory diseases.[9–12] Although standards for the performance of spirometry are well established,[13] and although diagnostic quality spirometers are widely available, primary-care physicians rarely use spirometry to detect COPD in smokers or to detect asthma or COPD in patients with respiratory symptoms.[14–17]

The failure of spirometry to meet the requirements for effective screening in general unselected populations (regardless of smoking status or symptoms) provided the basis for the unwillingness to support efforts to detect COPD early in its course, although the use of spirometry for "case finding" in patients who seek medical care for "unrelated" symptoms (during a clinical encounter), and who are at high risk for COPD due to a history of heavy cigarette smoking, was supported by a 1983 official statement of the American Thoracic Society (ATS).[18] Several lung function tests that initially were thought to be sensitive to early disease of small airways (closing volumes and nitrogen washout curves, for example) were too complex and were found not to predict the subsequent development of COPD.[19–22] When the use of spirometry was initially suggested for identifying smokers with asymptomatic lung disease,[23,24] little evidence could be found to suggest that early identification of COPD would have any impact on its course. Although there was mounting evidence that spontaneous smoking cessation improved the rates of decline in lung function toward normal,[25,26] selection bias and other factors may have accounted for these changes. Furthermore, outcomes in most smoking cessation programs were disappointing.

Since then, results from the National Health and Nutrition Examination Survey (NHANES) III and the multicenter Lung Health Study (LHS) have provided a new basis for early identification and intervention in COPD.[27,28] The LHS was the first study to demonstrate prospectively that early intervention in smokers identified to be at risk for COPD could modify the natural history of the disease. Both the NHANES III and the LHS also documented the ability of spirometry to detect mild airflow abnormalities in thousands of cigarette smokers, many of whom did not have symptoms that would have prompted them to seek medical attention.

Increased awareness of these issues has led to the formation of the National Lung Health Education Program (NLHEP), a project jointly sponsored by several professional societies crossing various medical disciplines and specialties.[29] The program is designed to increase the awareness of lung health in patients, health-care practitioners, and health-care organizations. As a part of the NLHEP, a subcommittee was organized to reevaluate the role of simple lung-function testing as a tool for assessing lung and overall health. Following an extensive literature review, Gary Ferguson developed the first draft of this report in early 1998, which then was reviewed by the NLHEP spirometry subcommittee. The American College of Chest Physicians (ACCP) and the National Heart, Lung, and Blood Institute (NHLBI) then held a conference on August 18, 1998, to review the report further. Paul Enright then revised the document based on discussions and comments from the conference attendees. The revised report was again reviewed during a second conference sponsored by the NHLBI in Bethesda, MD, on March 26, 1999. Both conferences included experts in spirometry and evidence-based medicine, including representatives from several professional associations and governmental agencies. This document represents the contributions of the participants of these conferences.

Indications for Office Spirometry

Recommendation

Primary-care providers (PCPs) should perform an office spirometry test for patients ≥ 45 years old who report smoking cigarettes (current smokers and those who quit during the previous year) in order to detect COPD.

Rationale: Several well-recognized criteria have been established for the use of medical tests that have been proposed for the early detection of disease,[30–34] and spirometry for the detection of COPD in adult cigarette smokers fulfills all of these criteria:

1. The disease, if not detected early, would go on to cause substantial morbidity or mortality;
2. Treatment is available that is more effective when used at the early stage before the development of symptoms than when used after the symptoms develop; and
3. A feasible testing and follow-up strategy is available that
   a. minimizes the false-positive and false-negative rates,
   b. is relatively simple and affordable,
   c. uses a safe test, and
   d. includes an action plan that minimizes potential adverse effects.

The above criteria are usually applied to screening tests, defined as medical tests done for individuals who have no symptoms or signs that suggest the possibility of disease. Office spirometry is considered

to be a part of a clinical evaluation and does not fall under the definition of a screening test when performed for patients with respiratory symptoms who are seen during a clinical encounter (whether or not they have a history of cigarette smoking). Also, if the patient has been diagnosed as having tobacco addiction (a disease with a code in the International Classification of Diseases, ninth revision), office spirometry may be indicated to assess the severity of that disease and is not then considered to be a screening test. Although the NLHEP does not recommend office spirometry for screening unselected populations or for testing patients who have no cardiopulmonary risk factors, the next section of this document provides evidence that office spirometry fulfills all of the criteria listed above when it is used to detect COPD in adult smokers.

The Disease, If Not Detected Early, Would Go On to Cause Substantial Morbidity or Mortality

COPD is the most important lung disease encountered and the fourth leading cause of death in the United States, and it affects at least 16 million people.[7,35] Of the top causes of mortality in the United States, only the death rate for COPD continues to rise, increasing by 22% in the past decade. The 10-year mortality rate for COPD after diagnosis is > 50%.[36] In addition, the number of patients with COPD has doubled in the last 25 years, with the prevalence of COPD now rising faster in women than in men.[37] Although the frequency of hospitalization for many illnesses is decreasing, the number of hospital discharges for COPD rose in the last decade. COPD causes 50 million days per year of bed disability and 14 million days per year of restricted activity.[38,39] COPD causes about 100,000 deaths per year, 550,000 hospitalizations per year, 16 million office visits per year, and $13 billion per year in medical costs, including home care.[35]

Treatment Is Available That Is More Effective When Used at the Early Stage of COPD, Before the Development of Symptoms, Than When Used After Symptoms Develop

COPD is a slowly progressive, chronic disease characterized by cough, sputum production, dyspnea, airflow limitation, and impaired gas exchange.[40] The early and common symptoms of chronic cough and sputum production usually are ignored by the patient (and often their physicians) as normal or expected for a smoker, and no intervention is deemed necessary. The disease usually is not diagnosed until the patient experiences dyspnea with only mild exertion, which interferes with the patient's quality of life. The diagnosis of COPD is made by clinicians (1) by noting the presence of at least one risk factor in the patient's medical history (usually > 20 pack-years of cigarette smoking), (2) by documenting moderate-to-severe airflow limitation using a diagnostic spirometry test, and (3) by excluding heart failure and asthma as the causes of airflow limitation.[12]

The LHS was a randomized clinical trial that demonstrated that COPD could be detected in its early stages in smokers with few symptoms.[28] Spirometry tests were performed for > 70,000 women and men who were current smokers (without regard to symptoms), 35 to 59 years old, from nine United States communities and Winnipeg, Canada.[41] About 25% of those tested were found to have borderline to moderate airflow obstruction. An additional 5% had severe airflow obstruction (< 50% of predicted), and they were excluded from the study and referred for treatment. Those taking medications for asthma also were excluded. About 6,000 smokers with borderline to moderate airflow obstruction were recruited and were followed up for 5 years. About half of the participants reported chronic cough (with a wide range of 26 to 81%, depending on gender, age group, and clinic site). Wheezing on most days and nights was reported by about one third of participants; only 2.8% reported a current diagnosis of asthma but were not taking any prescription medications for asthma.[42] Those who continued to smoke were documented to have faster rates of decline in lung function. Importantly, participation in a smoking cessation program significantly decreased the rate of decline in lung function in these individuals relative to those who continued to smoke. Those participants who continued not to smoke (sustained quitters) showed a small improvement in lung function over the first year compared to continuing smokers (mean rise in FEV_1, 57 mL vs mean fall in FEV_1, 38 mL, respectively) and had reduced rates of decline over the remaining 4 years of study (mean rate of decline in FEV_1, 34 vs 63 mL/yr, respectively).[28] Thus, the rate of decline of FEV_1 following successful smoking cessation was very similar to that seen in healthy nonsmoking adults (28 to 35 mL/yr).[43,44]

In addition to documenting the benefits of smoking cessation in modifying the natural history of COPD, the LHS documented the ability to successfully intervene with an intense smoking cessation program in relatively asymptomatic smokers.[28] At least 35% of the subjects studied were able to quit smoking for extended periods of time, and 22% of the subjects were able to quit and sustain smoking cessation for 5 years (as compared to 6% in the usual care group). The smoking recidivism rates during the 5 years equaled the repeat quitter rates, such that 35% of the subjects were nonsmokers at any cross-

sectional period of time. Of course, smoking cessation rates are likely to be lower in primary-care settings when compared to a clinical trial.[33,34]

Effective smoking cessation methods available to primary-care practitioners have dramatically improved in the last several years. Detailed recommendations are now available that synthesize the expanding smoking cessation knowledge base.[45,46] Awareness of different stages in the process of behavioral change have allowed for more focused efforts on subjects likely to quit smoking.[47,48] In addition, increasing success with repeated attempts at smoking cessation now is recognized. Significant advances in the understanding and treatment of nicotine addiction also have occurred.[49] Nicotine gum and patches[50] are now available over the counter in the United States. Bupropion hydrochloride (Zyban; Glaxo Wellcome; Research Triangle Park, NC), an oral medication that is even more effective than nicotine patches,[51,52] now is available by prescription in the United States. Comprehensive and effective community-based smoking cessation programs also are available in most communities in the United States.[53]

Recognizing that individual rates of decline in lung function vary, the LHS clearly documents that spirometry can identify large numbers of adult smokers at risk for COPD, and that smoking cessation programs can impact positively on the progression of COPD in those smokers who successfully quit. The regular use of β-agonists or ipratropium in current or former smokers with airways obstruction, but without asthma, apparently has no effect on COPD progression.[28,54,55] However, there is some recent evidence that high-dose inhaled corticosteroids given to smokers with spirometric evidence of mild-to-moderate airflow limitation reduces morbidity, improves quality of life.[56–58]

Spirometry Testing Probably Enhances Smoking Cessation Rates

Previous studies of lung function testing in the general population have had mixed results, with some showing no effect[19] and others suggesting that knowledge of an abnormal lung function test doubled the likelihood of quitting smoking, even when no other interventions were applied.[59–62] A recent review[63] concluded that spirometry meets all the criteria for a test for the early detection of COPD, except that there is no conclusive evidence that spirometry adds to the efficacy of standard smoking cessation advice, which is based on current clinical practice guidelines.[45] Two randomized clinical trials that address this issue have been performed. The first study of 923 Italian smokers found a 1-year quitting rate of 6.5% in those who received counseling with spirometry, 5.5% in those with counseling alone, and 4.5% in those who received only brief physician advice.[64] These rates did not differ significantly, but only half of the study participants who were asked to visit a laboratory for spirometry testing ever did so, and there was no evidence that the spirometry results even were discussed with those who performed the test; therefore, the study probably had inadequate power to show a difference (a type II error). The second study was population based and identified 2,610 young men who were current smokers, were aged 30 to 45 years, had low FEV_1 values, and were from 34 cities in Norway.[65] A random half of the men were mailed a personalized letter from a physician stating that they should quit smoking because they were at increased risk for smoking-related lung disease because of their low lung function. A 15-page smoking cessation pamphlet that emphasized behavioral modification was included in the letter. The self-reported 12-month sustained smoking cessation rates were 5.6% in the minimalist intervention group vs 3.5% in the control group (who were not informed of their spirometry results). After adjusting for age of smoking onset, cigarettes smoked per day, and history of asbestos exposure, the letter describing the abnormal spirometry results was responsible for a 50% improvement in the smoking cessation rates ($p < 0.01$). Even a 1 to 2% improvement in smoking cessation rates would result in a very large absolute number of lives saved each year in the United States.[66]

The Relationship Between Spirometry and COPD

Various studies have determined COPD risk factors. COPD occurs predominantly in current and former cigarette smokers, and there is a dose-response relationship. The risk of COPD is strongly associated with the intensity and duration of smoking.[42,67,68] Other factors that also increase COPD risk, but less commonly or to a lesser degree, include occupational dust exposure,[69] environmental tobacco smoke,[68] exposure to environmental air pollution,[70] a rare genetic deficiency of α_1-antitrypsin,[71] a history of childhood respiratory infections,[72] and the presence of airway hyperresponsiveness, as measured by spirometry.[73,74] Even moderate COPD cannot be detected reliably by a medical history or physical examination.[75–77]

Abnormal spirometry (*ie*, limitation of expiratory airflow, airways obstruction, or a low FEV_1/FVC ratio) is a strong predictor for rapid progression of COPD.[28] The degree of airways obstruction corre-

lates closely with pathologic changes in the lungs of smokers and patients with COPD.[78] Spirometry results are also a strong independent predictor of morbidity and mortality due to COPD,[79,80] mortality due to cardiovascular disease,[81] lung cancer,[82,83] as well as all-cause mortality.[84,85]

A Feasible Testing Strategy Is Available That Minimizes the Rates of False-Positive and False-Negative Results

The accuracy of a test for the early detection of disease is measured in terms of two indexes: sensitivity and specificity.[5] A test with poor sensitivity will miss cases (true-positive results), producing false-negative results, while a test with poor specificity will result in healthy persons being told that they have the disease, producing false-positive results.

An accepted reference standard (a "gold standard") must be available to provide the means for distinguishing between true-positive and false-positive results from the new test. The traditional "gold standard" for the diagnosis of COPD is the pathologic examination of lung tissue,[78] but this confirmation of the disease is inappropriate in routine practice due to the invasive nature of a lung biopsy. The finding of abnormally low lung densities on a high-resolution CT (HRCT) lung scan in adult smokers is very highly correlated with the pathologic grading of emphysema[86] and, therefore, may soon be considered a secondary reference for COPD, but HRCT lung scans are infrequently performed clinically due to their high cost. COPD, as determined by HRCT lung scans, is moderately correlated with lung function testing (FEV_1/FVC ratio and diffusing capacity of the lung for carbon monoxide) in adult smokers,[87] but emphysema (lung tissue destruction accompanied by lung hyperinflation) is only one component of COPD and may not be an important predictor of morbidity and mortality, independent of airflow obstruction. The widely accepted definition of COPD progression is an abnormal rate of decline in lung function.[54,80] The normal annual decline in FEV_1 in healthy, never-smoking adults who are 35 to 65 years old has been determined by several longitudinal studies to be a mean of 30 mL/yr with an upper limit of the normal range of 50 mL/yr, which may be used to define "rapid fallers."[88]

It is important that a high proportion of those who test positive actually have disease (positive predictive power). This proportion is higher when the prevalence of disease is high. The best estimates of the prevalence of airflow obstruction and COPD in the US population are now available from NHANES III (conducted from 1988 to 1994). In NHANES III, spirometry was measured in a sample of $> 16,000$ adults who represented the noninstitutionalized population of the United States. About 29% of all the adult participants reported current smoking, and 24% were former smokers. Normal reference values of several spirometry variables were developed from the "healthy" subset of the nonsmoking men and women who were free of respiratory symptoms and diseases. Lower limit of normal (LLN) values, which were specific for age, sex, and height, were set at the fifth percentile of the reference population values.[27] For this report, prevalence rates of low lung function in the US population were estimated by defining low lung function as a FEV_1/FEV_6 ratio less than the LLN and an FEV_1 value less than the LLN. See Table 1 for the results.

Prevalence rates of low lung function increase with age and are highest in current smokers, intermediate in former smokers, and lowest in never smokers. Rates are similar in men and women. Compared with rates in never smokers, rates are more than five times as high in current smokers at ≥ 45 years old and are more than three times as high in former smokers ≥ 55 years old. Prevalence rates also were compared in men and women who reported any respiratory condition or symptom with those who did not. A report of any of the following placed the individual in the symptomatic group: a doctor's

Table 1—*The Prevalence of Low Lung Function in the NHANES III Sample of the Adult US Population*

Age Group, yr	Current Smoker, %		Former Smoker, %		Never Smoker, %	
	Men	Women	Men	Women	Men	Women
17–24	5.9	2.2	1.5	0.0	2.9	3.0
25–34	5.3	3.3	0.3	3.0	2.6	2.0
35–44	5.2	6.7	2.6	2.2	2.3	2.3
45–54	13.1	19.2	4.1	4.0	2.8	1.8
55–64	21.3	28.4	8.8	10.5	3.3	3.5
65–74	30.9	20.9	13.6	14.6	2.9	3.0
75–89	24.8	15.4	13.8	12.8	9.1	2.7
Total*	9.6	9.6	6.5	6.7	2.9	2.5

*Values given as abnormality rate for all age groups.

diagnosis of asthma, chronic bronchitis, or emphysema; cough or phlegm on most days for ≥ 3 consecutive months during the year; shortness of breath on mild exertion; or chest wheezing or whistling apart from colds. Rates of low lung function were consistently three or more times higher in symptomatic men and women than in those who were asymptomatic.

We recommend that all patients ≥ 45 years old who are current smokers, as well as those with respiratory symptoms, perform office spirometry or diagnostic spirometry. Based on the NHANES III study, the numbers of patients eligible for spirometry under these recommendations, and the expected yield of abnormal spirometry tests are given in Table 2. About one quarter of current cigarette smokers with a respiratory symptom, a total of 9 million persons in the United States, can be expected to have low lung function (airway obstruction). Smokers ≥ 45 years old without respiratory symptoms also have a relatively high abnormality rate: about 9% of men and 14% of women. On the other hand, current and former smokers < 45 years old have spirometry abnormality rates that are similar to those of healthy never smokers (about 5%), reducing the value of spirometry testing of young adult smokers. Asymptomatic former smokers ages ≥ 55 years also have a sprirometry abnormality rate of 5%.

Office Spirometry Is Relatively Simple and Affordable

Spirometry is a relatively simple, noninvasive test. Office spirometry takes only a few minutes of the patient's and technician's time and includes a few athletic-type breathing maneuvers of 6 s duration. The economic costs of a spirometry test include the cost of the instrument and the cost of personnel time (both training and testing). Diagnostic spirometers currently cost about $2,000, and about $10 of time per test is spent in testing (including training time) and disposable supplies. Office spirometers will cost < $800 and require even less testing time than diagnostic spirometers. Adding a post-bronchodilator spirometry test for asthma adds about 15 min to the test time (but is not needed for COPD evaluations).

Spirometry Safety

Any medical test has both tangible and intangible costs. Adverse effects may occur (1) due to the procedure itself, (2) due to the investigation of abnormal results, or (3) due to the treatment of detected abnormalities or diseases.[33,34] There are no adverse side effects from spirometry testing, other than occasional minor discomfort. However, investigation and confirmation of abnormal spirometry results in some patients will cost both time and money and may result in psychological and social harm in some patients. The cost of diagnostic spirometry to confirm airflow obstruction when performed in a hospital-based pulmonary function (PF) laboratory ranges from $20 to $60. The estimated travel time, waiting time, and testing time spent by the patient ranges from 1 to 3 h. The possible psychological impact of being labeled as "ill" by self and others related to false-positive or even true-positive test results could lead to alterations in lifestyle and work and to seeking medical attention. Another potential adverse effect is the unmeasured risk of reinforcing the smoking habit in some of the four of five adult smokers who are told that they have normal results for spirometry testing. However, the clinician should counteract this possibility by taking the opportunity to tell the patient that normal results for spirometry testing do not mean that the patient's high risk of dying from a heart attack, lung cancer, or other smoking-related diseases is substantially reduced; therefore, smoking cessation remains very important.

Finally, the risk of an adverse effect caused by the intervention for COPD (smoking cessation) is very small. The side effects of over-the-counter nicotine replacement are minimal. Successful smoking cessation leads to a small average increase in body weight,[89] but the slight increase in medical risk from

Table 2—*The Number of Men and Women Eligible for Spirometry Testing in the United States and the Prevalence of Low Lung Function, as Estimated From the NHANES III Study*

Population Data	No. of Persons Eligible in US		Prevalence of Low Lung Function, %	
	Men	Women	Men	Women
Smokers, age 45+ yr	7,620,000	6,670,000	19.0	22.4
Symptomatic	4,770,000	4,100,000	25.1	27.5
Asymptomatic	2,850,000	2,560,000	8.9	14.4
Symptomatic, ages 25 yr and older	19,000,000	25,200,000	11.1	7.2
Never and former smokers	13,000,000	19,000,000	12.3	7.7
Current smokers, age 25–44 yr	6,000,000	6,200,000	8.6	5.5

minor weight gain is far exceeded by the benefits due to reduced morbidity and mortality and the economic savings in cigarette and cleaning costs.

The Action Plan

Even when test quality seems good, diagnostic spirometry is highly recommended to confirm abnormal office spirometry findings prior to initiating an expensive workup or an intervention with negative economic consequences (such as a recommendation to change jobs or to prescribe a medication).

The key focus of the NLHEP program is prevention and early intervention. Validated abnormal test results in a smoker should lead to a more detailed history and examination for pulmonary disease and cardiovascular risk factors (including hypertension, diabetes mellitus, obesity, hypercholesterolemia, etc). Consideration should be given to the presence of pulmonary diseases other than COPD, including asthma, restrictive lung and chest wall diseases, neuromuscular diseases, and cardiac disease.

When airway obstruction is identified in a smoker, the primary intervention is smoking cessation. In the event that a patient with airway obstruction continues to smoke cigarettes, a renewed or increased effort to assist with smoking cessation is essential. Future research may determine that other interventions, such as anti-inflammatory therapy, are effective in selected patients with airway obstruction. Referral to a subspecialist for further diagnostic testing should be considered in some patients, such as those in whom bronchiectasis or other lung diseases are suspected. Pre- and post-bronchodilator diagnostic spirometry is indicated if asthma is suspected.

Recommendation

Primary-care physicians should perform an office spirometry test in patients with respiratory symptoms such as chronic cough, sputum production, wheezing, or dyspnea on exertion in order to detect asthma or COPD.

Rationale: Analyses of data from a population sample of 25- to 75-year-old white men in Tucson, AZ, found that spirometry abnormality rates increased in those who reported respiratory symptoms, after excluding those who reported a physician diagnosis of asthma, chronic bronchitis, or asthma.[90] Abnormal spirometry was defined as an FEV_1 below the LLN, using the reference equations from the study by Crapo et al,[91] which reported spirometry reference values very similar to the NHANES III values. The comparison subjects, never smokers without respiratory symptoms, had a 3.8% spirometry abnormality rate, while asymptomatic former smokers and current smokers had abnormality rates of 9.2% and 11%, respectively. Former smokers and current smokers with any of three respiratory symptoms (chronic cough and sputum, dyspnea walking on level ground, or attacks of dyspnea with wheezing) had abnormality rates of 25.6% and 14.1%, respectively. These abnormality rates, and those from NHANES III (Tables 1, 2), demonstrate that the presence of respiratory symptoms in a former or current cigarette smoker substantially increases their pretest probability (risk) of having airflow obstruction (low lung function) or COPD.

The National Health Interview Survey (conducted from 1993 to 1995) estimated that 4 million adults (4.5% of those aged 35 to 65 years) have asthma (by self-report) and that 630,000 emergency department visits for asthma occur each year in this age group.[92] A survey of 59 primary-care practices with 14,000 patients in Wisconsin reported an asthma prevalence of 6.2% in adults ($\geq$ 20 years old), half of whom reported adult onset of the disease.[93] An additional 3.3% of the patients without a diagnosis of asthma reported attacks of wheezing with dyspnea during the previous year, suggesting, along with other investigations, that asthma is underdiagnosed in adults.[17] Spirometry is recommended by current clinical guidelines for patients with symptoms that suggest asthma in order to help confirm the diagnosis.[94]

Recommendation

Primary-care physicians may perform an office spirometry test for patients who desire a global health assessment (risk assessment).

Rationale: Lung function testing is now recognized as a measure of global health, predicting all-cause mortality and morbidity in adults.[85,95–97] In addition, lung function test results and changes in lung function over time have been shown to identify patients at high risk for lung cancer[82,83] and at increased risk for coronary artery disease,[98] congestive heart failure,[99] stroke and other heart and blood vessel disaeses,[100] and altered mental function in later years of life.[101] Early identification and recognition of increased global health risks also may allow for evaluation and for prevention and early intervention in other risk areas appropriate to each of these nonpulmonary disease categories. Office spirometry also may identify patients with subclinical asthma or restrictive lung processes in both adults and children, leading to the institution of appropriate evaluations and treatments. Although prophylactic interventions such as vaccination are recommended for

patients with respiratory illnesses, only a small percentage of them receive influenza and pneumococcal vaccines.[102] In adults, early intervention following early identification of lung function abnormalities can lead to improved smoking cessation, to occupational, avocational, or environmental changes, and to increased awareness and attention to cancer, cardiac, and other nonpulmonary health issues associated with abnormal lung function. Early identification of lung function abnormalities in relatively asymptomatic patients may provide "teachable moments" or specified times for a given patient when there is an increased awareness and response to medical education and intervention. Such moments may lead to an increased responsiveness to smoking cessation and to enhanced opportunities for other preventive therapies or modification of identifiable risk factors.

Why Not Use Peak Flow?

Assuming that lung function testing of selected individuals is a useful part of health care, it is essential that the test chosen is the best available. First, it must be able to detect mild disease. Although many lung function tests are available, previous studies examining the value of these tests have shown that most of them are unacceptable or ineffective as tools for the early detection of COPD.[19,20] The exceptions are peak expiratory flow (PEF) and spirometry. PEF measurements are recommended for asthma management by current clinical practice guidelines, but spirometry is recommended to help make the diagnosis of asthma.[94] Likewise, we do not recommend the use of PEF to evaluate patients for COPD. The advantages of PEF tests are the following: measurements within a minute (three short blows) using simple, safe, hand-held devices that, typically, cost < $20. On the other hand, the disadvantages of using PEF when compared to spirometry are as follows: PEF is relatively insensitive to obstruction of the small airways (mild or early obstruction); PEF is very dependent on patient effort; PEF has about twice the inter- and intrasubject variability[103]; and mechanical PEF meters are much less accurate than spirometers.[13]

Tracking Changes in Lung Function

Tracking of lung function over time has potential advantages over a single test.[104] However, there are no published data demonstrating that when the results of the first spirometry test are normal in a high-risk patient the measurement of annual changes in lung function (tracking) in the primary-care setting is better than simply repeating office spirometry at 3- to 5-year intervals, which we recommend.

In occupational medicine, diagnostic-quality spirometry tests often are performed regularly for the surveillance of employees at high risk.[104,105] Annual tests increase the likelihood of detecting changes in lung function earlier when compared to less frequent testing intervals. Infrequent testing (*eg*, every 5 years) may delay identification of lung function abnormality, reducing the benefits of identification, prevention, and early intervention in lung disease. However, when testing is performed more frequently, and when a less-than-optimal spirometry quality-assurance program is used, the false-positive rate increases. Office spirometry may be indicated for patients who report workplace exposures to chemicals, dusts, or fumes that are known to cause lung disease; however, a discussion of testing for occupational lung disease is beyond the scope of this document.

Technical Requirements for Office Spirometers

Recommendation

A new category of spirometers, office spirometers, should be available for use in the primary-care setting. Each new model must successfully pass a validation study (see Appendix 1).

Rationale: Traditionally, spirometry has been used as a diagnostic test, with the usefulness and accuracy of spirometry measurements depending on both the equipment and proper test performance. Although simple to learn, spirometry is an effort-dependent test that requires a cooperative patient and a trained person capable of administering the test. Specific recommendations have been developed by the ATS and other professional organizations to ensure accurate and reproducible measurements when using diagnostic spirometers.[13,106–109] In many cases, a diagnostic spirometer that meets ATS standards will be the preferred choice for a hospital, outpatient clinic, or doctor's office since it permits diagnostic and follow-up testing (tracking) of lung function. Currently available diagnostic spirometers also may be used in the primary-care setting to evaluate smokers for COPD. However, some characteristics of diagnostic spirometers create a barrier to their widespread use for this purpose. Advantages of the newly proposed category of office spirometers for this purpose include lower instrument cost, smaller size, less effort to perform the test, improved ease of calibration checks, and an improved quality-assurance program. Office spirometers should not be utilized for diagnostic testing, surveillance for occupational lung disease, disability evaluations, or research purposes.

Current ATS recommendations for diagnostic spi-

rometry[1] must be followed for office spirometry, except for the following seven factors.

1. Office Spirometers Must Only Report Values for FEV_1, FEV_6, and the FEV_1/FEV_6 Ratio

The reported FEV_1 and FEV_6 values should be rounded to the nearest 0.1 L and the percent predicted as an integer (for instance, 72%); and the FEV_1/FEV_6 ratio should be calculated as a fraction with only two decimal places (for instance, 0.65). An indication should be made next to the reported value (an asterisk for instance) when the patient's values fall below the LLN range for the variable. The false-positive rate increases when additional variables (for instance, the midexpiratory phase of forced expiratory flow) are used to define abnormality.[110]

Rationale: Spirometry is a simple test that measures the volume of air expelled from fully inflated lungs as a function time.[111] Following inspiration to a maximal lung volume, the patient is instructed to exhale as fast and hard as possible. Many lung function indexes may be derived from spirometry; however, the most valuable indexes are the total volume of exhaled air and the FEV_1.[1]

2. The ATS End-of-Test Criteria Should Be Modified for Office Spirometry

Rationale: The measurement of FVC should be replaced by that of FEV_6 so that each maneuver need last for only 6 s. The advantages of using FEV_6 for office spirometry are the following: (1) it is easier for the patient and the technician when maneuvers last only 6 s; (2) technical problems with flow sensors related to accurately measuring very low flows over several seconds of time (resolution and zero drift) are minimized; (3) the FEV_6 is more reproducible than the FVC in patients with airways obstruction; (4) using the FEV_6 reduces the overall time to perform a test; and (5) shorter maneuvers reduce the risk of syncope. The FEV_6 has long been proposed as a surrogate measurement for FVC[112]; however, reference values for FEV_6 and the FEV_1/FEV_6 ratio have only recently become available.[27] The validity of using FEV_6 as a surrogate for FVC is now being established. For example, unpublished data from the LHS suggest that the FEV_1/FEV_6 ratio is as good as the FEV_1/FVC ratio in predicting the decline in FEV_1 over the subsequent 5 years in adult smokers. Some healthy children and some young adults empty their lungs before 6 s has elapsed; in those cases, their FVC and FEV_6 values should be considered equivalent if their end-of-test volume is not too high (suggesting that their FEV_6 has been underestimated).

3. Airway Obstruction Will Be Interpreted When the FEV_1/FEV_6 Ratio and the FEV_1 Percent Predicted Are Both Below Their LLNs

The FEV_1 percent predicted may optionally be used to categorize the severity of the abnormality (Table 3). Report FEV_1 as a percent of predicted to patients. This is "the number" the patient should remember.

Rationale: The ATS recommends that the FEV_1/FVC ratio be used to diagnose airways obstruction.[13,106] The FEV_1/FEV_6 ratio is a good surrogate for the FEV_1/FVC ratio (see above). The LLN is now well defined for all ages of African Americans, Hispanic Americans, and whites, with a mean of about 73%, ranging from 70 to 76% depending on age, gender, and race.[27]

This recommendation for using the FEV_1/FEV_6 ratio with office spirometers should not discourage clinicians from continuing to use an older diagnostic-quality spirometer that reports the FEV_1/FVC ratio and its LLN, but not the FEV_1/FEV_6 ratio. However, the FVC is defined as the maximum amount of air that the patient can exhale, and most adult patients can exhale more air after 6 s. Therefore, when using traditional reference equations and an interpretation of airways obstruction based on the FEV_1/FVC ratio, airway obstruction may be missed (a false-negative result) if the patient is not coached to exhale completely (usually $\geq$ 10 s).

In patients with COPD, the FEV_1 percent predicted is directly proportional their quality of life and ability to perform exercise.[113] Clinicians and patients understand the semiquantitative terms *mild*, *moderate*, and *severe* better than *percent predicted* when discussing the relative severity of diseases. A stronger admonition and the patient's adherence to the recommended intervention may be more likely when the abnormality is reported as moderate or severe.

Table 3—*Interpretation of Office Spirometry Results*

1. First ensure that test quality is good (see Table 4).
2. Use the NHANES III reference values to calculate predicted values and LLNs for the FEV_1, FEV_6, and FEV_1/FEV_6 ratio (this should be done automatically by the spirometer).
3. If the FEV_1/FEV_6 ratio and the FEV_1 are both below the LLN in a test with good quality, airways obstruction is present. Report the FEV_1 percent predicted to the patient. Optionally, the severity of the obstruction may be graded using the FEV_1 % predicted as follows:
   FEV_1 LLN to 60% predicted FEV_1 = mild obstruction
   40 to 59% predicted FEV_1 = moderate obstruction
   < 40% predicted FEV_1 = severe obstruction
4. If FEV_1/FEV_6 ratio is above the LLN but the FEV_6 is below the LLN, the patient has a low vital capacity, perhaps due to restriction of lung volumes.

Also, when the abnormality is moderate or severe, the likelihood that the test result is falsely positive is much lower than when the abnormality is mild. The severity category cut-points suggested in Table 3 (40% and 60%) correspond roughly to z scores of 2 and 3 in the distribution of the percent predicted for FEV_1 in patients with COPD and are in widespread clinical use.[106]

4. Automated Maneuver Acceptability and Reproducibility Messages Must Be Displayed and Reported

Rationale: Many performance standards essential to reliable spirometry measurements[1] already have been automated and included within spirometry devices to reduce the likelihood of poor-quality test results.[40,112,114] Additional built-in performance checks are necessary for office spirometers that do not display or print spirograms or flow-volume curves, which the technician or physician can review for acceptability and reproducibility of the maneuvers. Table 4 lists quality control (QC) criteria that must be monitored electronically along with recommended messages to be displayed when these maneuver quality errors are detected. These thresholds were designed so that > 90% of adult patients (even the elderly) can pass all the QC checks within five maneuvers if coached by a technician who has good training, motivation, and experience. Devices should present the numeric spirometry results and interpretations only if all maneuver QC criteria are met. While we believe that these electronic quality checks will reasonably ensure good-quality tests, studies are necessary to validate their performance in primary-care settings.

Table 4—*Recommended Automated Maneuver QC Checks, Messages, and Grades**

Messages
If the BEV is > 150 mL, display "don't hesitate"
If the PEFT is > 120 ms, display "blast out faster"
If the FET is < 6.0 s and EOTV† was > 100 mL, display "blow out longer"
If the PEF values do not match within 1.0 L/s, display "blast out harder"
If the FEV_6 values do not match within 150 mL, display "deeper breath"
Only one error message is displayed (in the order of priority listed above)
After 2 acceptable maneuvers that match, the message is "good test session"
QC grades‡
A = at least 2 acceptable maneuvers with the largest two FEV_1 values matching within 100 mL and the largest two FEV_6 values matching better than 100 mL
B = at least 2 acceptable maneuvers with FEV_1 values matching between 101 and 150 mL
C = at least 2 acceptable maneuvers with FEV_1 values matching between 151 and 200 mL
D = only one acceptable maneuver, or more than one, but the FEV_1 values match > 200 mL (with no interpretation)
F = no acceptable maneuvers (with no interpretation)

*BEV = back extrapolated volume; EOTV = end-of-test volume (calculated as the change in exhaled volume during the last 0.5 s of the maneuver).

†A large EOTV indicates that a volume-time plateau was not obtained, so that the FEV_6 was probably underestimated. The appropriate PEFT and EOTV thresholds depend on several characteristics of the spirometer, such as frequency response, sampling rates, and filtering of the flow signal. For instance, for a given model of office spirometer, the PEFT threshold of 120 ms may be changed if based on the 95th percentile of PEFT from studies in which experienced technicians test > 200 adults. The 95th percentile of PEFT for school-age children and adolescents is about 160 ms.

‡A QC grade, which indicates the degree of confidence in the results, should be calculated, displayed, and reported along with the numeric results and the interpretation.

5. Displays and Printouts of Spirograms and Flow-Volume Curves Will Be Optional for Office Spirometers

Rationale: Standards for diagnostic spirometry require that graphs of the maneuvers be produced so that technicians who perform the tests, physicians who interpret the results, and those who later review the test reports may recognize problems with maneuver quality.[13] The graphs also assist physicians in the recognition of the characteristic patterns of different types of abnormalities, such as generalized airways obstruction, restriction of lung volumes, and the rare upper airways obstruction.[111,115] However, a graphic display or a printer usually increases the size, cost, and complexity of spirometers, reducing their widespread acceptability in the primary-care setting. It is also likely that many technicians and physicians will not learn to recognize the patterns of unacceptable spirometry maneuvers and that many physicians will not recognize the patterns of abnormality. We believe that automated-maneuver QC checks and messages are generally more reliable now for quality-assurance purposes than are programs to teach pattern recognition of spirometry graphs, although no published studies demonstrate this.

6. Office Spirometers Must Be Sold With Easy-to-Understand Educational Materials

These educational materials should include procedure manuals, audiovisual instructional aids (such as a videotape or multimedia CD ROM), and patient handouts that describe the potential risks and benefits of NLHEP spirometry, interpretation of the results, and limitations of the test.

Rationale: It is unlikely that many primary-care physicians will spend the time and money necessary

to send their technician or nurse to a 2-day spirometry training course.[116] Emphasis in training materials must be placed on effective interactions between the technician and the patient when performing spirometry tests (Table 5). In order to minimize the number of breathing maneuvers needed to obtain a good-quality test session, technicians always must demonstrate the correct maneuver themselves before instructing patients to perform them. The technician must then enthusiastically coach and watch the patient throughout the three phases of each maneuver: (1) maximal inhalation, (2) blast out quickly, and (3) continue exhalation for 6 s. Most maneuver errors are easily recognized by watching the patient. When the technician or the automated spirometer maneuver QC checks detect poor-quality maneuvers, the technician must tell the patient what went wrong and again demonstrate how to perform the maneuver correctly. After eight maneuvers are performed and the test session is of poor quality, the test should be rescheduled for a later date.

7. Simple Inexpensive Solutions Should Be Developed to Replace the Daily Use of 3-L Calibration Syringes to Check the Accuracy of Office Spirometers

Rationale: One-liter calibration syringes may be as effective as 3-L syringes, and they are smaller and less expensive. It is also possible that precisely manufactured plastic (Mylar; 3M Corp; St. Paul, MN) bags could be used to check volume accuracy on a daily basis. However, until alternative calibration methods are proven to check spirometer calibration effectively, the use of calibrated 3-L syringes on a regular basis is necessary. If a calibration syringe is not available in a primary-care setting, calibration checks using a standard 3.00-L calibration syringe may be performed at regular intervals by a local diagnostic PF laboratory at minimal cost. A proper interval cannot be arbitrarily set for all spirometers. Manufacturers should validate the acceptable calibration interval specified for their office spirometers that ensures that they remain accurate when used as directed in the primary-care setting. Third-party testing of the between-sensor (within-batch) accuracy of single-use flow sensors should be established.

Periodic testing of a biological control also should be used to check the long-term performance of office spirometers. The individuals chosen as biological control subjects must be >25 years old and must not have an obstructive lung disease. Their FEV_1 and FEV_6 first must be measured on 10 days, and the average values and ranges must be calculated. The range of measurements for FEV_1 and FEV_6 (largest minus smallest) should not exceed 10% of the average value, otherwise a different biological control subject should be chosen. If disposable flow sensors are used, the biological control subject may reuse a single-flow sensor, and it should be stored with the subject's name on it. The biological control subject then should be tested on each day that patients are tested. If the control subject's measured FEV_1 or FEV_6 is $>10\%$ from the average value, the test should be repeated. If the FEV_1 remains "out of bounds," even after replacing or cleaning the sensor, the device should not be used on patients until repaired.

Table 5—*Spirometry Steps*

1. Measure standing height in stocking feet
2. Record age, gender, height, and ethnicity
3. Explain and demonstrate the correct maneuver
4. Coach and watch the patient perform each maneuver
5. Repeat until 2 acceptable and matching maneuvers are obtained

The FEV_1 and FEV_6 Must Be Corrected to BTPS Conditions

The device should sense the temperature automatically if necessary for accurate body temperature, ambient temperature, and saturation with water vapor (BTPS) corrections. The technician should not be asked to enter the temperature.

Rationale: The measurement of ambient or spirometer temperature and barometric pressure may not be needed for some spirometers in which the design allows the use of a fixed BTPS correction factor.[117] Errors in measuring FEV_1 and FEV_6 must remain $<3\%$ (according to BTPS testing methods recommended by the ATS). Manufacturers must specify the range of ambient temperatures and altitudes in which the results remain accurate.

The Current ATS Recommendations Regarding Measures to Avoid Cross-Contamination Should Be Followed by Those Using Office Spirometers

Staff performing spirometry tests must be instructed to wash their hands before and after assisting each patient with the test. If patients are only exhaling through the devices, proper use of disposable mouthpieces is all that is needed to minimize the risk of the transmission of infections. In particular, disposable in-line filters are not mandated.[13,116] All devices should be inspected and kept clean to meet good hygiene standards. Devices with completely disposable flow sensors or with mouthpieces that have one-way valves should be used if testing is to be performed in patients likely to inhale through

the mouthpiece. Manufacturers should give explicit instructions about cleaning techniques and frequency of cleaning.

A New Billing Code Should Be Created for Office Spirometry Tests

Rationale: Charges should be kept as low as possible but should at least cover the real costs of the test. It seems imprudent to charge patients or third-party insurers for diagnostic-quality spirometry tests when office spirometry tests are performed, since office spirometry tests will require less expensive instruments, less technician time, and less training to interpret.

Further Research

There is insufficient published evidence related to many of the technical and procedural issues associated with the above recommendations for office spirometry. More detailed information is needed about the following issues: levels of training required to obtain results of acceptable quality; levels of inaccuracy and imprecision; reliability; durability; and the necessary frequency and type of calibration checks (see Appendix 1). Outcomes to be assessed include sensitivity of detection, frequency of false-positive test results, and the overall impact on patient care, quality of life, and cost-benefit analyses. These issues should be examined both for pulmonary diseases and as a part of total health care. Additional areas requiring research include the role of office spirometry in lower risk individuals (*ie*, nonsmokers, former smokers, and those without respiratory symptoms) and the prospective utility of office spirometry in the intervention and management of global disease processes. Research in these areas is strongly encouraged in order to validate and improve the above recommendations.

Appendix 1: Office Spirometer Validation Studies

Background

The NLHEP recommends the widespread use of spirometry by PCPs for detecting COPD in adult smokers and describes a new type of spirometer for this purpose: the office spirometer. The value of spirometry for aiding the diagnosis of COPD and asthma, when performed by trained technicians using diagnostic spirometers that meet current ATS recommendations, is widely accepted. The accuracy and precision of diagnostic-quality spirometry performed in the hospital PF laboratory, pulmonary research clinic, and occupational clinic settings by technicians who are trained and have considerable experience performing spirometry have been studied by many investigators and found to be acceptable for the purposes of detecting airways obstruction in individuals and for detecting abnormal declines in FEV_1 in groups of adults. However, the first prospective study of > 1,000 spirometry tests performed by nurses in the outpatient clinics of 30 randomly selected primary-care physicians in New Zealand found that less than one third of the test sessions included at least two acceptable maneuvers.[118] About one third of the maneuvers had a "slow start" (peak expiratory flow time [PEFT], > 85 ms [a substantially stricter criterion than those in the NLHEP document]). About two thirds of the maneuvers lasted for < 6 s (forced expiratory time [FET], < 6 s), and visual inspection of the volume-time curves suggested that most of these short-duration maneuvers underestimated the FVC (did not achieve an end-of-test plateau). On the positive side, after attending a 2-h spirometry training workshop, nurses were much more likely to obtain acceptable test sessions. These results confirm the necessity for each new office spirometry system to have a "real-world" validation study before it is marketed.

Several factors, other than instrument accuracy, are known to influence the real-world accuracy and repeatability of spirometry tests. These factors include the following: the technician's training, experience, number of tests performed per month, motivation, motivational skills, and patience; the patient's coordination, cooperation, strength, endurance, and motivation; maneuver and test session quality feedback (to the technician and patient); the training materials that accompany the spirometer; the type and frequency of calibration checks and actions taken to remedy equipment and sensor problems; the testing environment (space, lighting, noise, time constraints, and other stressors); and changes in these factors over the time period of measurement (*eg*, differing technicians, updated software, new flow sensors, etc).

Goals

The goal of an office spirometer validation study is to compare the spirometer's screening and tracking performance in adult patients in the PCP setting with that of diagnostic spirometers used by trained technicians. The following study protocol is designed to apply to any model of office spirometer. It is designed to be performed in a reasonable amount of time (6 months) and with reasonable resources (< $50,000 if a price of <$20 per test is negotiated with the PF laboratory). In order to minimize poststudy criticism, the limits of acceptable outcomes have been predetermined. The manufacturer or distributor of all office spirometers that claim to meet NLHEP specifications must conduct this study for that model and include the published results of the study with each office spirometer sold.

Methods

A study coordinator with experience in clinical trials, without a conflict of interest (such as one that an employee of the office spirometer manufacturer or distributor would have), shall be selected. Exactly the same instrument, sensors, manuals, calibration tools, accessories, and training materials that are sold (or provided) commercially as *the spirometry system* shall be used in the validation study. The same amount of in-service training with the same type of personnel shall be used during the study that will be used for actual commercial training (for instance, 45 min with a local distributor). The setting, staff, and patients will be selected to optimize the generalizability of the results to the real world. A single, representative sample of the office spirometer shall first undergo (and pass) independent testing for FEV_1 and FEV_6 accuracy and reproducibility, which will be performed by a third party using current ATS recommendations[1] and a spirometry waveform generator, including four waveforms generated using BTPS conditions (body temperature humidified air). All disposable flow sensors used for testing shall be saved in a plastic bag, labeled with the date and patient identification number, and sent to the study coordinator at the end of the study.

Recruitment of PCPs

Thirty PCPs shall be recruited from advertisements offering "a free spirometer and 6 months of spirometry supplies." At least two regions of the United States shall be represented. At least five PCPs (either medical doctors or doctors of osteopathy) shall be selected from each of the following specialties: family practice, general internal medicine, and general surgery. Allergists and pulmonary specialists shall be excluded. Staff who report that they have personally performed > 100 spirometry tests during the previous 5 years shall be excluded. PCPs who have used a spirometer in their office during the previous year shall be excluded. Each PCP must agree to perform spirometry testing for at least 20 adult patients per month (an average of one patient per weekday) for 6 months. The altitude of each office (within 500 feet) shall be recorded.

Recruitment of Patients

Inclusion criteria are consecutive outpatients, aged 45 to 85 years, who are current cigarette smokers or who quit smoking during the previous year. Patients with asthma (according to self-report or the medical record) and those previously noted to have a significant response to inhaled bronchodilators (FEV_1 increases, > 12% and > 0.2 L) shall be excluded from the study, since their FEV_1 values have inherently high short-term variability.

Follow-up Testing

At least one patient per week shall be asked by each PCP to return to their clinic within 1 month for repeat spirometry testing. A contract shall be made with a local hospital-based PF laboratory to perform follow-up diagnostic spirometry (including printed volume-time and flow-volume curves, but without a physician interpretation) on a subset of study patients. All patients with abnormal spirometry test results shall be scheduled to perform diagnostic spirometry testing at a local hospital-based PF laboratory within 2 weeks of the screening spirometry test. The cost of the diagnostic testing, and a $20 reimbursement for each patient, shall be paid for by the study. The PF lab shall send a copy of the results to the study coordinator. The results of the follow-up spirometry tests shall not be sent to the PCP until the end of the study.

Measurements

The long-term accuracy of a random sample of five of the study spirometers shall be measured by a third party using a waveform generator at the beginning and at the end of the 6-month study. A random sample of five used flow sensors shall be obtained for the long-term accuracy testing at the end of the study.

The demographics of all patients tested shall be determined and stored for analysis. The demographics must include a unique patient identification number, age, gender, height, weight, race, smoking status, asthma status, date, and technician identification number. The following parameters shall be stored digitally for all (or the best three) spirometry maneuvers: FEV_1, FEV_6, back extrapolation volume, PEFT, PEF, FET, sequence number, and the 50-point flow-volume curve (the average flow during each 2% segment of the FEV_6). This may require modifications to the office spirometers used in the study (when compared to those that will be sold commercially). These modifications should be designed to minimize technician interaction with the recording device. A written log shall be kept by the office staff of any problems with the spirometer, any calibration checks performed, any preventative maintenance, and any repairs.

Statistical Analysis

The study coordinator shall determine the long-term accuracy of the office spirometer instruments by comparing the baseline and 6-month FEV_1 and FEV_6 measurements from the "gold standard" waveform generator and the records of repairs, updates, or replacements. The quality of all spirometry test sessions (screening, follow-up, and diagnostic) shall be graded by the study coordinator using the stored data and the criteria listed in Table 4 of this document. The rates, trends, and correlates of unacceptable-quality test sessions (QC grades, D or F) shall be determined using logistic regression.

The false-positive and false-negative rates for detecting airways obstruction (after allowing for 3% error in the measured FEV_1/FEV_6 ratio) shall be determined by comparing the office spirometry results with the valid follow-up diagnostic tests performed in the PF laboratory. Results from the diagnostic-quality spirometry tests that are determined by the study coordinator (using the printed reports from the PF lab) to be valid (QC grades, A or B) are assumed for the purposes of this study to be the "gold standard." Both the false-negative rate and the false-positive rate shall be < 5% for the office spirometry system to be considered acceptable.

The value of office spirometry for "tracking" purposes shall be determined by calculating the short-term coefficient of repeatability of FEV_1 for the subset of patients who performed repeat tests. Acceptable repeatability is for ≥ 95% of the patients to have repeat FEV_1 values that match within 0.30 L. The predictors of poor repeatability shall be determined by logistic regression.

Appendix 2

Participants in the NHLBI/ACCP Consensus Conference (August 18, 1998; Chicago, IL)

William Bailey, MD, FCCP; Gary Ferguson, MD, FCCP; Michael Alberts, MD; A. Sonia Buist, MD; Paul L. Enright MD; John Hankinson, PhD; Millicent Higgins, MD, honorary FCCP; Deborah Shure, MD, FCCP; James Stoller, MD, FCCP; Brian Carlin, MD, FCCP; Ray Masferrer, RRT; Gregory Wagner, MD; David Mannino, MD; Gail Weinmann, MD; Robert O. Crapo, MD, FCCP; Bettina Hilman, MD, FCCP; John W. Georgitis, MD, FCCP; James Fink, MS, RRT; and Edward A. Oppenheimer, MD, FCCP. ACCP staff: Sydney Parker, PhD; David Eubanks, EdD, RRT; Mary Katherine Krause; and Barbi Mathesius.

Participants in the NHLBI-sponsored NLHEP Conference (March 26, 1999; Bethesda, MD)

Thomas Petty, MD, Master FCCP (chair); William Bailey, MD, FCCP; Frank Bright, MD; Bartolome Celli, MD, FCCP; Catherine Gordon, RN, MBA; A. Sonia Buist, MD; James Cooper (HCFA); Dennis Doherty, MD, FCCP; Paul Enright, MD; Gary Ferguson, MD, FCCP; Millicent Higgins, MD, honorary FCCP; Ray Masferrer, RT; Sreehar Nair, MD; Louise Nett; Edward Rosenow, MD, FCCP; Deborah Shure, MD, FCCP; and Gregory Wagner, MD. NHLBI staff: Frederick Rohde; Suzanne Hurd, PhD; Gregory Morosco, PhD; and J. Sri Ram, PhD.

Members of the Spirometry Subcommittee of NLHEP

Gary T. Ferguson (chair), MD, FCCP; William C. Bailey, MD, FCCP; A. Sonia Buist, MD; Robert Crapo, MD, FCCP; Dennis Doherty, MD, FCCP; Paul Enright, MD; Millicent Higgins, MD,

honorary FCCP; Ray Masferrer; Louise Nett; Stephen Rennard, MD, FCCP; Thomas Petty, MD, Master FCCP; James Stoller, MD, FCCP; and Gail Weinmann, MD.

Members of the Executive Committee of NLHEP

Thomas Petty, MD, Master FCCP (chair); William Bailey, MD, FCCP; John B. Bass, Jr. (representing the American College of Physicians); Gary Ferguson, MD, FCCP; Millicent Higgins, MD, honorary FCCP; Leonard D. Hudson, MD, FCCP (representing the ATS); Suzanne S. Hurd, PhD (representing the NHLBI); Ray Masferrer, RT (representing the American Association of Respiratory Care); Sreedhar Nair, MD; Louise M. Nett, RN, RRT; Stephen Rennard, MD, FCCP; Deborah Shure, MD, FCCP; and Gail Weinmann, MD.

ACKNOWLEDGMENT: The authors thank Millicent Higgins from the University of Michigan, David Mannino from the Center for Disease Control, and Gregory Wagner and Kathleen Fedan from the National Institute for Occupational Safety, who collaborated to provide new analyses for this document from the NHANES III database.

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ATS Pulmonary Function Laboratory Registry Newsletter

Edited by Neil MacIntyre

AMERICAN THORACIC SOCIETY 1905 ATS

Summer 2004

Primary Care Office Spirometry

Chronic obstructive pulmonary disease (COPD) is an important disease in the United States. Not only does COPD produce progressive disability and loss of function over many years, it also is very costly to the health care system. The good news is that COPD can both be prevented and managed to improve significantly the quality of life and the societal health care cost related to COPD. The bad news is the lack of awareness of COPD by both victims and caregivers. The fact that millions of Americans continue to smoke speaks volumes about the public's denial of the link between cigarette smoking and serious health problems. In addition, access to proper disease management strategies is seriously lacking among many of those afflicted with COPD, often because patients and caregivers are unaware of the many treatment options available.

To address these issues, the National Lung Health Education Program (NLHEP) with the support of many health profession organizations (including the American Thoracic Society) was created with a mission to increase both COPD awareness and education. The two specific goals of NLHEP are: 1) A global educational campaign to raise awareness among patients and health care givers about the impact of COPD and about the various ways to prevent it, detect it, and manage it once it is established; and 2) Encourage spirometry in the primary care setting as a tool to detect airflow obstruction in its early stages (Ferguson GT et al. Chest 2000; 117: 1146-1161).

It is well established that properly done spirometry with ATS quality devices can be very useful in detecting airway obstruction, even in its early stages before symptoms have developed. Because of this, widespread use of spirometry would seem to have intui-

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tive benefit. However, there are several concerns:

First, the NLHEP recommendation is to use a new type of spirometer, the "office spirometer". These devices would have the same technical specifications of the American Thoracic Society (ATS) spirometers (ATS. Am. J. Resp. Crit. Care Med. 1995; 152:1107-1136) but would only have to measure 6 seconds of expiratory flow and would not be required to have visual analogue displays of the expiratory maneuvers. In place of these analogue signals, automated algorithms would be provided to assure quality tracings. These devices would thus be less expensive and presumably easier to operate than pulmonary function laboratory "diagnostic" devices. It remains to be seen, however, if these automated quality control algorithms can really replace experienced technicians evaluating spirometric tracings in terms of assuring test acceptability and repeatability.

Second, the NLHEP recommendations for training of spirometric technicians is not well defined. This is a marked distinction from the specific ATS recommendion of at least a year of post high school in formal training and the AARC clinical practice guideline recommendations for certification as a registered pulmonary function technologist. (AARC Clinical Practice Guideline on spirometry. Respir Care 1996; 41:629-636). Sub-optimally trained technicians can have significant impact on the quality of the test. A large study from New Zealand assessing office spirometry involved only on the job trainees (Eaton T et al. Chest 1999; 116:416-423) and this was associated with large numbers of unacceptable tests. This study also found that interpreters of pulmonary function tests, if not properly trained, can misdiagnose tests up to 50% of the time.

Third, a dramatic increase in spirometry billing will not go unnoticed by payers such as Medicare. This could prompt a whole review of spirometry (and perhaps other PFTs) reimbursement. If we find ourselves advocating office spirometry performed by minimally trained office workers and interpreted by primary care physicians, a review by payers could have detrimental effects on both technical and professional payments.

The ATS PF committee would like your feedback on these issues. Please forward comments to: neil.macintyre@duke.edu.

Spirometry Course Offering

A one day "Spirometry update refresher" will be given by the University of Cincinnati on **October 25, 2004**. Refresher training is recommended by the American Thoracic Society (ATS), the American Association of Occupational Health Nurses (AAOHN), the American College of Occupational and Environmental Medicine (ACOEM), and others. This special one day course will be given by Roy McKay, Ph.D.. The course will review spirometry testing guidelines published by the ATS and will stress testing skills, technique, occupational surveillance needs, and interpretation techniques. Differences between ATS, ACOEM and "Office Spirometry" guidelines will be discussed. This course will also provide additional insight towards changes in lung function over time (ie, what is or is not a significant change?). Unlike initial spirometry training, this course does NOT have an exam. This is an excellent way to obtain answers to questions not foreseen during initial training and get nursing continuing education credit. This course is approved for 7 Continuing Education contact hours for nurses.

The University of Cincinnati an approved provider for Continuing Education credit.

Information regarding this course including on-line registration is available by contacting: www.DrMcKay.com or, by calling 513/475-7712 between 8 am and 5 pm (Eastern Standard Time). Ask for Jeff.

DLCO Reproducibility

As noted in previous newsletters, the DLCO standardization document is being updated by a joint ATS-ERS (European Respiratory Society) task force. One of the issues being discussed are the criteria for reproducibility. A large study from Johns Hopkins (Punjabi NM et al. Chest 2003; 123: 1082-1089) suggested that it would be reasonable to tighten these criteria to be to require two tests to be within 3 DLCO units (or 10% of the largest value) of each other. This is in contrast to the old standard of being within 3 DLCO units of the mean value. A recent survey of 16 ATS Registry labs provided data from duplicate DLCO measurements on almost 800 patients. Analysis of these data support these tighter standards and they will likely be adopted in the next DLCO standardization document.

Renewal Plans

The ATS Registry has now been in existence five years. Over that time, over 200 laboratories throughout North America have joined and, in so doing, expressed a commitment to upholding ATS testing standards. The Registry has provided valuable data on the characteristics of pulmonary function laboratories in North America (ATS Meeting 2002, Atlanta), DLCO reproducibility (see above), and formal feedback on the ATS Lab Manual that was critical for re-writing the latest edition. The Registry has also received priority in ATS Postgraduate Courses on Pulmonary Function Testing and has received twice yearly newsletters. It is time now to renew this commitment. Over the next several months, labs will be receiving information on the renewal process. The Registry is now out of its infancy and more projects are planned (see below). We hope that all will continue their commitment to these issues. To re-enroll your laboratory, please contact Bridget Nance at 212/315-8695 or bnance@thoracic.org

If you have re-enrolled, a certificate will be issued two to four weeks upon receipt of your request.

Interpretation Process Problems

Once a pulmonary function test is performed, it must be interpreted. The first step in this process is a technical assessment on test quality. The next step is for a comparison of the measured data to reference data. In addition, the graphical displays are examined to provide additional information. An interpretation on the patterns and severity of abnormality is then generated. Computer programs exist to assist in this process but automated graphical pattern recognition (eg flow-volume loops) is still sub-optimal and the effects of "noise" in the signal (especially from effort variation) is difficult for computer interpretation programs to handle.

The physician interpreter is thus still required to create a report. This can be an edit of a computer reading, a dictation to a transcriber, a paper/computer screen menu selection process, or manual typing. Finally, the physician interpreter must verify the accuracy of the report and sign it. Two big problems in this process are: 1) Speed of data availability and interpretation entry (printing/report delivery time or data display time on a computer screen/PDA); 2) The requirement by the physician interpreter using transcription services to essentially have to read the test a second time to verify report accuracy.

In addition to faster data processing strategies (including better remote access), there are several new

(Continued on page 5)

Interpretation Process Problems cont'd

(Continued from page 4)

interpretation processes that are being examined by industry. One is a voice recognition system that would type on a screen in real time. This could be an "over-read" of a computer interpretation.

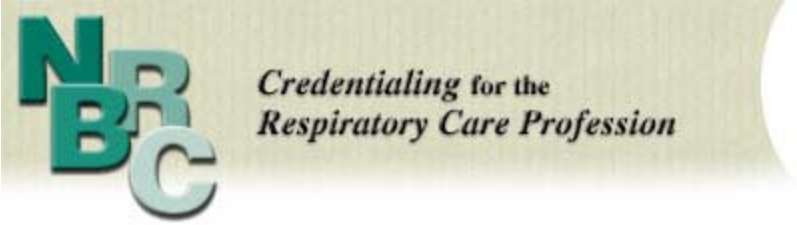
Another is the use of an optical scanner with standardized interpretation statements. This could also have computer interpretation "suggestions". Other options are also being considered.

In the next few weeks, we would like to survey the Registry members regarding current interpretive processes and views on newer strategies. We would appreciate your response to these.

Questions or comments about the development of this survey tool are welcome: neil.macintyre@duke.edu.

Is It Airway Obstruction or Airflow Limitation? Comments from Roy McKay

In recent years, it has become much more common for pulmonary physicians to use the term airflow limitation rather than airway obstruction, when interpreting PFTs. While some may argue it's just a matter of semantics, others feel differently. So what's the difference? As mentioned above, COPD has components of airway inflammation and destruction of lung parenchyma or emphysema. The consequences of this damage is airflow limitation during forced expiration on spirometry testing. When one examines the major determinants of expiratory flow in the lungs, we find that it is influenced by the driving pressure that promotes flow (elastic recoil of the lung) as well as the opposing resistance that inhibits flow (airway obstruction). The reduction in flow observed in COPD is, therefore, more correctly defined as airflow limitation (rather than airflow obstruction), since it is both the loss of elastic recoil and the increase in airway resistance that causes the reduction in flow observed during forced expiration. Personally, I frequently use the term obstructive pattern, which I believe does not specify location or mechanism. However, I'm sure many object to this term also.



National Board for
Respiratory Care, Inc.
8310 Nieman Road
Lenexa, KS 66214-1579
Phone: 913/599-4200
Fax: 913/541-0156

CPFT Admission Requirements

1. Applicants shall be 18 years of age or older.

2. Applicants shall satisfy ONE of the following:

   a. Have a minimum of an associate degree or obtain a certificate of completion/graduation from a respiratory therapy educational program supported by the Committee on Accreditation for Respiratory Care (CoARC), or its predecessor the Joint Review Committee for Respiratory Therapy Education (JRCRTE), or accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP).

   Or

   b. Be a graduate of and obtain a certificate of completion/graduation from an approved pulmonary function technology educational program.

   Or

   c. Be a Certified Respiratory Therapist (CRT) credentialed by the NBRC.

   Or

   d. Be a Registered Respiratory Therapist (RRT) credentialed by the NBRC.

   Or

   e. Complete 62 semester hours of college credit from a college or university accredited by its regional association or its equivalent, including college credit level courses in biology, chemistry and mathematics. A minimum of six months of clinical experience* in the field of pulmonary technology under the direction of a Medical Director of a pulmonary function laboratory or a special care area is also required prior to applying for the examination.

   Or

   f. Be a high school graduate (or the equivalent) and complete two years of clinical experience* in the field of pulmonary technology under the direction of a Medical Director of a pulmonary function laboratory or a special care area prior to applying for the examination.

*Clinical experience is defined as a minimum of eight hours per week for a calendar year in pulmonary technology under the supervision of a medical director of a pulmonary function laboratory or a special care area acceptable to the Board. Clinical experience must be completed before the candidate applies for this examination.

Back to CPFT

POSITION PAPER

Responsibilities of the Medical Director of Respiratory Care Services *and* Pulmonary Physiology Laboratories

The Medical Director of Respiratory Care Services and Pulmonary Physiology Laboratories is a highly skilled and experienced physician who is trained in the care and diagnosis of respiratory diseases and who provides authoritative scientific and clinical knowledge in all aspects of respiratory care delivered in hospitals and by home care agencies.

The Medical Director promotes high ethical and professional standards in the community by his knowledge and participation in the clinical practice of respiratory medicine. His professional activities directly influence the performance of other physicians, respiratory care practitioners, pulmonary technologists and pulmonary nurses. This influence has a major impact on the quality and cost-effectiveness of respiratory care, as well as on the prevention of complications and deterioration of respiratory illnesses, and the reduction of medico-legal criticisms of physicians and hospitals.

The California Thoracic Society affirms the medical necessity of a Medical Director of Respiratory Care Services and Pulmonary Physiology Laboratories. This is in accord with national standards set by the American Thoracic Society, the American College of Chest Physicians, the National Association for the Medical Direction of Respiratory Care, and the American Association of Respiratory Care.

Respiratory care services are optimally provided within the framework of an organized respiratory care department in a licensed health care facility. When respiratory care services are provided by personnel working outside the framework of the respiratory care department, the Medical Director is responsible for assuring that services provided are uniform, cost effective, medically necessary, of acceptable quality, and in compliance with current regulations and standards. This should be accomplished by the Medical Director's participation in the various health professionals' respiratory care activities including:

A. Development of clinical protocols,
B. Quality control evaluations, and
C. Identification and implementation of standardized procedures.

The responsibilities of the Medical Director are outlined below:

1. The Medical Director is responsible for the delivery of respiratory care services and is accountable to the Medical Staff for the quality of patient care delivered by the Respiratory Care Service personnel. As a result, respiratory care practitioners (RCP) should work under the direction of a qualified Medical Director at all times in order to assure their competency and to maximize their capabilities as described in their scope of practice.

2. The Medical Director will provide 24-hour availability (including, where necessary, an appropriately qualified designee(s) to share these responsibilities or assume them in the

director's absence).

3. The Medical Director interacts directly with respiratory care personnel and promotes bedside and laboratory problem solving and guidance.

4. The Medical Director has responsibility for developing and managing patient care protocols that guide and permit independent decision-making by RCPs, such as protocols for clinical assessment, treatment, case management and discharge planning.

5. The Medical Director participates in the Performance Improvement program of the department and the hospital.

6. The Medical Director assures the quality of respiratory therapies and pulmonary physiologic testing, including blood gas analysis.

7. The Medical Director monitors and prevents misutilization of respiratory therapies and respiratory diagnostic services.

8. The Medical Director has expert knowledge of the use of respiratory care equipment and oxygen utilization in the hospital, home, and extended care facilities and advises the Medical Staff of indications and regulations regarding these services.

9. The Medical Director is responsible for the formulation and implementation of policies governing diagnostic and therapeutic procedures performed by the departmental staff, for example:

    a. Sampling arterial/venous/capillary blood for gas analysis, measuring ventilatory parameters and inspired/expired gas concentrations, measuring ventilator weaning and artificial airway parameters.

    b. Protocols for endotracheal tube and tracheostomy tube management and intubation, chest physiotherapy, ventilator management, aerosol and inhaled bronchodilator therapy.

10. The Medical Director participates in the development, evaluation and introduction of new respiratory services, equipment and procedures and also monitors current respiratory services for their continued medical usefulness.

11. The Medical Director provides continuing education in the diagnosis and treatment of lung diseases for physicians, respiratory care practitioners, pulmonary technologists, registered nurses, administrators, physical therapists, patients, and the community.

12. The Medical Director coordinates respiratory care services in the institution, for example, with Administration, the Medical Staff, Nursing, Pharmacy, Emergency Care Unit, Critical Care Units, Post-Anesthesia Recovery Room, and other personnel who might utilize such services.

13. The Medical Director provides consultation to physicians with respect to availability and appropriateness of requested respiratory care and diagnostic services.

14. A Medical Director is required for any pulmonary laboratory which performs blood gas analysis and/or pulmonary function studies. In the absence of a Medical Director of Pulmonary Physiology Laboratories the Medical Director of Respiratory Care may provide medical direction of the Pulmonary Physiologic Testing Laboratories, including blood gas analysis (cf CTS statement on ***Responsibilities of the Medical Director of Pulmonary Physiology Laboratories***).

15. The Medical Director participates in the coordination of special respiratory services for other units, which may include respiratory intensive care units, pulmonary rehabilitation program, hyperbaric oxygen unit, smoking cessation clinics, and transportation of the critically ill patient within the hospital and between hospitals.

16. The Medical Director shares responsibility with and provides medical expertise regarding respiratory care:
    a. Equipment
    b. Personnel
    c. Supplies
    d. Budget
    e. Space
    f. Infection control
    g. Policies and procedures
    h. Safety
    i. Preventive maintenance
    j. Medical gas systems
    k. Record keeping
    l. Fiscal and regulatory agencies
    m. Disaster and casualty programs
    n. Discharge planning
    o. Patient care protocols
    p. Case management

17. The Medical Director is responsible for seeing that the Respiratory Care Service is in compliance with federal and state regulations, and accrediting organizations, for example: the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and/or the College of American Pathologists (CAP).

DEVELOPED FOR THE CTS CLINICAL PRACTICE ASSEMBLY (CPA) STEERING COMMITTEE

Approved by CTS Executive Committee and ©CTS 1992, reviewed 2004

CTS guidelines are developed to enhance a physician's ability to practice evidence-based medicine, but these should not be considered a substitute for the experience and judgment of a health care provider.

CALIFORNIA THORACIC SOCIETY Medical Section of the **AMERICAN LUNG ASSOCIATION**® of California

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CONTACT YOUR LOCAL AMERICAN LUNG ASSOCIATION: CALL 1-800-LUNG-USA, or

Download ALA public and patient items at www.lungusa.org

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We welcome your comments: see CTS contact information above!

Is Your Medical Assistant Practicing Beyond His or Her Scope of Training?

The Medical Board receives numerous inquiries concerning the use of medical assistants in a physician's office. (By law, a medical assistant may not be employed for inpatient care in a licensed general acute care hospital.)

Medical assistants are unlicensed, and may *only* perform basic administrative, clerical and technical supportive services as permitted by law. An unlicensed person *may not diagnose or treat or perform any task that is invasive or requires assessment*. The responsibility for the appropriate use of unlicensed persons in healthcare delivery rests with the physician.

The classification of medical assistant is defined under the provisions of the Medical Practice Act (Business and Professions Code sections 2069-2071). The law defines a "medical assistant" as a person who may be unlicensed who performs basic administrative, clerical, and technical supportive services under the supervision of a licensed physician or podiatrist.

"An unlicensed person *may not diagnose or treat or perform any task that is invasive or requires assessment.*"

Under the law, "technical supportive services" are deemed simple, routine medical tasks and procedures that may be safely performed by a medical assistant who has limited training and who functions under the supervision of a licensed physician or podiatrist. "Supervision" is defined to require the licensed physician or podiatrist *to be physically present in the treatment facility during the performance of those procedures*.

Prior to performing technical supportive services, a medical assistant shall receive training by a licensed physician and surgeon or podiatrist or instructor in an approved school program to assure the medical assistant's competence in performing a service at the appropriate standard of care.

A medical assistant, who has completed the minimum training prescribed by regulation, may administer medication by intradermal, subcutaneous, or intramuscular injections, perform skin tests, and other technical supportive services upon the specific authorization and supervision of a licensed physician and surgeon or podiatrist.

"Specific authorization" means a specific written order prepared by the supervising physician or podiatrist authorizing the procedures to be performed on a patient, which shall be placed in the patient's medical record; or a standing order prepared by the supervising physician or podiatrist authorizing the procedures to be performed, the duration of which shall be consistent with accepted medical practice. A notation of the standing order shall be placed in the patient's medical record.

Other technical supportive services which a medical assistant may perform have been established by regulation to include: applying and removing bandages and dressings, removing sutures, performing ear lavage, preparing patients for examinations, and shaving and disinfecting treatment sites. (The regulations governing medical assistants can be found in the California Code of Regulations at sections 1366-1366.4 of Title 16, Division 13.) Medical assistants who have completed the minimum training prescribed by regulation may draw blood.

Medical assistants are *not* allowed to perform such invasive procedures as:

- placing the needle or starting and disconnecting the infusion tube of an IV.
- administering medications or injections into the IV line.
- charting the pupillary responses.
- inserting a urine catheter.
- independently performing telephone triage.
- injecting collagen.
- using lasers to remove hair, wrinkles, scars, moles or other blemishes.
- administering chemotherapy.

Medical assistants may not interpret the results of skin tests, although they may measure and describe the test reaction and make a record in the patient chart.

In summary, medical assistants are not licensed, and it is not legal to use them to replace highly trained, licensed professionals. The medical assistant is present to assist and perform support services in the physician's office.

Those duties must be appropriate with the medical assistant's required training, which cannot be compared with licensed nurses or other health professionals who meet rigorous educational and examination requirements.

PULMONARY FUNCTION TESTING SURVEY RESULTS

QUESTION 1: Do you believe this practice is beneficial or essential to the health, safety and welfare of patients?

Yes	No
26	0

QUESTION 2: Do you believe the demand for pulmonary function testing services is greater than California facilities can currently provide? If yes, please identify what you believe are contributing factors:

Yes	No	Unsure	Too few facilities	Inability to find qualified personnel	Inadequate reimbursement	Awareness of the practice has grown	Practice becoming more accepted in med community	Other
7	11	6	2	5	4	1	2	3

QUESTION 3: Considering the current climate of health care costs and reimbursement for other services, do you believe State (MediCal) and Federal (Medicare) reimbursement is fair for pulmonary function services?

Yes	No	Unsure
6	11	9

QUESTION 4: Do you believe patients are not seeking or are not able to obtain these services as a result of little or no medical reimbursement?

Yes	No	Unsure
8	12	6

QUESTION 5: What are the current costs of services provided? Please provide a range of services from those with the lowest, medium, to highest costs and indicate whether this is an amount that is expected to by paid primarily by health insurance or by a patient; if billed to Medicare and/or MediCal, please also indicate the amount reimbursed. Also, please indicate if your figures are fairly accurate or "ballpark" amounts:

Accurate	Ballpark	No Idea	Service	Amt Billed (avg)	Paid by Patient	Paid by Ins	MediCare Amt (avg)	MediCal Amt (avg)
6	10	11	Vary	$956	0	17	$222	$75
	Accurate Only							

QUESTION 6: Do you believe State regulation/certification specific to "pulmonary function technicians" would increase the cost of services?

Yes	No	Unsure
7	11	5

Comments:

More regulation, certification will require higher labor costs. A regulated/certified tech costs facilities more.

Not in acute care facilities, where licensed personnel are already available, but in physician's offices.

In actuality it would probably save time and money from having to repeat tests done by unlicensed personnel working in doctor's offices.

Lower pool of "qualified" techs = higher salary

Less technicians available to do testing will lead to few areas to obtain testing. This could lead to higher costs.

Yes, but we wouldn't see any increase.

PULMONARY FUNCTION TESTING SURVEY RESULTS

QUESTION 7: Please identify the types of locations where these services are provided and estimate the percentage each type of location is used to provide these services in California.

Stand-Alone Facilities/Labs	Facilities/Labs within Acute-Care Setting	Physicians Offices	Facilities/Labs within Home Care Co	Hotel Rooms	Other
6%	65%	27%	2%	0%	0%

QUESTION 8: Are you aware of any person providing these services independently (as opposed to working under the auspices of an organization, an employer, or a supervisor)?

Yes	No	Unsure
4	20	1

If yes, please identify where services are provided and any other factors that may be of interest.

There are dr's offices in adjacent areas from hospital that are using secretaries to do their PFTs
I am aware of RRTs performing these services in physician offices as independent contractor
Orange County and downtown Los Angeles

QUESTION 9: How many days per week do you estimate each type of provider location is open and providing services directly to patients?

Stand-Alone Facilities/Labs	Facilities/Labs within Acute-Care Setting	Physicians Offices	Facilities/Labs within Home Care Co	Hotel Rooms	Other
5.0	5.5	4.8	4.3	0.0	0.0

QUESTION 10: How many technicians (performing PFT) do you estimate are working at each type of location on any given business day? (While some location types may vary in size, please provide the number of technicians you would estimate to be working at the most commonly sized location type.)

Stand-Alone Facilities/Labs	Facilities/Labs within Acute-Care Setting	Physicians Offices	Facilities/Labs within Home Care Co	Hotel Rooms	Other
1.0	2.0	1.2	0.9	0.0	0.0

QUESTION 11: How many patients do you estimate are seen by one technician on one business day at each location type?

Stand-Alone Facilities/Labs	Facilities/Labs within Acute-Care Setting	Physicians Offices	Facilities/Labs within Home Care Co	Hotel Rooms	Other
4.8	5.7	6.4	2.3	0.0	0.0

QUESTION 12: Please provide your estimated percentage of the following patient populations who use these services in California.

Less than 3 Mo	4 mo - 2 yrs	3-12 yrs	13-19 yrs	20-39 yrs	40-59 yrs	60-79 yrs	80 yrs or older
0%	0%	6%	6%	14%	26%	38%	8%

QUESTION 13: Please identify how patients are referred for pulmonary function testing services and what is the frequency of each referral type.

Self / Walk-in	Physician	RCP	RN Practitioner	RN	LVN	MA	Other
0%	92%	1%	4%	1%	0%	0%	0%

PULMONARY FUNCTION TESTING SURVEY RESULTS

QUESTION 14: Once a patient is referred, how is initial contact made with the patient and what is the frequency for each method?

Patient contacts facility	Facility/ Lab contacts patient	Other
53%	41%	5%

Comments:

Dr's office contacts the facility and the Dr's office then contacts the patient for the appointed time and place.

QUESTION 15: Do you believe consultation is necessary prior to the date of service?

Always	Frequently	Sometimes	Rarely	Never	Unsure
10	3	2	3	4	1

Comments:

If cardiopulmonary stress testing to be done consultation is always needed.
with PCP
Primarily based on medication use and type of testing requested.
Questions over phone helpful
Usually the pt seeks their physician for symptoms of shortness of breath. Some PFTs require that the pt not smoke, eat, take medications, or drive to testing.
Should always be ordered by MD or FNP
The degree of consulting would depend on the suspicion of Pulmonary complications.
Consult follows test
Consultation by whom? Physician (PCP) specialist (pulmonary) RCP, RNP

QUESTION 16: If you believe consultation is required prior to the date of service, do you believe this is occurring at all locations where these services are rendered?

Always	Frequently	Sometimes	Rarely	Never	Unsure	N/A
2	6	5	4	0	3	2

Comments:

The patient needs a physician order/referral for PFTs and most providers make contact prior to the PFT
don't understand "consultation".
Should always be ordered by MD or FNP

QUESTION 17: If consultation is provided prior to OR on the date of service, how long are consultations and in general, what information is shared or what training is provided?

N/A	< 30 min	30-60 min	1-2 hrs	2-3 hrs	> 3 hrs
4	14	1	0	0	0

Please give a brief description of the information shared or training provided during consultations.

Stress test range 12 lead ECG, PFT results, BP & HR PFT no prior consultation needed. (??)
What to expect. H&P current medical history respiratory medications, etc.
Review of Pts med's, history, special needs. Instructions on meds, what to (?), what to expect.
Medication pt is currently on related to breathing pt instructed on holding inhaler prior to testing
No smoking for 4-8 hrs, stop respiratory meds prior to testing hrs differ depending on medication. If stress testing is performed, then appropriate dress is required.
MDI, spacer, COPD, smoking risks, occupational risks, medications
Pre test instructions you (can eat) avoid caffeine, smoking 12 hours avoid inhalers 3 hours, take all other regular meds insulin, heart meds etc. The length of the test and general knowledge of what is going to happen during the tes
A presurgical screen would be initially indicated. Preventative medicine is the key to recovery. The need to get up asap. The need to splint your cough.

PULMONARY FUNCTION TESTING SURVEY RESULTS

QUESTION 18: Please identify the estimated waiting time, from the date a patient is referred or requests service, to the date service can be provided?

< 1 Wk	1-2 Wks	2-4 Wks	1-2 Mo	2-4 Mo	4-6 Mo	6-9 Mo	9-12 Mo	1-2 Yrs	2+ Yrs
7	11	4	0	0	0	0	0	0	0

QUESTION 19: Do you know of cases where the wait time has contributed to the deterioration of a patient's health?

Yes	No	Unsure
1	18	3

If yes or unsure, please elaborate.

Delay in surgery, if results not available to MD for clearance for surgery
MD referred pt for a PFT who had ALS. Patient waited 3 wks and suffered respiratory failure at PFT

QUESTION 20: Once service(s) are provided, how do technicians (non-physician personnel) handle test results, at facilities you are aware of in California (check all that apply)?

Verbally advise patients of results	Verbally advise physician of results	Send written results to patient	Send written results to physician	Refer patient elsewhere	Other
2	5	1	21	0	3

Other Description:

Results read by MD & dictated their results sent to pulmonary MD
1st send raw data & computer interpretation to physician; 2nd send interpreted by pul doc to dr (?)
fax to Dr's office
Fax raw data to physician office; occasionally HEPA form filled out per pt rqst to get results

QUESTION 21 : Please identify private credentialing agencies that accredit lab areas or facilities specific to this practice in addition to the Joint Commission on Accreditation of Healthcare Organizations as part of acute-care facility accreditation.

Answers:

None, but PFT labs are expected to follow ATS standards.
ATS
None
JCAHO
CLIA, NBRC, HCFA
CTS in the 1990's sent a (?) to PF lab to certify the lab, but this may have stopped. ABG lab, DHS
None - that is part of the problem and why regulation is required NOW - College of American Pathologists for Blood Gas Analysis
DHS
ADA
CTS/ATS had certification. I don't know if they still have

QUESTION 22: Please identify governmental agencies that inspect and/or oversee the licensure of the lab areas specific to this practice?

Answers:

JCAHO
CAP or ATS if ABG machine in lab

PULMONARY FUNCTION TESTING SURVEY RESULTS

DHS
JCAHO
ABG lab (not PF lab); DHS in CA
None outside of JCAHO or DHS
JCAHO

QUESTION 23a: If labs (not necessarily technicians) specific to this practice were all regulated by one agency, do you believe it would bring about more awareness or confidence in these services?

Yes	No	Unsure
13	5	5

QUESTION 23b: If yes, do you think this would result in more consumers using these services?

Yes	No	Unsure
2	5	6

If no, please explain.

Patients already have confidence, and regulation would decrease access to care.
Tests are done in MD offices with minimal or no training with questionable results.
I don't see why having one agency vs. 2 or 3 would maximize(?) awareness as confidence in these services.
I don't think the public thinks about it 0 they expect that labs know what they are doing!

QUESTION 24: How many non-physician personnel would you estimate are currently practicing PFT in California?

< 500	500-1000	1001-1500	1501-2000	Other
3	11	2	4	2

Comments:

1/3 to 1/2 of RCP + unlicensed
If you include Dr's office spirometry impossible to estimate

QUESTION 25: Please estimate the percentage of each of the following types of personnel who make up the non-physician personnel identified in Question 24.

Lic RCP	Lic RNP	Lic RN	LVN	Unlicensed Personnel	Other Lic Profession	Other Lic Profession Description
55%	2%	3%	3%	1%	33%	CPFT; RPFT; Secretary

Comments:

If you include physician offices / clinics / medical groups / hospitals who perform spirometry and complete PFTs, this is my estimate.

QUESTION 26: To the best of your knowledge, of those personnel identified in Question 25 as "Unlicensed Personnel," what would you estimate are the education levels of this population?

4 years or more of college education with course of study in medical science/ technology	4 years or more of college education in an unrelated field of study	At least 2, but less than 4 years of college education with course of study in medical science/ technology	At least 2, but less than 4 years of college education in an unrelated field of study	At least 1 but less than 2 years of college education with course of study in medical science/ technology	At least 1, but less than 2 years of college education in an unrelated field of study	Less than 1 year of college education with course of study in medical science/ technology	Less than 1 year of college education in an unrelated field of study	No college education	Other
2%	2%	6%	1%	6%	1%	26%	17%	40%	0%

PULMONARY FUNCTION TESTING SURVEY RESULTS

QUESTION 27: Please identify the type(s) of credentials/certificates issued by private organizations, that you know are ***commonly*** **held by non-physician personnel currently working in this field (in addition to those already listed):**

Credential/Certificate	Organization
NONE IDENTIFIED	

QUESTION 28: Please identify all the " ***working titles*** " you are familiar with that are used in this field by non-physician personnel (check all that apply).

Unsure	PF Technologist	PF Technician	CPFT	RPFT	RCP	RN Practitioner
1	21	21	20	20	19	4

RN	LVN	EMT	Lab Asst/Aid	MA	Other
7	4	0	2	10	1

QUESTION 29: Have you heard of any case(s) where a ***patient(s) had to be retested*** as a result of personnel failing to perform a test or treatment correctly or ensuring equipment was calibrated properly?

Yes	No
15	9

If yes, please give as many details you feel comfortable providing.

Industrial tests mis-diagnosed lung disease(?) private physician referred for diagnostic tests multiple occurrences.

Referred to hospital PFT lab from physician office due to questionable results in office.

Patient went to doctor for mandatory physical, but failed PFT. Doctor didn't believe it because everything else was normal, I.e., lab work, chest x-ray, etc. PFT was done in doctor's office by unlicensed, untrained individual. Doctor sent patient to our hospital for testing by RRT. Patient passed with no problem and a normal PFT.

Noseclips were forgotten

I would only know of this if there was media attention given to it.

Equipment poorly maintained. Lack of documented calibrations.

But I am sure that this happens.

Stand alone facilities - poor calibration and pt testing; Doctors Offices - poor personnel training, poor pt testing, poor calibration.

We have had referrals to our lab D/T poor results or conducted studies from other facilities using poorly trained individuals.

As a RPFT, I have worked in a Dr's office, after working a full shift at the hospital, testing patients for surgery screens. I would get referrals from other Dr's offices where I had to retest the patient because the surgeon was questioning the data obtained by a non-licensed person.

Happens occasionally with high tech equipment in hospital EQ is very couple (??)

PCP will send pt to main hospital if they do not believe results in his/her office practice to compare.

Many, many, many times after the course of the last 15 years. Pts that were tested at the local Air Force Base medical clinic, local physicians offices and clinics and physician groups. Pts told that they had pulmonary disease and were treated as such or vice versa. I wished I had dept the documentation.

QUESTION 30: Have you heard of any case(s) where a ***patient(s) was harmed*** as a result of personnel failing to perform a test or treatment correctly or ensuring equipment was calibrated properly?

Yes	No
3	21

If yes, please give as many details you feel comfortable providing.

Have witnessed a patient hyperventilate and pass out from C02 rebreathing due to used canister of sodasorb not checked by PFT tech.

PULMONARY FUNCTION TESTING SURVEY RESULTS

I would only know of this if there was media attention given to it.

Only delay in diagnosis.

I don't know if "harmed" is correct, but I do know patients were placed on bronchodilator medication that shouldn't have been. This is due to the fact that the testing was reported as "low" or "severe" numbers, when in fact it was "poor effort".

Yes as in question 29, medications were withheld or given when a pt did or did not have a disease process that may or may not have been diagnosed with poor quality PFT testing. PFT testing in 100% pt effort dependent, and their maximum effort must be assured during testing.

QUESTION 31: Do you believe this practice, if performed by inexperienced personnel (untrained/uneducated), could result in serious patient harm or even patient death?

Yes	No	Unsure
16	6	2

If no, please explain.

I don't think death would be a normal outcome of a PFT by organ(?), but the test results would be suspect and unreliable, which might lead the physician to treat the patient inappropriately or ineffectively.

I believe it is difficult to seriously harm or cause a patient death with PFT's.

Not if results are reviewed by a qualified medical specialist (physician). This assumes procedures being performed are non-invasive. Bronchoscopy and ABG procedures can cause serious damage if performed incorrectly.

Perhaps, serious in the long run as in tx misdiagnosed, therefore, not treated correctly.

Yes, 1) cardio-pulmonary stress tests; 2) any external(?) testing; 3) bronchial challenge testing

Improper Dx & Tx

QUESTION 32: In the interest of preventing either direct or indirect patient harm, identify how much education and/or clinical experience you believe is necessary to perform with minimum competency (including the assurance of accurate test results) for each of the following levels of this practice.

MINIMUM LEVEL OF PRACTICE:

A. College-Level				
4 yrs	2 yrs	1 yr	No College	Other
0	11	9	3	0

B. Clinical Experience								
> 300 hrs	200-299 hrs	100-199 hrs	50-99 hrs	25-49 hrs	16-24 hrs	9-16 hrs	1-8 hrs	No exp
5	3	7	3	1	3	2	0	0

GENERAL LEVEL OF PRACTICE:

A. College-Level				
4 yrs	2 yrs	1 yr	No College	Other
1	19	4	0	0

B. Clinical Experience								
> 300 hrs	200-299 hrs	100-199 hrs	50-99 hrs	25-49 hrs	16-24 hrs	9-16 hrs	1-8 hrs	No exp
7	5	5	5	1	0	1	0	0

ADVANCED LEVEL OF PRACTICE:

A. College-Level				
4 yrs	2 yrs	1 yr	No College	Other
7	17	0	0	0

B. Clinical Experience								
> 300 hrs	200-299 hrs	100-199 hrs	50-99 hrs	25-49 hrs	16-24 hrs	9-16 hrs	1-8 hrs	No exp
14	2	5	2	1	0	0	0	0

PULMONARY FUNCTION TESTING SURVEY RESULTS

QUESTION 33: Please identify education or training programs that are designed specifically for pulmonary function testing (exclusive of respiratory care and cardiovascular programs).

Training/ Education Prgm	Organization/ Institution	State	Course Duration
Bio-Medical Technician			
Sensormedics program			2 days
Spirometry Review	American Thoracic Society	National	2 days
Crafton Hills College	CRTT; RRT Program	CA	
RPFT / CPFT	Kettering Seminars	OH	
UCLA	Exercise Stress Testing	CA	
Kettering Seminar F/ CPFT & RPFT	Kettering Institute	Varied	2 days
Training from manufacturer			40 hrs
CPFT & RPFT Exams			

QUESTION 34a: If technicians (non-physician personnel) specific to this practice were regulated, do you believe it would bring about more awareness or confidence in these services?

Yes	No	Unsure
17	5	2

QUESTION 34b: If yes, do you think this would result in more consumers using these services?

Yes	No	Unsure
4	8	6

If no, please explain.

It would limit access to care.
More awareness or confidence by who?
I don't believe current practices result in patient dissatisfaction
Patients don't ask if the technologist is certified - they presume they know what they are doing. If they assume anything, the patient thinks the technologist is a "nurse" or "doctor".
NIH is marketing program "know your numbers". They believe office spirometry is like taking a B/P

QUESTION 35: If technicians (non-physician personnel) specific to this practice were regulated, do you believe physicians would have more options for viable resources to perform pulmonary function testing?

Yes	No	Unsure
13	8	3

If no, please explain.

It would make it much harder to hire PFT techs.
I believe it will reduce options.
Most testing is done in physician's private practice. Most of these physicians are not willing to pay more for a "regulated" technician.
Pulmonologists perform these tests in their offices with secretaries performing testing. Regulation would lead to less options for pulmonologists.
I don't believe the resources would change. I believe the credence of the practice would increase.

QUESTION 36: If technicians (non-physician personnel) specific to this practice were regulated, do you believe it would bring about more educational/training programs?

Yes	No	Unsure
21	0	3

If no, please explain.

But the added cost would be passed on to the consumer.

PULMONARY FUNCTION TESTING SURVEY RESULTS

QUESTION 37: Given the nature of this practice, identify on a scale from 1-5 the ability for a patient's personal rights to be violated or well being to be jeopardized should a technician have a criminal history of: (5 representing highest probability)

Fraud/ Theft	Alcohol Abuse	Drug Abuse	Battery	Sexual Misconduct
3.2	3.3	3.6	3.4	3.6

SCALE
5 = Absolute possibility
4 = Significant possibility
3 = Some possibility
2 = Little possibility
1 = No possibility

Comments:

All employees should have background checks, by the hospital or hiring physician
Those exhibiting criminal behavior must undergo behavior modification/ education with reasonable assurance that repeat offenses don't occur. Quality service should be performed in a safe environment.
Tests are generally conducted in a closed room one on one w/ pts up to 2 hrs of contact for a complete PFT study. Technicians w/ histories of criminal physical & sexual abuse could put vulnerable pts at high risks.
This question is too vague. If one were in a rehab program, it could be significant. If one's abuse or theft was 10 years prior, you could consider them. Of course it depends on the gravity of the known abuse or theft!

QUESTION 38: Have you heard of any case(s) where a patient(s) alleged or was found to be the victim of:

Fraud/ Theft		Battery		Sexual Misconduct	
Yes	No	Yes	No	Yes	No
2	20	1	21	2	21

If yes, please give as many details as you feel comfortable providing.

Verbal abuse is a high possibility and is known to occur, as per patients reports to me
But only through media attention or lack of this focus.
An RT (2) acting & talking inappropriately @ pts & staff
Verbally abusive behavior has been described to me by numerous patients.
I've heard of patients missing items from their bedside desk. I would say the Glendale, "Angel of Death" committed battery!

QUESTION 39: Have you heard of any case(s) where it was suspected or found that diagnostic testing or treatment by the technician was impaired due to the technician being under the influence of alcohol and/or drugs?

Yes	No
4	20

If yes, please give as many details you feel comfortable providing.

I have fired Pulmonary Function Technologists for use of alcohol while on the job. Unimpaired judgment is required whenever working with medical patients.
But only through media attention or lack of this focus.
Just that the tech was older than dirt and became senile.
I have in the past worked with an individual who years later confessed he at times had been under the influence of drugs when testing pts. When that occurred, he felt he did not have the pts best interest as his main concern. In other words, he rushed the patient through testing just to get it over with.

QUESTION 40: What percentage of each type of employer do you believe performs a criminal background check on non-physician personnel prior to hire?

Stand-Alone Facilities/Labs	Facilities/Labs within Acute-Care Setting	Physicians Offices	Facilities/Labs within Home Care Co	Facilities/ Labs in Hotel Rooms	Other
17%	81%	11%	9%	0%	0%

PULMONARY FUNCTION TESTING SURVEY RESULTS

QUESTION 41: Are you aware of any lab that posts or distributes to patients, information on technician behaviors that constitute competent performance?

Yes	No	Unsure
2	18	3

If yes, please elaborate.

Many facilities post the NBRC credentials earned by the lab personnel

QUESTION 42: Is there a standard in the industry for advising patients of their rights to file a complaint either against an employee or the facility?

Yes	No	Unsure
9	7	7

If yes, what is this standard; where are patients referred?

Patient rights
Patient bill of rights, hotline medical
Per CMS & DHS regulations, we have it posted.
HIPPA - from the health care facilities
Hospital policy - posted in waiting rooms - referred to hospital administration.
Dept of Consumer Affairs or the Dept of Health
Patient bill of rights is posted in reception area and a P&P is written

QUESTION 43: Which of the following components of regulation (if employed to certify "pulmonary function technicians") do you believe would protect a patient's rights and prevent patient harm (check all that apply)?

Competency Testing	Formal Training	Continuing Education/ Training	Formal Education	Criminal Background Check	None	Other
20	18	19	19	20	1	1

If "none," please identify what standards or practices are in place to protect patients' personal rights and health and safety.

Standards from professional societies (ATS) and also California medical licensing
I train Respiratory Therapists and PF technologists for a living. A professional license does not guarantee competence, integrity, or patient safety. It does not protect the public from harm. It does however, limit the number of peopl who can practice, thereby increasing their worth and salaries accordingly. All of the mechanisms listed in PFT 43 would contribute to a better trained, more qualified PF technologist, but at a significant cost to both sides. Formal schooling is always preferable to OTJ training, and there is no substitute for experience. But you cannot legislate competence. If you could, there would not be any physician malpractice suits. Every day, hundreds of lawsuits are filed against incompetent "regulated" physicians. The overall responsibility for a patient's care lies on the shoulders of the patient. Programs aimed at making patients aware of the levels of training of the practitioners who are testing them, and giving patients the options of choosing who tests and treats them would go further to ensure safer, higher quality medical care. As long as testing must be ordered by a physician (not the patient) and is usually paid for by a third party insurer, patients will remain in the dark and exercise few choices. ...cont..
...cont... Regulating the technicians will not protect patients from harm anymore than regulating the physicians protects patients from harm. That does not mean technicians should not be well trained and supervised - professiona credentials are already available to those who qualify (RRT, CRT, CPFT, RPFT). The average patient (and many MDs and RNs) don't know the difference between an RCP, an RRT and a CRT.
I believe you should specify the type of testing. Many offices perform spirometry only. This is a different requirement than those who perform full studies.

State of New Jersey
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF RESPIRATORY CARE
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NOTICE OF THE BOARD OF RESPIRATORY CARE REGARDING PULMONARY FUNCTION TESTING

Performance of pulmonary function testing is within the scope of respiratory care practice pursuant to N.J.S.A. 45:14E-3 which defines respiratory care as a health care specialty including:

> ...testing techniques to assist in diagnosis, monitoring, treatment and research, including but not necessarily limited to, the measurement of cardio-respiratory volumes, pressure and flow,...

as further implemented by N.J.A.C. 13:44F-3.1, the Board of Respiratory Care rule regarding the scope of practice.

In the past, the Board of Respiratory Care has deferred enforcement of the statute regarding those individuals involved in performing such testing until full examination of the issue of the performance of pulmonary function testing could take place. After carefully examining the issues, at this time the Board has determined that as a license to practice respiratory care is required in order to perform the scope of practice of respiratory therapy, which includes pulmonary function testing, and as the Board believes that unlicensed individuals may be continuing to perform such testing under certain circumstances, and as some of these individuals have been certified and registered as pulmonary function technologists, the Board believes it is appropriate to notify the pulmonary function community that although licensure is required, the continuation of such practice will be permitted during a transition period in order to enable individuals to obtain appropriate education and successfully complete Board testing requirements. Therefore, on and after September 1, 2005, the Board will begin to take enforcement action against individuals it becomes aware are performing pulmonary function testing without a license to practice respiratory care, with the exceptions indicated below:

1) Health care providers licensed by appropriate agencies of the State of New Jersey, who are practicing under the accepted standards of the licensee's profession, will continue to be able to perform diagnostic pulmonary function testing.

2) Properly trained individuals who do not possess a license to practice respiratory care nor a license in another health care field, will continue to be able to perform "basic screening spirometry" limited to peak flow, forced vital capacity (FVC), slow vital capacity (SVC) and maximum voluntary ventilation (MVV) measurements.

June, 2002

CALIFORNIA THORACIC SOCIETY

SUPPORT FOR PATIENT ACCESS OF MEDICALLY APPROPRIATE DIAGNOSTIC TESTING BY POLYSOMNOGRAPHIC AND PULMONARY FUNCTION TECHNOLOGISTS

In order to assure quality diagnostic testing and patient safety, all polysomnographic technologists and pulmonary function technologists should conduct all patient testing under the direction and general supervision of a physician licensed in California who is knowledgeable in the performance of the diagnostic tests.

The physician's responsibilities include:

- assuring the training and/or credential requirements of the testing personnel performing the specific diagnostic tests
- assuring that the testing is performed in compliance with standards established by national professional organizations
- assuring the quality and safety of the testing performed
- performing an appropriate background check on all testing personnel
- promoting high ethical and professional standards, as well as competence of the testing personnel
- establishing protocols for all testing procedures
- developing, implementing, and monitoring performance improvement of the diagnostic test, including establishing a quality control program to assure accuracy and reliability of the test results
- assuring proper infection control procedures

The California Thoracic Society (CTS) position is that diagnostic testing performed under these circumstances assures that patients are properly and safely served, and as such does not require licensure or other forms of legal credentialing of the testing personnel.

The CTS is concerned that creating the process of licensing or other forms of legal credentialing will significantly decrease the number of available testing personnel without improving quality, and thus will be a barrier limiting patient access to appropriate diagnostic testing and care.

Developed For CTS Executive Committee. Prepared by: Paul Selecky, MD, Chair, Tom Addison, MD, David Claman, MD, Christine Garvey, FNP, MPA, MSN AE-C, Timothy A. Morris, MD, Paul Sherman, MS, RCP, RRT, RPFT

Approved by CTS Executive Committee 11/2004

PS v 10/11/04; 11/24/04
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RESPIRATORY CARE BOARD

2012-2013 Sunset Oversight Review

Response to the "Background Paper for the Respiratory Care Board" prepared by the Senate Committee on Business, Professions and Economic Development and Assembly Committee on Business, Professions and Consumer Protection

April 2013

ISSUE #1 - BREEZE IMPLEMENTATION

The Board states that all of the features and tracking mechanisms in its current multiple databases and spreadsheets are expected to be included in the new BreEZe system. The Board is included in the first phase of the rollout which was set to take place in early 2013. What is the status of The BreEZe Project?

Staff Recommendation: The Board should provide an update of anticipated timelines, existing impediments and the current status of BreEZe.

Board Response: As a result of the Consumer Protection Enforcement Initiative, the DCA relaunched its effort and was successful in acquiring the support and resources needed to establish a system that would replace the antiquated licensing and enforcement database, referred to as CAS (Consumer Affairs System), and numerous independent work-around databases.

The new BreEZe system promises to provide all applicant, license and enforcement tracking, eliminating the need for the numerous independent databases created by boards over the years. BreEZe will also provide many web-enabled processes for users, such as applying for licensure, renewing a license, and filing a complaint online. Users will also be able to monitor the status of any of these processes and make updates to their records. Currently, the Board uses a separate Cost Recovery Database, Probation Monitoring Database and complex spreadsheets to track caseloads. The Cost Recovery database also provides for automated invoicing of outstanding cost recovery, monthly probation monitoring fees, and fines as a result of citations issued. These features will be all inclusive in the new BreEZe system.

BreEZe was expected to be fully implemented throughout the Department by the end of 2013. However, after careful consideration and consultation with the California Technology Agency, the Department made the very prudent decision to push back the first release to May 2013. The Department believes it would be in the State's best interest to take all precautions, ensuring that the vendor is putting quality first. This will also push the other tentative releases out to November for Release Two and May of 2014 for Release Three. Although the project is late in its releases, the Department and the Technology Agency are working with the vendor to ensure the quality that was requested and is expected is delivered prior to acceptance and payment.

ISSUE #2 - SCHOOL APPROVALS

What is the Board's role in approving schools and RCP programs in the state? How does the Board work with the Bureau for Private Postsecondary Education to ensure student protections?

Staff Recommendation: The Board should comment on its ability to approve RCP programs with its current resources and staff that have RCP subject matter expertise. The Board should comment on its satisfaction with CoARC approval. The Board should advise the Committee on whether it would be appropriate to provide the Board with additional authority to oversee schools. The Board should provide the Committee with an update on its current working relationship with the Bureau.

Board Response: There are currently 36 approved respiratory care programs in California compared to approximately 20 since the Board was last reviewed in 2002. The Board's authority and oversight of respiratory education programs had a significant shift years ago. In the late 1990s, the oversight body specific to respiratory care programs went defunct, leaving the only oversight to accrediting agencies approved by the US Department of Education, which is generally not specific to disciplines, but rather to the school overall. At that time, the Board developed specific education criteria, including the requirement to possess an Associate Degree, and through the review of each transcript, did its best to determine if those requirements were being met.

Shortly thereafter, in about 2001, a new accrediting agency, the Committee on Accreditation for Respiratory Care, CoARC for short, was formed and assumed oversight responsibility for respiratory programs. Also, following the Board's 2002 review, the Joint Legislative Sunset Review Committee questioned the Board's authority to require an Associate Degree via regulation and recommended a number of changes. In 2002, legislation was enacted to 1) codify the requirement of an Associate Degree, 2) add a definition of approved education to include a program that held CoARC accreditation and school accreditation from an agency approved by the US Department of Education and 3) allow the Board to waive certain educational requirements to prevent roadblocks to reciprocity.

Since this time, transcript review, for the most part, has consisted of ensuring an applicant possesses a minimum of an Associate Degree and has completed an "approved" respiratory care program. The Board's law still provides that the board may "disapprove" a school, but the Board learned in more recent years, that this authority was limited, given the fact that the Board did not actually "approve" schools.

The Board has received a handful of complaints in the last ten years from students that have been referred to the CoARC and if in operation, the Bureau for Postsecondary Education (BPPE). The Board had issue with one school in particular that issued multiple transcripts to students with numerous deficiencies. The Board reviewed this school over a two year period, as a means to hold this school accountable, as the BPPE was defunct at the time.

It was during this review, that the Board was advised that it did not have the authority to actually "disapprove" this school. This paper review was a significant drain on Board resources. The Board was not equipped nor authorized to investigate the school further to determine if greater deficiencies existed. The Board will begin investigating the feasibility of it approving respiratory care programs and working with the BPPE for school and program oversight, to prevent similar roadblocks in the future.

Also, the most commonly expressed concern received from the profession, are that students are not fully competent or seasoned in their clinical practice and require additional clinical training. The Board decided

at its February 1, 2013 meeting that it will be moving forward with establishing the nationally administered more "advanced" Registered Respiratory Therapist examination as the minimum requirement for licensure; The advanced examination tests clinical competency and all current California graduates qualify to take this examination. The Board believes this measure will significantly improve the quality of education and success of our graduates.

ISSUE #3 - CONTINUING EDUCATION AUDITS

Is the Board effectively determining that licensees complete mandatory continuing education?

Staff Recommendation: The Board should report on any consequences arising from a lack of CE audits during a two year period. The Board should report on whether it has the staffing necessary for these important evaluations.

Board Response: In 2004, the Board targeted five to eight percent of its renewals to audit. However, in 2009, the Board temporarily halted its CE audit program in order to redirect resources needed to respond to numerous drills presented by the Administration at that time, as well as the Consumer Protection Enforcement Initiative (CPEI). In 2011, the Board resumed performing CE audits and was on track to audit five percent of its licensees in FY 2012-13 as reported in its Sunset Report submitted in October 2012.

CE Audits Performed					
	FY 07/08	**FY 08/09**	**FY 09/10**	**FY 10/11**	**FY 11/12**
Renewals Audited	598	315	0	0	213

However, since January 2013, the Board has been unable to perform any additional CE audits due to the lack of staff resources. There a several contributing factors to the reduction in resources, but the redirection of staff to accommodate the implementation of the BreEZe database and the more recent Administrative directive to reduce banked vacation hours are significant contributors.

The Board's auditing process is very thorough and demands sufficient and qualified resources. Records submitted by the licensee are reviewed to determine if all required information is present and required "clinical" hours of CE have been obtained. The Board's auditor will also verify many of the records received with the actual provider to verify authenticity. There are significant written and oral communications that are exchanged. Licensees who fail a CE audit are initially subject to their license being placed in an inactive status. These matters are then referred to enforcement where cases are investigated to determine if unlicensed practice has also taken place. Once a matter is investigated, if the licensee has still not produced records verifying completion of required CE (also verified by Board staff), a citation and fine will be issued.

While there are no "documented" consequences as a result of the Board's failure to perform continuing education audits from FY 09/10 through FY 10/11, clearly the intended benefit of CE is not being fully realized. Approximately 3-10% of those licensees audited fail to meet the CE requirements. Over a period of time, it is surmised there could be many licensees who miss out on opportunities that could ultimately impact patient care. The Board will be submitting another BCP this year to attempt again, to increase staffing in our licensing program.

ISSUE #4 - SUBSTANCE ABUSE RECOVERY

Have Uniform Standards been adopted?

Staff Recommendation: The Board should update the Committee on the implementation of the "Uniform Substance Abuse Standards" and whether more frequent testing is an appropriate mechanism for monitoring probationers who abuse substances. The Board should also address whether it believes the Uniform Standards are providing the intended consumer protections, for example is increased testing resulting in desired outcomes.

Board Response: SB 1441 (Statutes of 2008), created the Substance Abuse Coordination Committee (SACC) charged with developing uniform standards for each healing arts board to use in addressing substance-abusing licensees placed in diversion or on probation. The "Uniform Standards Regarding Substance-Abusing Healing Arts Licensees" were adopted in April 2011 by the SACC. The Board itself, adopted the Uniform Standards by way of revising its Disciplinary Guidelines through the regulatory process. The rulemaking process was completed on May 25, 2012, and the Board's revised Disciplinary Guidelines became effective on June 24, 2012.

During the development of the Uniform Standards, the Board began to increase the frequency of random drug testing of probationers. Prior to 2009, probationers were tested 6 to 8 times per year. This figure gradually increased and by July 2011, probationers were being tested between 36 and 104 times per year (see Table 5d in the Sunset Report for more specific data).

While the Uniform Standards were being developed, one of the caveats specific to Standard 4 concerning drug testing frequency, was to require data collection to better determine if the higher frequency and standards were effective. A computer generated model identifying the mean average days to a positive urine test considering the frequency of drug use vs. the frequency of urine testing, was referenced when developing this standard. As stated in the "Drug Testing Proposed Amendments - Rationale" **(Attachment 4 of the Sunset Report)**, "In principal, testing a licensee an average of two times per week sounds like a sound practice to detect alcohol/drug use. However, the number of days substance use is detected in the more chronic user (and therefore, in most scenarios, the greater the risk) varies much less, regardless of the frequency of testing. One could make the argument that this is evidence for more frequent testing. However, given consideration to the risk factor of a person who uses once a month or less, the importance of "randomness" in testing, and the need to find a reasonable and pragmatic approach, this solution would appear to be implausible."

As noted in the Board's Sunset Report (Table 5b. Enforcement Statistics/Extended Probation Data) the number of tests ordered has more than doubled and positive test results nearly doubled. However, closer examination of this data reveals that the number of probationers who tested positive remained unchanged from FY 2009-10 to FY 2011-12. In fact, review of the data showed the number of probationers who actually tested positive for a banned substance, eliminating those probationers with valid (and legitimate) prescriptions, actually fell from five in FY 2009-10 to four in FY 2011-12.

While this data does not take into consideration earlier detection, it does appear to present signs that more frequent testing is *not* conducive to more probationers testing positive. It is possible, that because the Respiratory Care Board does not generally place chronic substance users/abusers on probation and generally revokes or denies licensure to these individuals, that more frequent testing will not show desired results for this Board. However, the Board acknowledges that it is far too early to make any conclusions until further data is gathered.

The Board has also tracked probationers who surrendered their license in lieu of discipline separate from those who voluntarily request to surrender their license. Of its approximately 100 total probationers, six probationers voluntarily surrendered their license during FY 11/12. Four of these surrenders were a direct result of the increase in testing that jumped to 36-104 times per year in July 2011. These probationers

stated they could not afford all the costs associated with probation (e.g. Cost Recovery, Monthly Probation Monitoring Costs, Drug Testing Costs), specifically citing the costs for drug testing that could be as much as $3,500 to $7,000 the first year of probation. While these costs are not a consideration, whatsoever, in enforcing public protection, they should be taken into consideration should it be found that a more frequent testing - especially a one size fits all approach - is not increasing public protection.

Effective July 1, 2012, the Board also gained authority to issue "cease practice" notices to probationers for major violations of probation. As of March 31, 2013, the Board has issued 25 cease practice orders. Of all the efforts to develop uniform standards, the authority to "cease practice" is by far the most effective consumer protection measure, allowing the Board to immediately remove alleged dangerous practitioners from practice. It is also an incredibly efficient tool in achieving greater compliance with terms and conditions of probation for those probationers who may commit a violation that is not serious enough to warrant revocation (until a pattern is established or multiple less serious violations have occurred).

The Board plans to collect additional data over the next several years that will allow it to evaluate its program more effectively. It is expected that new ideas, approaches, and processes will eventually evolve, that will continue to improve consumer protection.

ISSUE #5 - DIFFICULTY OBTAINING LOCAL LAW ENFORCEMENT RECORDS

The Board, as well as other boards at DCA, is having problems obtaining important records from local government agencies pertaining to its licensees. What type of information is the Board having difficulty accessing? How does this potential inability to access records, such as arrest documents, impede the Board's enforcement efforts?

Staff Recommendation: Section 144.5. should be added to the Business and Professions Code as follows:

> *Notwithstanding any other provision of law, a board described in Section 144 is authorized to receive certified records from a local or state agency of all arrests and convictions, certified records regarding probation, and any and all other related documentation needed to complete an applicant or licensee investigation. The local or state agency is authorized to provide those records to the board upon receipt of such a request.*

Board Response: Over the last couple of years, the Board has come across some local law enforcement agencies that have refused to release criminal records to our Board without an "authorization to release" from the licensee, citing section 432.7 of the Labor Code. However, this issue is not isolated to just our Board. It is affecting many of the boards and bureaus under the Department of Consumer Affairs' umbrella.

It is customary for most boards and bureaus to obtain complete arrest, conviction and other-related documentation as part of an applicant or licensee investigation. Each board relies upon various authorities to retrieve documentation, and until two years ago, it was unheard of that a local government agency would refuse to release any such records to a state agency, without an authorization to release records submitted by the party in question.

It is crucial to the mission of every board and bureau of consumer safety, to be able to access all arrest, court and other related documentation through the course of an applicant or licensee investigation. Requiring an authorization to release records impedes the ability of licensing entities' to efficiently take appropriate disciplinary action or thoroughly investigate applicants. Given that a licensee is not required to provide the release, it could ultimately result in a licensing entity's inability to take disciplinary action. Furthermore, obtaining an authorization to release records, drastically slows the investigative and disciplinary processes.

The Board believes the Committee-staff suggested amendments to the general provisions of the B&P will resolve the problems. The Board believes that the language is very precise and clearly provides that boards are authorized to receive these records, regardless of any other statute, and that local law enforcement agencies will respond positively to such an amendment.

ISSUE #6 - STAFFING LEVELS CAN BE INCREASED TO BETTER MEET GOALS

The Board's fund condition shows a healthy reserve, the monies of which may need to be spent to prevent the Board from having to pursue a fee decrease or fee suspension. Boards like the Respiratory Care Board have been discouraged from submitting budget change proposals (BCPs) and those that are submitted have typically been denied. What are the Board's current staffing needs to effectively serve consumers and maintain a robust, timely licensing and enforcement program?

Staff Recommendation: The Board should state its current staffing needs and how additional positions could help the Board reduce licensing and enforcement timelines.

Board Response: Since the Board was last reviewed in 2002, it has reduced enforcement processing timelines and timelines associated with obtaining initial licensure, applications for licensure have nearly tripled, several new programs or functions have been added, and a number of other improvements have been established. The Board has made this progress over the last 12 years without any augmentations in authorized personnel.

The Board credits much of this success, to its low turnover rate and experienced staff. Of its currently 18 filled staff positions, the Board has been successful in retaining 14 of the same employees that were employed when the Board was last reviewed in 2002. Most staff members have worked in more than one program area and all have acquired very valuable skill sets. They have been instrumental in identifying weaknesses, areas where improvements can be made, and have made it possible for the Board to operate efficiently while making improvements, without augmenting staff. They have also been extremely committed and reliable - even more so over the last four years when unusual demands on our workforce have been presented. The Board believes that it has peaked in maximizing its resources and cannot sustain, let alone improve, the same production without augmenting staff.

Over the last three years, the Board has faced challenges in acquiring new personnel authority. Not only has the Board's efforts to increase staffing to pursue greater efficiencies been denied, but the most recent cuts to staffing have also placed the Board in a vulnerable position.

Budget change proposals were submitted for fiscal years 11/12 and 12/13 to improve enforcement processing times, including developing a new program where more routine legal pleadings could be prepared in-house. The Board believes this would not only significantly reduce the overall time to complete the formal discipline process for a majority of cases, but that it would also result in cost savings. The Board also submitted a BCP in 11/12 to increase licensing staffing to address increased workload. The Board submitted these BCPs for personnel authority only and would have absorbed the costs for these positions within its existing budget. Despite the fact that the board is funded entirely by special funds collected from its licensees and that it would have absorbed funding for the positions within its existing budget, all of these BCPs were denied.

In addition, last June, the Board learned it would need to reduce staffing by 1.6 personnel years, pursuant to Budget Letter 12-03. This resulted in the loss of one of the Board's two special investigator positions and reduced an existing staff person's office assistant position to less than full-time.

While the special investigator position was vacant, it was being kept in the event the Board ever lost its highly experienced retired annuitant, which unfortunately just occurred last December. The Board is currently pursuing the hire of another uniquely and highly qualified retired annuitant, however new laws and other restrictions have left uncertainty if we will be able to accomplish this. Further, the Board was advised that should the person working full-time in the reduced time base Office Assistant position ever leave, the Board would need to fill it in a part-time capacity. These reductions made last Summer, could ultimately prove to cripple many of the Board's functions.

In addition, there are several other factors that are affecting the Board's workforce. Restrictions on hiring retired annuitants and student assistants have had a substantial impact on workload. Over the last four years, staff have been subjected to various furloughs, while being asked to do more with less. Many staff have forgone vacations they would have normally taken to address Administration demands and additional workload. Meanwhile, because of the low turn over rate, the majority of the Board's staff have 20+years of state service therefore accruing vacation at a higher rate. Last month, the Board received a directive from the Administration advising the Board that it must step up its efforts to ensure staff use banked vacation in excess of the 640 hour maximum and all furlough hours.

In order to maintain processing timelines and address existing workload the Board suspects it needs 2-3 additional PYs. In order for the Board to enhance its Enforcement program, including establishing an in-house program to process routine pleadings, it will need 2-3 additional staff. So in total, the Board estimates it needs 4-6 additional personnel in order to effectively serve consumers and maintain robust and timely licensing and enforcement programs. The Board will again, be seeking additional personnel authority this year.

ISSUE #7 - PROTRACTED PROCESS TO SUSPEND RCP LICENSE

The Board must go through a cumbersome process to suspend the license of a RCP who may pose an immediate threat to patients or who have committed a serious crime and may even be incarcerated. What are the Board's proposed efforts to reduce ISO timelines?

Staff Recommendation: The Board should seek to extend the timeframe placed on the AG to file an accusation. This will allow the AG to utilize the ISO process without being subject to the currently limited timeframe.

Board Response: For several years, the Board has pursued avenues that would allow it to immediately suspend a license upon learning of an arrest related to sexual misconduct or serious bodily harm. Licensed RCPs who are arrested or convicted for malicious and egregious crimes such as lewd and lascivious acts against a child under 14, possession of child pornography, and attempted murder, to name a few, are permitted to continue practicing while waiting for their case to be adjudicated. RCPs work in many settings, including homes and children's hospitals, and with all types of vulnerable patients, including children and the elderly. In most cases, those RCPs who have been arrested for malicious and egregious crimes can continue to work for weeks, months, even years, all the while with no public notice, placing the public health, welfare, and safety at immediate and significant risk. As discussed in greater detail in the Board's Sunset Report, the current processes to obtain a suspension, prevents early public disclosure and includes several barriers to secure a suspension swiftly.

Combining the proposed alternatives that were presented in the Board's Sunset Report with the "Staff Recommendation" above, the Board is proposing the following language that authorizes the Board to extend the timeframe to file an Accusation and lower the evidence threshold for matters adjudicated through the Interim Suspension Order (ISO) process, as well as have the authority to share arrest information with the public. This alternative would allow the Board to use the existing framework of the ISO process with the exception of reducing the level of proof for the ISO process from a "preponderance of evidence" to "substantial evidence." The "clear and convincing" standard would continue to apply to the matter concerning the Accusation to Revoke the license. However, instead of having to file an Accusation within 30 days, the Board would be afforded sufficient time to gather evidence needed to meet the "clear and convincing" standard of proof and prevent an estoppel effect.

Section 3769.7 is added to the Business and Professions Code to read:

3769.7. Public information; arrests

The board may inform all known employers, potential employers and the public and post on the Internet any information concerning an arrest of any applicant or licensee for a period of up to 60 days after any criminal matter has been adjudicated and all appeals have been exhausted or the time to appeal has elapsed. The board shall ensure it possesses certified copies of an arrest report or charging documents prior to making any such information available for public display.

Section 3753 of the Business and Professions Code is amended to read:

§ 3753. Application of provisions of Administrative Procedure Act

(a) The procedure in all matters and proceedings relating to the denial, suspension, or revocation of licenses under this chapter shall be governed by the provisions of the Administrative Procedure Act (Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).

(b) Notwithstanding Ettinger v Board of Medical Quality Assurance, Department of Consumer Affairs (1982) 135 Cal.App.3d 853, and section 494 of this code, the standard of proof applied in all proceedings requesting an Interim Suspension Order shall be by some credible evidence.

(c) Notwithstanding section 494 of this code, in all proceedings concerning an Interim Suspension Order, an accusation shall be filed within 60 days from the date an interim suspension is ordered or if the interim suspension order is issued based on an act that results in the filing of criminal charges, within 150 days after all criminal matters are adjudicated, all rights to an appeal are exhausted or all time periods to appeal have lapsed, whichever is greater.

ISSUE #8 - LACK OF CLARITY IN DEFINITION OF UNPROFESSIONAL CONDUCT MAY DELAY ENFORCEMENT

The Board is concerned that a lack of definition for unprofessional conduct in the RCPA may be impacting its ability to take necessary action against RCPs.

Staff Recommendation: The Board should consider pursuing legislation that will help clarify the definition of unprofessional conduct and specify the Board's ability to follow through with administrative suspension and discipline.

Board Response: The Board has encountered barriers within its existing statutory framework in pursuing discipline for acts of unprofessional conduct or the commission of crimes that may not result in a conviction. Many DAGs believe the Board's existing codes do not allow it to pursue administrative suspension or discipline for some sexually related crimes, unless there is a conviction.

Sections 3752.5 and 3752.6 clearly show sexual misconduct and attempted bodily injury cases are substantially related to the practice. However, the authority to take action is limited to either §3750(d), conviction of a crime; §3750(j), a corrupt act; or §3755, unprofessional conduct. Absent a criminal conviction, some DAGs have been reluctant to take action solely based on §3750(j) and §3755 because the language is too broad. One example cited was that the term "corrupt" has never been defined by the courts.

The Board has also received two complaints involving serious allegations of sexual harassment (that did not result in an arrest) and has since found that it has no basis to pursue disciplinary action in these types of cases. The Board is also concerned with other behaviors of "unprofessional conduct" at the workplace, that warrant discipline, but are currently not covered by the RCPA.

The Board is seeking to:

- Substantially relate "acts" (not just convictions) for all egregious crimes and sexual misconduct violations.
- Expand the definition of "unprofessional conduct" to include inappropriate behavior in a care setting;

The Board would also like to seek legislative remedies to:

- Substantially relate any crime against a child, dependent adult, or the elderly; and
- Ensure the Board continues to maintain jurisdiction in disciplinary matters that are finalized after a license has cancelled.

The proposed language:

- Amends §3750 to add that "Commission of any crime substantially related to the qualifications, functions, duties or practice of an RCP or the respiratory care practice" and "Commission of any act in violation of any provision of Division 2" are grounds to deny, suspend, revoke or impose probationary terms and conditions upon a license.
- Adds §3752.3 to make the commission of a crime involving a minor, any person under 18 years of age, substantially related to the qualifications, functions or duties of an RCP.
- Adds §3752.4 to make the commission of a crime involving an elder, any person 65 years of age or older, or dependent adult, as described in Section 368 of the Penal Code, substantially related to the qualifications, functions, or duties of an RCP.
- Amends §3752.7 to provide clarity of sexually related crimes that are grounds for revocation.
- Adds §3754.8 to give the board continuing jurisdiction of a disciplinary matter despite the expiration or cancellation of a license.
- Amends §3755 to include inappropriate behavior, including but not limited to, verbally or physically abusive behavior, sexual harassment, or any other behavior that is inappropriate for any care setting.

§ 3750. Causes for denial of, suspension of, revocation of, or probationary conditions upon license

The board may order the denial, suspension, or revocation of, or the imposition of probationary conditions upon, a license issued under this chapter, for any of the following causes:

(a) Advertising in violation of Section 651 or Section 17500.

(b) Fraud in the procurement of any license under this chapter.

(c) Knowingly employing unlicensed persons who present themselves as licensed respiratory care practitioners.

(d) Conviction of a crime that substantially relates to the qualifications, functions, or duties of a respiratory care practitioner. The record of conviction or a certified copy thereof shall be conclusive evidence of the conviction.

(e) Impersonating or acting as a proxy for an applicant in any examination given under this chapter.

(f) Negligence in his or her practice as a respiratory care practitioner.

(g) Conviction of a violation of any of the provisions of this chapter or of any provision of Division 2 (commencing with Section 500), or violating, or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate any provision or term of this chapter or of any provision of Division 2 (commencing with Section 500).

(h) The aiding or abetting of any person to violate this chapter or any regulations duly adopted under this chapter.

(i The aiding or abetting of any person to engage in the unlawful practice of respiratory care.

(j) The commission of any fraudulent, dishonest, or corrupt act which is substantially related to the qualifications, functions, or duties of a respiratory care practitioner.

(k) Falsifying, or making grossly incorrect, grossly inconsistent, or unintelligible entries in any patient, hospital, or other record.

(l) Changing the prescription of a physician and surgeon, or falsifying verbal or written orders for treatment or a diagnostic regime received, whether or not that action resulted in actual patient harm.

(m) Denial, suspension, or revocation of any license to practice by another agency, state, or territory of the United States for any act or omission that would constitute grounds for the denial, suspension, or revocation of a license in this state.

(n) Except for good cause, the knowing failure to protect patients by failing to follow infection control guidelines of the board, thereby risking transmission of blood-borne infectious diseases from licensee to patient, from patient to patient, and from patient to licensee. In administering this subdivision, the board shall consider referencing the standards, regulations, and guidelines of the State Department of Health Services developed pursuant to Section 1250.11 of the Health and Safety Code and the standards, regulations, and guidelines pursuant to the California Occupational Safety and Health Act of 1973 (Part 1 (commencing with Section 6300) of Division 5 of the Labor Code) for preventing the transmission of HIV, hepatitis B, and other blood-borne pathogens in health care settings. As necessary, the board shall consult with the California Medical Board, the Board of Podiatric Medicine, the Board of Dental Examiners, the Board of Registered Nursing, and the Board of Vocational Nursing and Psychiatric Technicians, to encourage appropriate consistency in the implementation of this subdivision. The board shall seek to ensure that licensees are informed of the responsibility of licensees and others to follow

infection control guidelines, and of the most recent scientifically recognized safeguards for minimizing the risk of transmission of blood-borne infectious diseases.

(o) Incompetence in his or her practice as a respiratory care practitioner.

(p) A pattern of substandard care or negligence in his or her practice as a respiratory care practitioner, or in any capacity as a health care worker, consultant, supervisor, manager or health facility owner, or as a party responsible for the care of another.

(q) Commission of any crime substantially related to the qualifications, functions, duties or practice of a respiratory care practitioner or the respiratory care practice.

(r) Commission or the attempted commission of any act in violation of any provision of Division 2, including, but not limited to, any act that if convicted, would be grounds for discipline.

Added Stats 1982 ch 1344 § 1, operative July 1, 1983. Amended Stats 1987 ch 839 § 6; Stats 1991 ch 654 § 25 (AB 1893); Stats 1992 ch 1289 § 28 (AB 2743), ch 1350 § 7.5 (SB 1813); Stats 1993 ch 589 § 8 (AB 2211); Stats 1994 ch 1274 § 16 (SB 2039); Stats 1997 ch 759 § 27 (SB 827). Amended Stats 1998 ch 553 § 3 (AB 123). Amended Stats 2003 ch 586 § 11 (AB 1777). [NOTE: The change to subdivision (p) is language included in SB 1575 submitted this year]

§ 3752.3. Crime involving a minor

For purposes of Division 1.5 (commencing with Section 475) and this chapter, the commission of a crime involving a minor, any person under 18 years of age, whether or not the child was a patient, shall be considered a crime substantially related to the qualifications, functions or duties of a respiratory care practitioner.

§ 3752.4. Crime involving an elder/dependent adult

For purposes of Division 1.5 (commencing with Section 475) and this chapter, the commission of a crime involving an elder, any person 65 years of age or older, or any dependent adult, as described in subdivision (a) of section 368 of the Penal Code, whether or not the elder or dependent adult was a patient, shall be considered a crime substantially related to the qualifications, functions or duties of a respiratory care practitioner.

3752.7. Sexual contact with patient; Conviction of sexual offense; Revocation

Notwithstanding Section 3750, any proposed decision or decision issued under this chapter in accordance with the procedures set forth in Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, that contains any finding of fact that the licensee or registrant engaged in or attempted to engage in, any act of sexual contact, as defined in Section 729, with a patient, or has committed, or attempted to commit an act or been convicted of a sex offense as defined in Section 44010 of the Education Code, or Section 290 of the Penal Code, shall contain an order of revocation. The revocation shall not be stayed by the administrative law judge. For purposes of this section, the patient shall no longer be considered a patient of the respiratory care practitioner when the order for respiratory procedures is terminated, discontinued, or not renewed by the prescribing physician and surgeon.

3754.8. The expiration, cancellation, forfeiture, or suspension of a license, practice privilege, or other authority to practice respiratory care by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of or action or disciplinary proceeding against the licensee, or to render a decision suspending or revoking the license.

§ 3755. Action for unprofessional conduct

The board may take action against any respiratory care practitioner who is charged with unprofessional conduct in administering, or attempting to administer, direct or indirect respiratory care or in any care setting. Unprofessional conduct includes, but is not limited to, ~~repeated~~ any acts of clearly administering directly or indirectly inappropriate or unsafe respiratory care procedures, protocols, therapeutic regimens, or diagnostic testing or monitoring techniques, inappropriate behavior, including but not limited to, verbally or physically abusive behavior, sexual harassment, infliction of pain, humiliation, intimidation, ridicule, coercion, threat, mental abuse, or any other conduct which is inimical to the health, morals, welfare, or safety, whether or not the victim is a patient, a patient friend or family member or employee, and violation of any provision of Section 3750. The board may determine unprofessional conduct involving any and all aspects of respiratory care performed by anyone licensed as a respiratory care practitioner. Any person who engages in repeated acts of unprofessional conduct shall be guilty of a misdemeanor and shall be punished by a fine of not more than one thousand dollars ($1,000), or by imprisonment for a term not to exceed six months, or by both that fine and imprisonment.

Added Stats 1986 ch 1347 § 3. Amended Stats 1988 ch 1396 § 3, effective September 26, 1988; Stats 1990 ch 1072 § 3 (AB 3256); Stats 1991 ch 654 § 31 (AB 1893); Stats 1992 ch 1289 § 31 (AB 2743); Stats 1994 ch 1274 § 22 (SB 2039).

ISSUE #9 - INCREASED DEMAND FOR RCPs WITH AFFORDABLE CARE ACT IMPLEMENTATION AND AGING CALIFORNIANS NEEDING RESPIRATORY SERVICES

How will the Board meet increased demand for RCPs? What trends has the Board noticed in its licensing numbers? Is the Board prepared for an increase in the potential number of applicants and licensees?

Staff Recommendation: The Board should explain what additional efforts it can take or models it can follow to increase the RCP workforce and ensure participation of its licensees in the state's health care delivery system.

Board Response: In 2006, the Board contracted the services of the Institute for Social Research of the California State University, Sacramento to conduct a study to forecast the State's RCP workforce needs. The Study was completed in 2007 and found "the potential for a 'perfect storm' scenario driven by a constellation of factors that would create serious shortages of RCPs available to meet the needs of the California population in the coming decades." Key factors identified were:

- The age distribution of the current RCP workforce, suggesting a large group about to leave the workforce through retirement;
- Indication that a significant portion of those in education programs, about to enter the profession, is comprised of older individuals returning to school, which will result in shorter career spans for individuals entering the profession as new licensees; and
- A growing California population and within California's growing population, a disproportionately larger number of 65 and older individuals who consume an especially large portion of available respiratory care services.

The workforce study was prepared prior to the Affordable Care Act and therefore, no consideration was given to the workforce demands that the Act will present.

At the time the study was completed, the Board had approximately 15,000 active licensees. The Study projected that the Board would need:

16,665 licensees by 2015;
18,000 by 2020;
19,000 by 2025; and
21,000 by the year 2030.

The Board currently has over 20,000 active licensees, and expects to be at the Study's projected growth needs for the year 2030 within the next 12 months.

The number of active licensees has grown significantly and is largely attributed to new applications for licensure. Since the Board was last reviewed in 2002, the number of applications received each year has nearly tripled from approximately 600 applications received in 2002 to nearly 1,600 applications received last fiscal year.

There are a number of efforts that may have contributed to this jump including:

1) The US Department of Labor's publication of the RCP shortage as found in the Board's 2007 Workforce Study;
2) The number of education programs increasing from 25 in 2005 to 36 in 2012;
3) Significant outreach conducted by the Board including attendance at numerous high school fairs and career search events in 2006 and 2007. And of course, many of our education programs have and continue to attend various career fairs as well; and
4) In 2009, the Board developed a media kit which included new brochures, a DVD that the Board developed, and posters and give aways that pointed them to a new website the Board created to recruit new students into RCP education programs. The Board was able to distribute approximately 370 of these media kits to high schools throughout California, concentrating on those geographical areas with greater need.

However, the Board's Marketing Plan that had just been put into motion in 2009, was halted as a result of various administrative directives, before the board could complete many of the strategies it had outlined.

The Board does not anticipate additional spikes in applicants anytime in the near future. The Board generally receives notice of a new education program opening between 12 and 24 months in advance of the first graduating class. Therefore, the Board does have a small window of opportunity to request additional resources if needed.

In regard to the Affordable Care Act, the Board believes California's Respiratory Care Practitioners play a key role in filling the workforce gap to meet the demand of an estimated 4-7 million more California consumers who will be seeking care. Moreover, the Board believes that moving toward a Physician-led "team" approach in delivering care would now allow all patients to receive the expertise offered by RCPs, in treating ailments affecting the pulmonary and associated aspects of the cardiopulmonary systems. Millions of people, many of whom are baby boomers, suffer from COPD and would now have access to providers specializing in this area, with the team approach. Not to mention, the millions of people who are treated for other respiratory ailments or trauma victims who rely on artificial ventilation.

The RCP scope of practice does create somewhat of a barrier for allowing RCPs to practice to their full scope of practice. Approximately 1/3 of RCPs hold a baccalaureate degree or higher and the Board believes these practitioners, as well as some others, are highly qualified to be direct providers. The Board is currently working toward proposals to provide RCPs greater authority to write orders, as well as a number of other proposals that will still fall within their speciality and their scope of practice, yet provide better care and greater access.

As one of the three most common bedside practitioners, who can improve outcomes and reduce costs pursuant to evidence-based research, the Board intends to keep RCPs on the radar as reform takes place to fully implement the Affordable Care Act as intended.

ISSUE #10 - POLYSOMNOGRAPHY TECHNICIAN REGULATION

The Board took efforts over a number of years to license technicians working in sleep laboratories. What is the Board's impression of regulation by the Medical Board of California of polysomnography technicians? Does the Board still get complaints about these individuals? How do the two boards interact to promote consumer protection for individuals receiving services at sleep labs?

Staff Recommendation: The Board should outline its view on the current registration and regulation of those who engage in the practice of polysomnography, including any continuing problems and ideas for more robust consumer protections if applicable.

Board Response: Legislation (SB 132) enacted in 2009 established the regulation of polysomnography personnel by the Medical Board of California (MBC). Between the enactment of this legislation and the time the MBC actually began "registering" trainees, technicians and technologists in April 2012, the MBC developed regulations necessary to successfully implement the regulatory program. Since then, the MBC has registered near 300 polysomnography personnel. The Board's interaction with the MBC in this regard has been limited to providing comments on proposed regulations and referring approximately five complaints a year to the MBC.

However, following legislation requiring polysomnography technicians to be registered with the Medical Board, the California Department of Public Health (CDPH) issued a directive requiring registered nurses (RNs) to oversee these personnel, which created a major shift in the current practice. In April 2010, the CDPH issued an "All Facilities Letter (AFL)" that, in brief, provided that an RN must provide patient assessments and be responsible for the nursing service in outpatient facilities. This directive only applied to those sleep centers associated with a licensed acute care hospital as the CDPH has no oversight of free-standing facilities (where greater concerns exist). The Board (and members of the respiratory care community) met with CDPH representatives on several occasions, to educate them on the existing practice in sleep labs, the respiratory care practice (many RCPs work in sleep labs), and the unnecessary costs that were being assumed by these hospitals. In 2011, with newly appointed CDPH staff (including RNs), the AFL was modified to correctly provide guidance for necessary oversight and eliminated unnecessary RN staffing and those associated costs.

As this profession evolves, the Board hopes that, in the interest of strengthening consumer protection, the definition of "Approved polysomnographic education program" as found in Section 1379.40 of Chapter 4.3 of Title 16 of the California Code of Regulations (CCR) will be modified to only include formal bona fide education programs accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP) or by the Commission on Accreditation for Respiratory Care (CoARC). Currently, this section also recognizes programs accredited by the American Academy of Sleep Medicine (AASM) and the Board of Registered Polysomnographic Technologists (BRPT). When the Board reviewed these programs prior to the implementation of this program, these educational programs consisted primarily of on-the-job training programs and were not recognized by the US Department of Education. Further, the Board believes it is in the best interest of consumers that the education component be separate from the organization offering the professional credential (BRPT), as well as the organization that is highly vested in representing physicians' interests and advocating for recognition of the profession (AASM).

ISSUE #11 - CONTINUED REGULATION BY RESPIRATORY CARE BOARD

Should the licensing and regulation of respiratory care therapists be continued and be regulated by the current Board membership?

Staff Recommendation: Recommend that the respiratory care professional profession continue to be regulated by the current Board members in order to protect the interests of the public and be reviewed once again in four years.

Board Response: The Board is firmly committed to its mandate and continually strives to increase consumer protection in the most efficient manner through its licensing and enforcement programs. The Board concurs with this recommendation that the Respiratory Care Board of California regulation of RCPs should be extended.

2013 LEGISLATION OF INTEREST

AB 186	Author:	Maienschein [R]
	Title:	Professions and vocations: military spouses; temporary licenses.
	Last Amended:	4/1/13
	Status:	**4/2/13: Re-referred to Committee on Business, Professions, and Consumer Protection**
	Summary:	Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law provides for the issuance of reciprocal licenses in certain fields where the applicant, among other requirements, has a license to practice within that field in another jurisdiction, as specified. Existing law requires a board within the department to expedite the licensure process for an applicant who holds a current license in another jurisdiction in the same profession or vocation and who supplies satisfactory evidence of being married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in California under official active duty military orders. This bill would authorize a board within the department to issue a provisional license to an applicant who qualifies for an expedited license pursuant to the above-described provision. The bill would prohibit a provisional license from being provided to any applicant who has committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license at the time the act was committed, or has been disciplined by a licensing entity in another jurisdiction, or is the subject of an unresolved complaint, review procedure, or disciplinary proceeding conducted by a licensing entity in another jurisdiction. The bill would require the board to approve a provisional license based on an application that includes an affidavit that the information submitted in the application is accurate and that verification documentation from the other jurisdiction has been requested. The bill would require the provisional license to expire after 18 months or at the issuance of the expedited license.
	Staff Recommended Position	**WATCH**

AB 258	Author:	Chavez [R]
	Title:	State agencies: veterans.
	Last Amended:	N/A
	Status:	**4/4/13: Re-referred to Committee on Appropriations**
	Summary:	Existing law provides for the governance and regulation of state agencies, as defined. Existing law provides certain benefits and protections for members of the Armed Forces of the United States. This bill would require every state agency that requests on any written form or written publication, or through its Internet Web site, whether a person is a veteran, to request that information in a specified manner.
	Staff Recommended Position	**WATCH**

AB 291	Author:	Nestande [R]
	Title:	California Sunset Review Commission.
	Last Amended:	N/A
	Status:	**4/15/13: In committee (double referred to Committee on Accountability and Administrative Review and the Committee on Business, Professions, and Consumer Protection). Set, first hearing. Hearing canceled at the request of author.**
	Summary:	Existing law establishes the Joint Sunset Review Committee, a legislative committee comprised of 10 Members of the Legislature, to identify and eliminate waste, duplication, and inefficiency in government agencies and to conduct a comprehensive analysis of every "eligible agency" for which a date for repeal has been established, to determine if the agency is still necessary and cost effective. Existing law requires each eligible agency scheduled for repeal to submit a report to the committee containing specified information. Existing law requires the committee to take public testimony and evaluate the eligible agency prior to the date the agency is scheduled to be repealed, and requires that an eligible agency be eliminated unless the Legislature enacts a law to extend, consolidate, or reorganize the agency. Existing law also requires the committee to review eligible agencies and evaluate and determine whether each has demonstrated a public need for its continued existence and to submit a report to the Legislature detailing whether an agency should be terminated, continued, or whether its functions should be modified. This bill would abolish the Joint Sunset Review Committee on January 1 or an unspecified year. The bill would, commencing on that same January 1, establish the California Sunset Review Commission within the executive branch to assess the continuing need for any agency, as defined, to exist. The commission would consist of 10 members, with 8 members appointed by the Governor and 2 Members of the Legislature each appointed by the Senate Committee on Rules and the Speaker of the Assembly, subject to specified terms. The commission would be under the direction of a director appointed by the commission members. The bill would require the commission to meet regularly and to work with each agency subject to review to evaluate the need for the agency to exist, identify required statutory, regulatory, or management changes, and develop legislative proposals to enact those changes. The bill would require the commission to prepare a report, containing legislative recommendations based on its agency review, to be submitted to the Legislature and would also require the commission to meet certain cost-savings standards within 5 years. This bill would require an agency to submit a specified self-evaluation report to the commission prior to its review. The bill would require the Legislative Analyst's Office to provide the commission with an estimate of the staffing needed to perform the commission's work.
	Staff Recommended Position	**WATCH**

AB 512	Author:	Rendon [D]
	Title:	Healing arts: licensure exemption.
	Last Amended:	N/A
	Status:	**4/17/13: Passed by Committee on Appropriations**
	Summary:	Existing law provides for the licensure and regulation of various healing arts practitioners by boards within the Department of Consumer Affairs. Existing law provides an exemption from these requirements for a health care practitioner licensed in another state who offers or provides health care for which he or she is licensed during a state of emergency, as defined, and upon request of the Director of the Emergency Medical Services Authority, as specified. Existing law provides, until January 1, 2014, an exemption from the licensure and regulation requirements for a health care practitioner, as defined, licensed or certified in good standing in another state or states, who offers or provides health care services for which he or she is licensed or certified through a sponsored event, as defined, (1) to uninsured or underinsured persons, (2) on a short-term voluntary basis, (3) in association with a sponsoring entity that registers with the applicable healing arts board, as defined, and provides specified information to the county health department of the county in which the health care services will be provided, and (4) without charge to the recipient or a 3rd party on behalf of the recipient, as specified. Existing law also requires an exempt health care practitioner to obtain prior authorization to provide these services from the applicable licensing board, as defined, and to satisfy other specified requirements, including payment of a fee as determined by the applicable licensing board. This bill would delete the January 1, 2014, date of repeal, and instead allow the exemption to operate until January 1, 2018.
	Staff Recommended Position	**WATCH**

AB 809	Author:	Logue [R]
	Title:	Healing arts: telehealth.
	Last Amended:	4/3/13
	Status:	**4/9/13: In committee (Health): Set, first hearing. Hearing canceled at the request of author.**
	Summary:	Existing law requires a health care provider, as defined, prior to the delivery of health care services via telehealth, as defined, to verbally inform the patient that telehealth may be used and obtain verbal consent from the patient for this use. Existing law also provides that failure to comply with this requirement constitutes unprofessional conduct. This bill would instead require the health care provider at the originating site to provide the patient with a waiver for the course of treatment involving telehealth services to obtain informed consent for the agreed upon course of treatment. The bill would require the signed waiver to be contained in the patient's medical record. The bill would make additional conforming changes. This bill would declare that it is to take effect immediately as an urgency statute.
	Staff Recommended Position:	**WATCH**

AB 1013	Author:	Gomez [D]
	Title:	Consumer affairs.
	Last Amended:	N/A
	Status:	**3/7/13: Referred to Committee on Business, Professions, and Consumer Protection.**
	Summary:	Under existing law, the Department of Consumer Affairs is comprised of boards that license and regulate various professions and vocations. Existing law provides that these boards are established to ensure that private businesses and professions are regulated to protect the people of this state. Existing law authorizes the director or the Attorney General to intervene in a matter or proceeding pending before any state commission, regulatory agency, department, or agency, or any court, which the director finds may affect substantially the interests of consumers within California, in any appropriate manner to represent the interests of consumers. Existing law also authorizes the director, or any officer or employee designated by the director for that purpose, or the Attorney General to thereafter present evidence and argument to the agency, court of department, as specified, for the effective protection of the interests of consumers. This bill would additionally authorize any employee designated by the Attorney General to make those presentations.
	Staff Recommended Position:	**WATCH**

AB 1057	Author:	Medina [D]
	Title:	Professions and vocations: licenses: military service.
	Last Amended:	4/9/13
	Status:	**4/17/13: From Committee on Appropriations: Do pass. To consent calendar.**
	Summary:	Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law authorizes a licensee or registrant whose license expired while the licensee or registrant was on active duty as a member of the California National Guard or the United States Armed Forces to, upon application, reinstate his or her license without penalty and without examination, if certain requirements are satisfied, unless the licensing agency determines that the applicant has not actively engaged in the practice of his or her profession while on active duty, as specified. This bill would require each board, commencing January 1, 2015, to inquire in every application for licensure if the applicant is serving in, or has previously served in, the military.
	Staff Recommended Position:	**WATCH**

SB 305	Author:	Price [D]
	Title:	Healing arts: boards. **[RCB SUNSET EXTENSION BILL]**
	Last Amended:	4/15/13
	Status:	**4/15/13: Re-referred to Committee on Business, Professions, and Economic Development**
	Summary:	Existing law, the Optometry Practice Act, provides for the licensure and regulation of optometrists by the State Board of Optometry. The Respiratory Care Act provides for the licensure and regulation of respiratory care practitioners by the Respiratory Care Board of California. Each of those acts authorizes the board to employ an executive officer. Existing law repeals these provisions on January 1, 2014 and subjects the boards to review by the Joint Committee on Boards, Commissions, and Consumer Protection. This bill would extend the operation of these provisions until **January 1, 2018**, and provide that the repeal of these provisions subjects the boards to review by the appropriate policy committees of the Legislature. The Respiratory Care Act also prohibits a person from engaging in the practice of respiratory care unless he or she is a licensed respiratory care practitioner. However, the act does not prohibit specified acts, including, among others, the performance of respiratory care services in case of an emergency or self-care by a patient. This bill would additionally authorize the performance of pulmonary function testing by persons who are currently employed by Los Angeles county hospitals and have performed pulmonary function testing for at least 15 years. This bill would make legislative findings and declarations as to the necessity of a special statute for the persons described above. Existing law requires specified regulatory boards within the Department of Consumer Affairs to require an applicant for licensure to furnish to the board a full set of fingerprints in order to conduct a criminal history record check. This bill would additionally authorize those boards to request and receive from a local or state agency certified records of all arrests and convictions, certified records regarding probation, and any and all other related documentation needed to complete an applicant or licensee investigation and would authorize a local or state agency to provide those records to the board upon request.
	Staff Recommended Position:	**SUPPORT**

SB 690	Author:	Price [D]
	Title:	Licenses.
	Last Amended:	N/A
	Status:	**3/11/13: Referred to Committee on Rules**
	Summary:	Existing law provides for the licensing of various professions and vocations by boards within the Department of Consumer Affairs. Existing law defines license to mean a license, certificate, registration, or other means to engage in a business or profession, as provided. This bill would expand the definition of license to include a permit.
	Staff Recommended Position:	**WATCH**

AMENDED IN ASSEMBLY APRIL 1, 2013

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL No. 186

Introduced by Assembly Member Maienschein
(Principal coauthor: Assembly Member Hagman)
(Coauthors: Assembly Members Dahle, Donnelly, Beth Gaines, Harkey, Olsen, and Patterson)
(Coauthors: Senators Fuller and Huff)

January 28, 2013

An act to amend Section 115.5 of the Business and Professions Code, relating to professions and vocations, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 186, as amended, Maienschein. Professions and vocations: military spouses: temporary licenses.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law provides for the issuance of reciprocal licenses in certain fields where the applicant, among other requirements, has a license to practice within that field in another jurisdiction, as specified. ~~Under existing law, licensing fees imposed by certain boards within the department are deposited in funds that are continuously appropriated.~~ Existing law requires a board within the department to expedite the licensure process for an applicant who holds a current license in another jurisdiction in the same profession or vocation and who supplies satisfactory evidence of being married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces

of the United States who is assigned to a duty station in California under official active duty military orders.

This bill would authorize a board within the department to issue a provisional license to an applicant who qualifies for an expedited license pursuant to the above-described provision. *The bill would prohibit a provisional license from being provided to any applicant who has committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license at the time the act was committed, or has been disciplined by a licensing entity in another jurisdiction, or is the subject of an unresolved complaint, review procedure, or disciplinary proceeding conducted by a licensing entity in another jurisdiction. The bill would require the board to approve a provisional license based on an application that includes an affidavit that the information submitted in the application is accurate and that verification documentation from the other jurisdiction has been requested.* The bill would require the provisional license to expire after 18 months *or at the issuance of the expedited license*.

By creating provisional licenses for which a fee may be collected and deposited into a continuously appropriated fund, this bill would make an appropriation.

Vote: majority. Appropriation: yes. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 115.5 of the Business and Professions
2 Code is amended to read:
3 115.5. (a) A board within the department shall expedite the
4 licensure process for an applicant who meets both of the following
5 requirements:
6 (1) Supplies evidence satisfactory to the board that the applicant
7 is married to, or in a domestic partnership or other legal union
8 with, an active duty member of the Armed Forces of the United
9 States who is assigned to a duty station in this state under official
10 active duty military orders.
11 (2) Holds a current license in another state, district, or territory
12 of the United States in the profession or vocation for which he or
13 she seeks a license from the board.
14 (b) *(1)* For each applicant who is eligible for an expedited
15 license pursuant to subdivision (a) *and meets the requirements in*

paragraph (2), the board ~~may~~ *shall* provide a provisional license while the board processes the application for licensure. *The board shall approve a provisional license based on an application that includes an affidavit that the information submitted in the application is accurate and that verification documentation from the other jurisdiction has been requested.* The provisional license shall expire 18 months after issuance *or upon issuance of the expedited license*.

(2) (A) The applicant shall not have committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license under this code at the time the act was committed.

(B) The applicant shall not have been disciplined by a licensing entity in another jurisdiction and shall not be the subject of an unresolved complaint, review procedure, or disciplinary proceeding conducted by a licensing entity in another jurisdiction.

(c) A board may adopt regulations necessary to administer this section.

ASSEMBLY BILL No. 258

Introduced by Assembly Member Chávez

February 7, 2013

An act to add Section 11019.11 to the Government Code, relating to state agencies.

LEGISLATIVE COUNSEL'S DIGEST

AB 258, as introduced, Chávez. State agencies: veterans.

Existing law provides for the governance and regulation of state agencies, as defined. Existing law provides certain benefits and protections for members of the Armed Forces of the United States.

This bill would require every state agency that requests on any written form or written publication, or through its Internet Web site, whether a person is a veteran, to request that information in a specified manner.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 11019.11 is added to the Government Code, to read:

11019.11. (a) Every state agency that requests on any written form or written publication, or through its Internet Web site, whether a person is a veteran, shall request that information only in the following format: "Have you ever served in the military?"

(b) This section shall apply only to a written form or written publication that is newly printed on or after January 1, 2014.

ASSEMBLY BILL No. 291

Introduced by Assembly Member Nestande

February 11, 2013

An act to amend and repeal Sections 9147.7, 9148.50, 9148.51, and 9148.52 of, to amend, repeal, and add Section 9148.8 of, and to add Article 7.6 (commencing with Section 9147.9) to Chapter 1.5 of Part 1 of Division 2 of Title 2 of, the Government Code, relating to state government.

LEGISLATIVE COUNSEL'S DIGEST

AB 291, as introduced, Nestande. California Sunset Review Commission.

Existing law establishes the Joint Sunset Review Committee, a legislative committee comprised of 10 Members of the Legislature, to identify and eliminate waste, duplication, and inefficiency in government agencies and to conduct a comprehensive analysis of every "eligible agency" for which a date for repeal has been established, to determine if the agency is still necessary and cost effective. Existing law requires each eligible agency scheduled for repeal to submit a report to the committee containing specified information. Existing law requires the committee to take public testimony and evaluate the eligible agency prior to the date the agency is scheduled to be repealed, and requires that an eligible agency be eliminated unless the Legislature enacts a law to extend, consolidate, or reorganize the agency. Existing law also requires the committee to review eligible agencies and evaluate and determine whether each has demonstrated a public need for its continued existence and to submit a report to the Legislature detailing whether an

agency should be terminated, continued, or whether its functions should be modified.

This bill would abolish the Joint Sunset Review Committee on January 1 or an unspecified year. The bill would, commencing on that same January 1, establish the California Sunset Review Commission within the executive branch to assess the continuing need for any agency, as defined, to exist. The commission would consist of 10 members, with 8 members appointed by the Governor and 2 Members of the Legislature each appointed by the Senate Committee on Rules and the Speaker of the Assembly, subject to specified terms. The commission would be under the direction of a director appointed by the commission members. The bill would require the commission to meet regularly and to work with each agency subject to review to evaluate the need for the agency to exist, identify required statutory, regulatory, or management changes, and develop legislative proposals to enact those changes. The bill would require the commission to prepare a report, containing legislative recommendations based on its agency review, to be submitted to the Legislature and would also require the commission to meet certain cost-savings standards within 5 years.

This bill would require an agency to submit a specified self-evaluation report to the commission prior to its review. The bill would require the Legislative Analyst's Office to provide the commission with an estimate of the staffing needed to perform the commission's work.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 9147.7 of the Government Code is amended to read:

9147.7. (a) For the purpose of this section, "eligible agency" means any agency, authority, board, bureau, commission, conservancy, council, department, division, or office of state government, however denominated, excluding an agency that is constitutionally created or an agency related to postsecondary education, for which a date for repeal has been established by statute on or after January 1, 2011.

(b) The Joint Sunset Review Committee is hereby created to identify and eliminate waste, duplication, and inefficiency in government agencies. The purpose of the committee is to conduct

a comprehensive analysis over 15 years, and on a periodic basis thereafter, of every eligible agency to determine if the agency is still necessary and cost effective.

(c) Each eligible agency scheduled for repeal shall submit to the committee, on or before December 1 prior to the year it is set to be repealed, a complete agency report covering the entire period since last reviewed, including, but not limited to, the following:

(1) The purpose and necessity of the agency.

(2) A description of the agency budget, priorities, and job descriptions of employees of the agency.

(3) Any programs and projects under the direction of the agency.

(4) Measures of the success or failures of the agency and justifications for the metrics used to evaluate successes and failures.

(5) Any recommendations of the agency for changes or reorganization in order to better fulfill its purpose.

(d) The committee shall take public testimony and evaluate the eligible agency prior to the date the agency is scheduled to be repealed. An eligible agency shall be eliminated unless the Legislature enacts a law to extend, consolidate, or reorganize the eligible agency. No eligible agency shall be extended in perpetuity unless specifically exempted from the provisions of this section. The committee may recommend that the Legislature extend the statutory sunset date for no more than one year to allow the committee more time to evaluate the eligible agency.

(e) The committee shall be comprised of 10 members of the Legislature. The Senate Committee on Rules shall appoint five members of the Senate to the committee, not more than three of whom shall be members of the same political party. The Speaker of the Assembly shall appoint five members of the Assembly to the committee, not more than three of whom shall be members of the same political party. Members shall be appointed within 15 days after the commencement of the regular session. Each member of the committee who is appointed by the Senate Committee on Rules or the Speaker of the Assembly shall serve during that committee member's term of office or until that committee member no longer is a Member of the Senate or the Assembly, whichever is applicable. A vacancy on the committee shall be filled in the same manner as the original appointment. Three Assembly Members and three Senators who are members of the committee shall constitute a quorum for the conduct of committee business.

Members of the committee shall receive no compensation for their work with the committee.

(f) The committee shall meet not later than 30 days after the first day of the regular session to choose a chairperson and to establish the schedule for eligible agency review provided for in the statutes governing the eligible agencies. The chairperson of the committee shall alternate every two years between a Member of the Senate and a Member of the Assembly, and the vice chairperson of the committee shall be a member of the opposite house as the chairperson.

(g) This section shall not be construed to change the existing jurisdiction of the budget or policy committees of the Legislature.

(h) This section shall remain in effect only until January 1, 20__, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 20__, deletes or extends that date.

SEC. 2. Article 7.6 (commencing with Section 9147.9) is added to Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code, to read:

Article 7.6. California Sunset Review Commission

9147.9. This article may be cited as the California Sunset Review Commission Act.

9147.11. For the purpose of this section, the following definitions shall apply:

(a) "Agency" means any agency, authority, board, bureau, commission, conservancy, council, department, division, or office of state government, however denominated, excluding an agency that is constitutionally created or an agency related to postsecondary education.

(b) "Commission" means the California Sunset Review Commission.

(c) "Act" means the California Sunset Review Commission Act.

9147.13. The California Sunset Review Commission is hereby created within the executive branch of state government. The commission shall be located in Sacramento.

9147.15. (a) The commission shall consist of 10 members.

(1) The Governor shall appoint 8 members to serve a term of four years.

(2) The Senate Committee on Rules shall appoint one Member of the Senate to serve a term of two years or until that Member is no longer a Member of the Senate, whichever is applicable.

(3) The Speaker of the Assembly shall appoint one Member of the Assembly to serve a term of two years or until that Member is no longer a Member of the Assembly, whichever is applicable.

(b) The commission shall appoint a chairperson from its members appointed pursuant to paragraph (1).

(c) The Members of the Legislature appointed to the commission shall serve at the pleasure of the appointing power and shall participate in the activities of the commission to the extent that the participation is not incompatible with their respective positions as Members of the Legislature.

(d) A vacancy on the commission shall be filled in the same manner as the original appointment.

(e) (1) The members of the commission shall serve without compensation, except that each member appointed by the Governor shall receive fifty dollars ($50) for each day's attendance at a meeting of the commission.

(2) Each member shall be allowed actual expenses incurred in the discharge of his or her duties, including travel expenses.

9147.17. (a) The commission shall be under the direction of a director appointed by the commission members.

(b) The director shall employ sufficient staff to carry out the commission's responsibilities.

(c) The Legislative Analyst's Office shall estimate the staffing needed to manage the workload of the commission.

9147.19. (a) The commission shall serve in an advisory capacity and shall meet regularly to assess and review the continuing need for an agency to exist.

(b) Prior to the commission's review of an agency, the commission staff shall work with each agency to evaluate the need for the agency to exist, identify required statutory, regulatory, or management changes, and develop recommendation for legislative proposals to enact those changes. The commission shall also consult with interest groups, affected agencies, and other interested parties in reviewing an agency.

(c) In carrying out its duties pursuant to this section, the commission shall evaluate an agency pursuant to the following criteria, as applicable:

(1) The efficiency and effectiveness of the agency's operations.

(2) Whether the agency has been successful in achieving its mission, goals, and objectives.

(3) Whether the agency performs duties that are not statutorily authorized and, if so, identify the authority for those activities and whether those activities are needed.

(4) Whether the agency has any authority related to fees, inspections, enforcement, and penalties.

(5) Whether the agency's functions and operations could be less burdensome or restrictive while still serving the public.

(6) Whether the functions of the agency could be effectively consolidated or merged with another agency to promote efficiency in government.

(7) Whether the agency's programs and jurisdiction duplicate those of other state agencies.

(8) Whether the agency promptly and effectively addresses complaints.

(9) Whether the agency utilizes public participation for rulemaking and decisions and, if so, whether it is done in an effective manner.

(10) Whether the agency complied with federal and state requirements regarding equal employment, privacy rights, and purchasing guidelines for underutilized businesses.

(11) Whether the agency effectively enforces rules regarding the potential conflicts of interest of its employees.

(12) Whether abolishing the agency would cause federal government intervention or loss of federal funds.

(13) Whether the agency's statutory reporting requirements effectively fulfill a useful purpose; and whether there are reporting requirements of this agency that are duplicative of other agencies or can effectively be combined or consolidated into another agency that has similar requirements.

(d) The commission shall take public testimony from agency staff, interest groups, and affected parties relating to whether an agency should continue in existence.

(e) (1) The commission shall prepare a staff report to be submitted to the Legislature. The report shall include, but not be limited to, specific recommendations to the Legislature to enact legislation to do the following:

(A) Repeal unnecessary, outdated, or unnecessary statutes, regulations, and programs.

(B) Develop reorganization plans that abolish and streamline existing agencies, if needed.

(2) A report to the Legislature pursuant to this section shall be submitted in compliance with Section 9795.

(3) This subdivision shall become inoperative on January 1, 2018, pursuant to Section 10231.5

9147.21. Prior to review by the commission, an agency shall submit a self-evaluation report to the commission. The report shall include, but not be limited to, the criteria described in subdivision (c) of Section 9147.19.

9147.23. In order to ensure accountability, the commission shall demonstrate a 5-to-1 cost savings within the first five years of sunset review hearings, and every five years thereafter. For every dollar it costs to run the commission, five dollars ($5) shall be saved in streamlining the government process and eliminating unnecessary agencies.

9147.25. This article shall become operative on January 1, 20__.

SEC. 3. Section 9148.8 of the Government Code is amended to read:

9148.8. (a) The appropriate policy committee of the Legislature may evaluate a plan prepared pursuant to Section 9148.4 or 9148.6. The chairperson of a policy committee may alternatively require that the Joint Sunset Review Committee evaluate and provide recommendations on any plan prepared pursuant to Section 9148.4 or 9148.6, or any other legislative issue or proposal to create a new state board.

(b) The Joint Sunset Review Committee shall provide to the respective policy and fiscal committees of the Legislature any evaluation and recommendations prepared pursuant to this section.

(c) If an appropriate policy committee does not evaluate a plan prepared pursuant to Section 9148.6, then the Joint Sunset Review Committee shall evaluate the plan and provide recommendations to the Legislature.

(d) This section shall remain in effect only until January 1, 20__, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 20__, deletes or extends that date.

SEC. 4. Section 9148.8 is added to the Government Code, to read:

9148.8. (a) The appropriate policy committee of the Legislature may evaluate a plan prepared pursuant to Section 9148.4 or 9148.6. The chairperson of a policy committee may alternatively require that the California Sunset Review Commission evaluate and provide recommendations on any plan prepared pursuant to Section 9148.4 or 9148.6, or any other legislative issue or proposal to create a new state board.

(b) The California Sunset Review Commission shall provide to the respective policy and fiscal committees of the Legislature any evaluation and recommendations prepared pursuant to this section.

(c) If an appropriate policy committee does not evaluate a plan prepared pursuant to Section 9148.6, then the California Sunset Review Commission shall evaluate the plan and provide recommendations to the Legislature.

This section shall become operative on January 1, 20__.

SEC. 5. Section 9148.50 of the Government Code is amended to read:

9148.50. The Legislature finds and declares all of the following:

(a) California's multilevel, complex governmental structure today contains more than 400 categories of administrative or regulatory boards, commissions, committees, councils, associations, and authorities.

(b) These administrative or regulatory boards, commissions, committees, councils, associations, and authorities have been established without any method of periodically reviewing their necessity, effectiveness, or utility.

(c) As a result, the Legislature and residents of California cannot be assured that existing or proposed administrative or regulatory boards, commissions, committees, councils, associations, and authorities adequately protect the public health, safety, and welfare.

(d) This section shall remain in effect only until January 1, 20__, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 20__, deletes or extends that date.

SEC. 6. Section 9148.51 of the Government Code is amended to read:

9148.51. (a) It is the intent of the Legislature that all existing and proposed eligible agencies, as defined in subdivision (a) of Section 9147.7, be subject to review to evaluate and determine

whether each has demonstrated a public need for its continued existence in accordance with enumerated factors and standards as set forth in Article 7.5 (commencing with Section 9147.7).

(b) If any state board becomes inoperative or is repealed in accordance with the act that added this section, any provision of existing law that provides for the appointment of board members and specifies the qualifications and tenure of board members shall not be implemented and shall have no force or effect while that state board is inoperative or repealed.

(c) Any provision of law authorizing the appointment of an executive officer by a state board subject to the review described in Article 7.5 (commencing with Section 9147.7), or prescribing his or her duties, shall not be implemented and shall have no force or effect while the applicable state board is inoperative or repealed.

(d) This section shall remain in effect only until January 1, 20__, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 20__, deletes or extends that date.

SEC. 7. Section 9148.52 of the Government Code is amended to read:

9148.52. (a) The Joint Sunset Review Committee established pursuant to Section 9147.7 shall review all eligible agencies.

(b) The committee shall evaluate and make determinations pursuant to Article 7.5 (commencing with Section 9147.7).

(c) Pursuant to an evaluation made as specified in this section, the committee shall make a report which shall be available to the public and the Legislature on whether an agency should be terminated, or continued, or whether its functions should be revised or consolidated with those of another agency, and include any other recommendations as necessary to improve the effectiveness and efficiency of the agency. If the committee deems it advisable, the report may include proposed legislative proposals that would carry out its recommendations.

(d) This section shall remain in effect only until January 1, 20__, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 20__, deletes or extends that date.

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ASSEMBLY BILL No. 512

Introduced by Assembly Member Rendon

February 20, 2013

An act to amend Section 901 of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 512, as introduced, Rendon. Healing arts: licensure exemption.

Existing law provides for the licensure and regulation of various healing arts practitioners by boards within the Department of Consumer Affairs. Existing law provides an exemption from these requirements for a health care practitioner licensed in another state who offers or provides health care for which he or she is licensed during a state of emergency, as defined, and upon request of the Director of the Emergency Medical Services Authority, as specified.

Existing law provides, until January 1, 2014, an exemption from the licensure and regulation requirements for a health care practitioner, as defined, licensed or certified in good standing in another state or states, who offers or provides health care services for which he or she is licensed or certified through a sponsored event, as defined, (1) to uninsured or underinsured persons, (2) on a short-term voluntary basis, (3) in association with a sponsoring entity that registers with the applicable healing arts board, as defined, and provides specified information to the county health department of the county in which the health care services will be provided, and (4) without charge to the recipient or a 3rd party on behalf of the recipient, as specified. Existing law also requires an exempt health care practitioner to obtain prior authorization to provide these services from the applicable licensing

board, as defined, and to satisfy other specified requirements, including payment of a fee as determined by the applicable licensing board.

This bill would delete the January 1, 2014, date of repeal, and instead allow the exemption to operate until January 1, 2018.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 901 of the Business and Professions Code is amended to read:

901. (a) For purposes of this section, the following provisions apply:

(1) "Board" means the applicable healing arts board, under this division or an initiative act referred to in this division, responsible for the licensure or regulation in this state of the respective health care practitioners.

(2) "Health care practitioner" means any person who engages in acts that are subject to licensure or regulation under this division or under any initiative act referred to in this division.

(3) "Sponsored event" means an event, not to exceed 10 calendar days, administered by either a sponsoring entity or a local government, or both, through which health care is provided to the public without compensation to the health care practitioner.

(4) "Sponsoring entity" means a nonprofit organization organized pursuant to Section 501(c)(3) of the Internal Revenue Code or a community-based organization.

(5) "Uninsured or underinsured person" means a person who does not have health care coverage, including private coverage or coverage through a program funded in whole or in part by a governmental entity, or a person who has health care coverage, but the coverage is not adequate to obtain those health care services offered by the health care practitioner under this section.

(b) A health care practitioner licensed or certified in good standing in another state, district, or territory of the United States who offers or provides health care services for which he or she is licensed or certified is exempt from the requirement for licensure if all of the following requirements are met:

(1) Prior to providing those services, he or she does all of the following:

(A) Obtains authorization from the board to participate in the sponsored event after submitting to the board a copy of his or her valid license or certificate from each state in which he or she holds licensure or certification and a photographic identification issued by one of the states in which he or she holds licensure or certification. The board shall notify the sponsoring entity, within 20 calendar days of receiving a request for authorization, whether that request is approved or denied, provided that, if the board receives a request for authorization less than 20 days prior to the date of the sponsored event, the board shall make reasonable efforts to notify the sponsoring entity whether that request is approved or denied prior to the date of that sponsored event.

(B) Satisfies the following requirements:

(i) The health care practitioner has not committed any act or been convicted of a crime constituting grounds for denial of licensure or registration under Section 480 and is in good standing in each state in which he or she holds licensure or certification.

(ii) The health care practitioner has the appropriate education and experience to participate in a sponsored event, as determined by the board.

(iii) The health care practitioner shall agree to comply with all applicable practice requirements set forth in this division and the regulations adopted pursuant to this division.

(C) Submits to the board, on a form prescribed by the board, a request for authorization to practice without a license, and pays a fee, in an amount determined by the board by regulation, which shall be available, upon appropriation, to cover the cost of developing the authorization process and processing the request.

(2) The services are provided under all of the following circumstances:

(A) To uninsured or underinsured persons.

(B) On a short-term voluntary basis, not to exceed a 10-calendar-day period per sponsored event.

(C) In association with a sponsoring entity that complies with subdivision (d).

(D) Without charge to the recipient or to a third party on behalf of the recipient.

(c) The board may deny a health care practitioner authorization to practice without a license if the health care practitioner fails to

comply with this section or for any act that would be grounds for denial of an application for licensure.

(d) A sponsoring entity seeking to provide, or arrange for the provision of, health care services under this section shall do both of the following:

(1) Register with each applicable board under this division for which an out-of-state health care practitioner is participating in the sponsored event by completing a registration form that shall include all of the following:

(A) The name of the sponsoring entity.

(B) The name of the principal individual or individuals who are the officers or organizational officials responsible for the operation of the sponsoring entity.

(C) The address, including street, city, ZIP Code, and county, of the sponsoring entity's principal office and each individual listed pursuant to subparagraph (B).

(D) The telephone number for the principal office of the sponsoring entity and each individual listed pursuant to subparagraph (B).

(E) Any additional information required by the board.

(2) Provide the information listed in paragraph (1) to the county health department of the county in which the health care services will be provided, along with any additional information that may be required by that department.

(e) The sponsoring entity shall notify the board and the county health department described in paragraph (2) of subdivision (d) in writing of any change to the information required under subdivision (d) within 30 calendar days of the change.

(f) Within 15 calendar days of the provision of health care services pursuant to this section, the sponsoring entity shall file a report with the board and the county health department of the county in which the health care services were provided. This report shall contain the date, place, type, and general description of the care provided, along with a listing of the health care practitioners who participated in providing that care.

(g) The sponsoring entity shall maintain a list of health care practitioners associated with the provision of health care services under this section. The sponsoring entity shall maintain a copy of each health care practitioner's current license or certification and shall require each health care practitioner to attest in writing that

his or her license or certificate is not suspended or revoked pursuant to disciplinary proceedings in any jurisdiction. The sponsoring entity shall maintain these records for a period of at least five years following the provision of health care services under this section and shall, upon request, furnish those records to the board or any county health department.

(h) A contract of liability insurance issued, amended, or renewed in this state on or after January 1, 2011, shall not exclude coverage of a health care practitioner or a sponsoring entity that provides, or arranges for the provision of, health care services under this section, provided that the practitioner or entity complies with this section.

(i) Subdivision (b) shall not be construed to authorize a health care practitioner to render care outside the scope of practice authorized by his or her license or certificate or this division.

(j) (1) The board may terminate authorization for a health care practitioner to provide health care services pursuant to this section for failure to comply with this section, any applicable practice requirement set forth in this division, any regulations adopted pursuant to this division, or for any act that would be grounds for discipline if done by a licensee of that board.

(2) The board shall provide both the sponsoring entity and the health care practitioner with a written notice of termination including the basis for that termination. The health care practitioner may, within 30 days after the date of the receipt of notice of termination, file a written appeal to the board. The appeal shall include any documentation the health care practitioner wishes to present to the board.

(3) A health care practitioner whose authorization to provide health care services pursuant to this section has been terminated shall not provide health care services pursuant to this section unless and until a subsequent request for authorization has been approved by the board. A health care practitioner who provides health care services in violation of this paragraph shall be deemed to be practicing health care in violation of the applicable provisions of this division, and be subject to any applicable administrative, civil, or criminal fines, penalties, and other sanctions provided in this division.

(k) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall

not affect other provisions or applications that can be given effect without the invalid provision or application.

(*l*) This section shall remain in effect only until January 1, ~~2014,~~ *2018,* and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, ~~2014,~~ *2018,* deletes or extends that date.

AMENDED IN ASSEMBLY APRIL 3, 2013

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL No. 809

Introduced by Assembly Member Logue

February 21, 2013

An act to amend Sections 1626.2, 2290.5, 4980.01, 4982, 4989.54, 4992.3, 4996, and 4999.90 of the Business and Professions Code, relating to telehealth, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

AB 809, as amended, Logue. Healing arts: telehealth.

Existing law requires a health care provider, as defined, prior to the delivery of health care services via telehealth, as defined, to verbally inform the patient that telehealth may be used and obtain verbal consent from the patient for this use. Existing law also provides that failure to comply with this requirement constitutes unprofessional conduct.

This bill would ~~delete those provisions~~ *instead require the health care provider at the originating site to provide the patient with a waiver for the course of treatment involving telehealth services to obtain informed consent for the agreed upon course of treatment. The bill would require the signed waiver to be contained in the patient's medical record*. The bill would make additional conforming changes.

This bill would declare that it is to take effect immediately as an urgency statute.

Vote: ⅔. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 1626.2 of the Business and Professions Code is amended to read:

1626.2. A dentist licensed under this chapter is a licentiate for purposes of paragraph (2) of subdivision (a) of Section 805, and thus is a health care practitioner subject to the provisions of Section 2290.5.

SEC. 2. Section 2290.5 of the Business and Professions Code is amended to read:

2290.5. (a) For purposes of this division, the following definitions shall apply:

(1) "Asynchronous store and forward" means the transmission of a patient's medical information from an originating site to the health care provider at a distant site without the presence of the patient.

(2) "Distant site" means a site where a health care provider who provides health care services is located while providing these services via a telecommunications system.

(3) "Health care provider" means a person who is licensed under this division.

(4) "Originating site" means a site where a patient is located at the time health care services are provided via a telecommunications system or where the asynchronous store and forward service originates.

(5) "Synchronous interaction" means a real-time interaction between a patient and a health care provider located at a distant site.

(6) "Telehealth" means the mode of delivering health care services and public health via information and communication technologies to facilitate the diagnosis, consultation, treatment, education, care management, and self-management of a patient's health care while the patient is at the originating site and the health care provider is at a distant site. Telehealth facilitates patient self-management and caregiver support for patients and includes synchronous interactions and asynchronous store and forward transfers.

(b) Prior to the delivery of health care via telehealth, the health care provider at the originating site shall provide the patient with a waiver for the course of treatment involving telehealth services

to obtain informed consent for the agreed upon course of treatment. The signed waiver shall be contained in the patient's medical record.

(c) Nothing in this section shall preclude a patient from receiving in-person health care delivery services during a course of treatment after agreeing to receive services via telehealth.

(d) The failure of a health care provider to comply with this section shall constitute unprofessional conduct. Section 2314 shall not apply to this section.

~~(b)~~

(e) This section shall not be construed to alter the scope of practice of any health care provider or authorize the delivery of health care services in a setting, or in a manner, not otherwise authorized by law.

~~(c)~~

(f) All laws regarding the confidentiality of health care information and a patient's rights to his or her medical information shall apply to telehealth interactions.

~~(d)~~

(g) This section shall not apply to a patient under the jurisdiction of the Department of Corrections and Rehabilitation or any other correctional facility.

~~(e)~~

(h) (1) Notwithstanding any other provision of law and for purposes of this section, the governing body of the hospital whose patients are receiving the telehealth services may grant privileges to, and verify and approve credentials for, providers of telehealth services based on its medical staff recommendations that rely on information provided by the distant-site hospital or telehealth entity, as described in Sections 482.12, 482.22, and 485.616 of Title 42 of the Code of Federal Regulations.

(2) By enacting this subdivision, it is the intent of the Legislature to authorize a hospital to grant privileges to, and verify and approve credentials for, providers of telehealth services as described in paragraph (1).

(3) For the purposes of this subdivision, "telehealth" shall include "telemedicine" as the term is referenced in Sections 482.12, 482.22, and 485.616 of Title 42 of the Code of Federal Regulations.

SEC. 3. Section 4980.01 of the Business and Professions Code is amended to read:

4980.01. (a) Nothing in this chapter shall be construed to constrict, limit, or withdraw the Medical Practice Act, the Social Work Licensing Law, the Nursing Practice Act, the Licensed Professional Clinical Counselor Act, or the Psychology Licensing Act.

(b) This chapter shall not apply to any priest, rabbi, or minister of the gospel of any religious denomination when performing counseling services as part of his or her pastoral or professional duties, or to any person who is admitted to practice law in the state, or who is licensed to practice medicine, when providing counseling services as part of his or her professional practice.

(c) (1) This chapter shall not apply to an employee working in any of the following settings if his or her work is performed solely under the supervision of the employer:

(A) A governmental entity.

(B) A school, college, or university.

(C) An institution that is both nonprofit and charitable.

(2) This chapter shall not apply to a volunteer working in any of the settings described in paragraph (1) if his or her work is performed solely under the supervision of the entity, school, or institution.

(d) A marriage and family therapist licensed under this chapter is a licentiate for purposes of paragraph (2) of subdivision (a) of Section 805, and thus is a health care practitioner subject to the provisions of Section 2290.5.

(e) Notwithstanding subdivisions (b) and (c), all persons registered as interns or licensed under this chapter shall not be exempt from this chapter or the jurisdiction of the board.

SEC. 4. Section 4982 of the Business and Professions Code is amended to read:

4982. The board may deny a license or registration or may suspend or revoke the license or registration of a licensee or registrant if he or she has been guilty of unprofessional conduct. Unprofessional conduct includes, but is not limited to, the following:

(a) The conviction of a crime substantially related to the qualifications, functions, or duties of a licensee or registrant under this chapter. The record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime

in order to fix the degree of discipline or to determine if the conviction is substantially related to the qualifications, functions, or duties of a licensee or registrant under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere made to a charge substantially related to the qualifications, functions, or duties of a licensee or registrant under this chapter shall be deemed to be a conviction within the meaning of this section. The board may order any license or registration suspended or revoked, or may decline to issue a license or registration when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal, or, when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw a plea of guilty and enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

(b) Securing a license or registration by fraud, deceit, or misrepresentation on any application for licensure or registration submitted to the board, whether engaged in by an applicant for a license or registration, or by a licensee in support of any application for licensure or registration.

(c) Administering to himself or herself any controlled substance or using of any of the dangerous drugs specified in Section 4022, or of any alcoholic beverage to the extent, or in a manner, as to be dangerous or injurious to the person applying for a registration or license or holding a registration or license under this chapter, or to any other person, or to the public, or, to the extent that the use impairs the ability of the person applying for or holding a registration or license to conduct with safety to the public the practice authorized by the registration or license. The board shall deny an application for a registration or license or revoke the license or registration of any person, other than one who is licensed as a physician and surgeon, who uses or offers to use drugs in the course of performing marriage and family therapy services.

(d) Gross negligence or incompetence in the performance of marriage and family therapy.

(e) Violating, attempting to violate, or conspiring to violate any of the provisions of this chapter or any regulation adopted by the board.

(f) Misrepresentation as to the type or status of a license or registration held by the person, or otherwise misrepresenting or permitting misrepresentation of his or her education, professional qualifications, or professional affiliations to any person or entity.

(g) Impersonation of another by any licensee, registrant, or applicant for a license or registration, or, in the case of a licensee, allowing any other person to use his or her license or registration.

(h) Aiding or abetting, or employing, directly or indirectly, any unlicensed or unregistered person to engage in conduct for which a license or registration is required under this chapter.

(i) Intentionally or recklessly causing physical or emotional harm to any client.

(j) The commission of any dishonest, corrupt, or fraudulent act substantially related to the qualifications, functions, or duties of a licensee or registrant.

(k) Engaging in sexual relations with a client, or a former client within two years following termination of therapy, soliciting sexual relations with a client, or committing an act of sexual abuse, or sexual misconduct with a client, or committing an act punishable as a sexually related crime, if that act or solicitation is substantially related to the qualifications, functions, or duties of a marriage and family therapist.

(*l*) Performing, or holding oneself out as being able to perform, or offering to perform, or permitting any trainee or registered intern under supervision to perform, any professional services beyond the scope of the license authorized by this chapter.

(m) Failure to maintain confidentiality, except as otherwise required or permitted by law, of all information that has been received from a client in confidence during the course of treatment and all information about the client that is obtained from tests or other means.

(n) Prior to the commencement of treatment, failing to disclose to the client or prospective client the fee to be charged for the professional services, or the basis upon which that fee will be computed.

(o) Paying, accepting, or soliciting any consideration, compensation, or remuneration, whether monetary or otherwise, for the referral of professional clients. All consideration, compensation, or remuneration shall be in relation to professional counseling services actually provided by the licensee. Nothing in

this subdivision shall prevent collaboration among two or more licensees in a case or cases. However, no fee shall be charged for that collaboration, except when disclosure of the fee has been made in compliance with subdivision (n).

(p) Advertising in a manner that is false, fraudulent, misleading, or deceptive, as defined in Section 651.

(q) Reproduction or description in public, or in any publication subject to general public distribution, of any psychological test or other assessment device, the value of which depends in whole or in part on the naivete of the subject, in ways that might invalidate the test or device.

(r) Any conduct in the supervision of any registered intern, associate clinical social worker, or trainee by any licensee that violates this chapter or any rules or regulations adopted by the board.

(s) Performing or holding oneself out as being able to perform professional services beyond the scope of one's competence, as established by one's education, training, or experience. This subdivision shall not be construed to expand the scope of the license authorized by this chapter.

(t) Permitting a trainee or registered intern under one's supervision or control to perform, or permitting the trainee or registered intern to hold himself or herself out as competent to perform, professional services beyond the trainee's or registered intern's level of education, training, or experience.

(u) The violation of any statute or regulation governing the gaining and supervision of experience required by this chapter.

(v) Failure to keep records consistent with sound clinical judgment, the standards of the profession, and the nature of the services being rendered.

(w) Failure to comply with the child abuse reporting requirements of Section 11166 of the Penal Code.

(x) Failure to comply with the elder and dependent adult abuse reporting requirements of Section 15630 of the Welfare and Institutions Code.

(y) Willful violation of Chapter 1 (commencing with Section 123100) of Part 1 of Division 106 of the Health and Safety Code.

(z) (1) Engaging in an act described in Section 261, 286, 288a, or 289 of the Penal Code with a minor or an act described in Section 288 or 288.5 of the Penal Code regardless of whether the

act occurred prior to or after the time the registration or license was issued by the board. An act described in this subdivision occurring prior to the effective date of this subdivision shall constitute unprofessional conduct and shall subject the licensee to refusal, suspension, or revocation of a license under this section.

(2) The Legislature hereby finds and declares that protection of the public, and in particular minors, from sexual misconduct by a licensee is a compelling governmental interest, and that the ability to suspend or revoke a license for sexual conduct with a minor occurring prior to the effective date of this section is equally important to protecting the public as is the ability to refuse a license for sexual conduct with a minor occurring prior to the effective date of this section.

(aa) Engaging in any conduct that subverts or attempts to subvert any licensing examination or the administration of an examination as described in Section 123.

SEC. 5. Section 4989.54 of the Business and Professions Code is amended to read:

4989.54. The board may deny a license or may suspend or revoke the license of a licensee if he or she has been guilty of unprofessional conduct. Unprofessional conduct includes, but is not limited to, the following:

(a) Conviction of a crime substantially related to the qualifications, functions, and duties of an educational psychologist.

(1) The record of conviction shall be conclusive evidence only of the fact that the conviction occurred.

(2) The board may inquire into the circumstances surrounding the commission of the crime in order to fix the degree of discipline or to determine if the conviction is substantially related to the qualifications, functions, or duties of a licensee under this chapter.

(3) A plea or verdict of guilty or a conviction following a plea of nolo contendere made to a charge substantially related to the qualifications, functions, or duties of a licensee under this chapter shall be deemed to be a conviction within the meaning of this section.

(4) The board may order a license suspended or revoked, or may decline to issue a license when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal, or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under

Section 1203.4 of the Penal Code allowing the person to withdraw a plea of guilty and enter a plea of not guilty or setting aside the verdict of guilty or dismissing the accusation, information, or indictment.

(b) Securing a license by fraud, deceit, or misrepresentation on an application for licensure submitted to the board, whether engaged in by an applicant for a license or by a licensee in support of an application for licensure.

(c) Administering to himself or herself a controlled substance or using any of the dangerous drugs specified in Section 4022 or an alcoholic beverage to the extent, or in a manner, as to be dangerous or injurious to himself or herself or to any other person or to the public or to the extent that the use impairs his or her ability to safely perform the functions authorized by the license. The board shall deny an application for a license or revoke the license of any person, other than one who is licensed as a physician and surgeon, who uses or offers to use drugs in the course of performing educational psychology.

(d) Advertising in a manner that is false, fraudulent, misleading, or deceptive, as defined in Section 651.

(e) Violating, attempting to violate, or conspiring to violate any of the provisions of this chapter or any regulation adopted by the board.

(f) Commission of any dishonest, corrupt, or fraudulent act substantially related to the qualifications, functions, or duties of a licensee.

(g) Denial of licensure, revocation, suspension, restriction, or any other disciplinary action imposed by another state or territory or possession of the United States or by any other governmental agency, on a license, certificate, or registration to practice educational psychology or any other healing art. A certified copy of the disciplinary action, decision, or judgment shall be conclusive evidence of that action.

(h) Revocation, suspension, or restriction by the board of a license, certificate, or registration to practice as an educational psychologist, a clinical social worker, professional clinical counselor, or marriage and family therapist.

(i) Failure to keep records consistent with sound clinical judgment, the standards of the profession, and the nature of the services being rendered.

(j) Gross negligence or incompetence in the practice of educational psychology.

(k) Misrepresentation as to the type or status of a license held by the licensee or otherwise misrepresenting or permitting misrepresentation of his or her education, professional qualifications, or professional affiliations to any person or entity.

(*l*) Intentionally or recklessly causing physical or emotional harm to any client.

(m) Engaging in sexual relations with a client or a former client within two years following termination of professional services, soliciting sexual relations with a client, or committing an act of sexual abuse or sexual misconduct with a client or committing an act punishable as a sexually related crime, if that act or solicitation is substantially related to the qualifications, functions, or duties of a licensed educational psychologist.

(n) Prior to the commencement of treatment, failing to disclose to the client or prospective client the fee to be charged for the professional services or the basis upon which that fee will be computed.

(o) Paying, accepting, or soliciting any consideration, compensation, or remuneration, whether monetary or otherwise, for the referral of professional clients.

(p) Failing to maintain confidentiality, except as otherwise required or permitted by law, of all information that has been received from a client in confidence during the course of treatment and all information about the client that is obtained from tests or other means.

(q) Performing, holding himself or herself out as being able to perform, or offering to perform any professional services beyond the scope of the license authorized by this chapter or beyond his or her field or fields of competence as established by his or her education, training, or experience.

(r) Reproducing or describing in public, or in any publication subject to general public distribution, any psychological test or other assessment device the value of which depends in whole or in part on the naivete of the subject in ways that might invalidate the test or device. An educational psychologist shall limit access to the test or device to persons with professional interests who can be expected to safeguard its use.

(s) Aiding or abetting an unlicensed person to engage in conduct requiring a license under this chapter.

(t) When employed by another person or agency, encouraging, either orally or in writing, the employer's or agency's clientele to utilize his or her private practice for further counseling without the approval of the employing agency or administration.

(u) Failing to comply with the child abuse reporting requirements of Section 11166 of the Penal Code.

(v) Failing to comply with the elder and adult dependent abuse reporting requirements of Section 15630 of the Welfare and Institutions Code.

(w) Willful violation of Chapter 1 (commencing with Section 123100) of Part 1 of Division 106 of the Health and Safety Code.

(x) (1) Engaging in an act described in Section 261, 286, 288a, or 289 of the Penal Code with a minor or an act described in Section 288 or 288.5 of the Penal Code regardless of whether the act occurred prior to or after the time the registration or license was issued by the board. An act described in this subdivision occurring prior to the effective date of this subdivision shall constitute unprofessional conduct and shall subject the licensee to refusal, suspension, or revocation of a license under this section.

(2) The Legislature hereby finds and declares that protection of the public, and in particular minors, from sexual misconduct by a licensee is a compelling governmental interest, and that the ability to suspend or revoke a license for sexual conduct with a minor occurring prior to the effective date of this section is equally important to protecting the public as is the ability to refuse a license for sexual conduct with a minor occurring prior to the effective date of this section.

(y) Engaging in any conduct that subverts or attempts to subvert any licensing examination or the administration of the examination as described in Section 123.

(z) Impersonation of another by any licensee or applicant for a license, or, in the case of a licensee, allowing any other person to use his or her license.

(aa) Permitting a person under his or her supervision or control to perform, or permitting that person to hold himself or herself out as competent to perform, professional services beyond the level of education, training, or experience of that person.

SEC. 6. Section 4992.3 of the Business and Professions Code is amended to read:

4992.3. The board may deny a license or a registration, or may suspend or revoke the license or registration of a licensee or registrant if he or she has been guilty of unprofessional conduct. Unprofessional conduct includes, but is not limited to, the following:

(a) The conviction of a crime substantially related to the qualifications, functions, or duties of a licensee or registrant under this chapter. The record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime in order to fix the degree of discipline or to determine if the conviction is substantially related to the qualifications, functions, or duties of a licensee or registrant under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere made to a charge substantially related to the qualifications, functions, or duties of a licensee or registrant under this chapter is a conviction within the meaning of this section. The board may order any license or registration suspended or revoked, or may decline to issue a license or registration when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal, or, when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw a plea of guilty and enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

(b) Securing a license or registration by fraud, deceit, or misrepresentation on any application for licensure or registration submitted to the board, whether engaged in by an applicant for a license or registration, or by a licensee in support of any application for licensure or registration.

(c) Administering to himself or herself any controlled substance or using any of the dangerous drugs specified in Section 4022 or any alcoholic beverage to the extent, or in a manner, as to be dangerous or injurious to the person applying for a registration or license or holding a registration or license under this chapter, or to any other person, or to the public, or, to the extent that the use impairs the ability of the person applying for or holding a

registration or license to conduct with safety to the public the practice authorized by the registration or license. The board shall deny an application for a registration or license or revoke the license or registration of any person who uses or offers to use drugs in the course of performing clinical social work. This provision does not apply to any person also licensed as a physician and surgeon under Chapter 5 (commencing with Section 2000) or the Osteopathic Act who lawfully prescribes drugs to a patient under his or her care.

(d) Incompetence in the performance of clinical social work.

(e) An act or omission that falls sufficiently below the standard of conduct of the profession as to constitute an act of gross negligence.

(f) Violating, attempting to violate, or conspiring to violate this chapter or any regulation adopted by the board.

(g) Misrepresentation as to the type or status of a license or registration held by the person, or otherwise misrepresenting or permitting misrepresentation of his or her education, professional qualifications, or professional affiliations to any person or entity. For purposes of this subdivision, this misrepresentation includes, but is not limited to, misrepresentation of the person's qualifications as an adoption service provider pursuant to Section 8502 of the Family Code.

(h) Impersonation of another by any licensee, registrant, or applicant for a license or registration, or, in the case of a licensee, allowing any other person to use his or her license or registration.

(i) Aiding or abetting any unlicensed or unregistered person to engage in conduct for which a license or registration is required under this chapter.

(j) Intentionally or recklessly causing physical or emotional harm to any client.

(k) The commission of any dishonest, corrupt, or fraudulent act substantially related to the qualifications, functions, or duties of a licensee or registrant.

(*l*) Engaging in sexual relations with a client or with a former client within two years from the termination date of therapy with the client, soliciting sexual relations with a client, or committing an act of sexual abuse, or sexual misconduct with a client, or committing an act punishable as a sexually related crime, if that

act or solicitation is substantially related to the qualifications, functions, or duties of a clinical social worker.

(m) Performing, or holding one's self out as being able to perform, or offering to perform or permitting, any registered associate clinical social worker or intern under supervision to perform any professional services beyond the scope of one's competence, as established by one's education, training, or experience. This subdivision shall not be construed to expand the scope of the license authorized by this chapter.

(n) Failure to maintain confidentiality, except as otherwise required or permitted by law, of all information that has been received from a client in confidence during the course of treatment and all information about the client that is obtained from tests or other means.

(o) Prior to the commencement of treatment, failing to disclose to the client or prospective client the fee to be charged for the professional services, or the basis upon which that fee will be computed.

(p) Paying, accepting, or soliciting any consideration, compensation, or remuneration, whether monetary or otherwise, for the referral of professional clients. All consideration, compensation, or remuneration shall be in relation to professional counseling services actually provided by the licensee. Nothing in this subdivision shall prevent collaboration among two or more licensees in a case or cases. However, no fee shall be charged for that collaboration, except when disclosure of the fee has been made in compliance with subdivision (o).

(q) Advertising in a manner that is false, fraudulent, misleading, or deceptive, as defined in Section 651.

(r) Reproduction or description in public, or in any publication subject to general public distribution, of any psychological test or other assessment device, the value of which depends in whole or in part on the naivete of the subject, in ways that might invalidate the test or device. A licensee shall limit access to that test or device to persons with professional interest who are expected to safeguard its use.

(s) Any conduct in the supervision of any registered associate clinical social worker, intern, or trainee by any licensee that violates this chapter or any rules or regulations adopted by the board.

(t) Failure to keep records consistent with sound clinical judgment, the standards of the profession, and the nature of the services being rendered.

(u) Failure to comply with the child abuse reporting requirements of Section 11166 of the Penal Code.

(v) Failure to comply with the elder and dependent adult abuse reporting requirements of Section 15630 of the Welfare and Institutions Code.

(w) Willful violation of Chapter 1 (commencing with Section 123100) of Part 1 of Division 106 of the Health and Safety Code.

(x) (1) Engaging in an act described in Section 261, 286, 288a, or 289 of the Penal Code with a minor or an act described in Section 288 or 288.5 of the Penal Code regardless of whether the act occurred prior to or after the time the registration or license was issued by the board. An act described in this subdivision occurring prior to the effective date of this subdivision shall constitute unprofessional conduct and shall subject the licensee to refusal, suspension, or revocation of a license under this section.

(2) The Legislature hereby finds and declares that protection of the public, and in particular minors, from sexual misconduct by a licensee is a compelling governmental interest, and that the ability to suspend or revoke a license for sexual conduct with a minor occurring prior to the effective date of this section is equally important to protecting the public as is the ability to refuse a license for sexual conduct with a minor occurring prior to the effective date of this section.

(y) Engaging in any conduct that subverts or attempts to subvert any licensing examination or the administration of the examination as described in Section 123.

SEC. 7. Section 4996 of the Business and Professions Code is amended to read:

4996. (a) Only individuals who have received a license under this article may style themselves as “Licensed Clinical Social Workers.” Every individual who styles himself or herself or who holds himself or herself out to be a licensed clinical social worker, or who uses any words or symbols indicating or tending to indicate that he or she is a licensed clinical social worker, without holding his or her license in good standing under this article, is guilty of a misdemeanor.

(b) It is unlawful for any person to engage in the practice of clinical social work unless at the time of so doing that person holds a valid, unexpired, and unrevoked license under this article.

(c) A clinical social worker licensed under this chapter is a licentiate for purposes of paragraph (2) of subdivision (a) of Section 805, and thus is a health care practitioner subject to the provisions of Section 2290.5.

SEC. 8. Section 4999.90 of the Business and Professions Code is amended to read:

4999.90. The board may refuse to issue any registration or license, or may suspend or revoke the registration or license of any intern or licensed professional clinical counselor, if the applicant, licensee, or registrant has been guilty of unprofessional conduct. Unprofessional conduct includes, but is not limited to, the following:

(a) The conviction of a crime substantially related to the qualifications, functions, or duties of a licensee or registrant under this chapter. The record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime in order to fix the degree of discipline or to determine if the conviction is substantially related to the qualifications, functions, or duties of a licensee or registrant under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere made to a charge substantially related to the qualifications, functions, or duties of a licensee or registrant under this chapter shall be deemed to be a conviction within the meaning of this section. The board may order any license or registration suspended or revoked, or may decline to issue a license or registration when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal, or, when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw a plea of guilty and enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

(b) Securing a license or registration by fraud, deceit, or misrepresentation on any application for licensure or registration submitted to the board, whether engaged in by an applicant for a

license or registration, or by a licensee in support of any application for licensure or registration.

(c) Administering to himself or herself any controlled substance or using any of the dangerous drugs specified in Section 4022, or any alcoholic beverage to the extent, or in a manner, as to be dangerous or injurious to the person applying for a registration or license or holding a registration or license under this chapter, or to any other person, or to the public, or, to the extent that the use impairs the ability of the person applying for or holding a registration or license to conduct with safety to the public the practice authorized by the registration or license. The board shall deny an application for a registration or license or revoke the license or registration of any person, other than one who is licensed as a physician and surgeon, who uses or offers to use drugs in the course of performing licensed professional clinical counseling services.

(d) Gross negligence or incompetence in the performance of licensed professional clinical counseling services.

(e) Violating, attempting to violate, or conspiring to violate any of the provisions of this chapter or any regulation adopted by the board.

(f) Misrepresentation as to the type or status of a license or registration held by the person, or otherwise misrepresenting or permitting misrepresentation of his or her education, professional qualifications, or professional affiliations to any person or entity.

(g) Impersonation of another by any licensee, registrant, or applicant for a license or registration, or, in the case of a licensee or registrant, allowing any other person to use his or her license or registration.

(h) Aiding or abetting, or employing, directly or indirectly, any unlicensed or unregistered person to engage in conduct for which a license or registration is required under this chapter.

(i) Intentionally or recklessly causing physical or emotional harm to any client.

(j) The commission of any dishonest, corrupt, or fraudulent act substantially related to the qualifications, functions, or duties of a licensee or registrant.

(k) Engaging in sexual relations with a client, or a former client within two years following termination of therapy, soliciting sexual relations with a client, or committing an act of sexual abuse, or

sexual misconduct with a client, or committing an act punishable as a sexually related crime, if that act or solicitation is substantially related to the qualifications, functions, or duties of a licensed professional clinical counselor.

(*l*) Performing, or holding oneself out as being able to perform, or offering to perform, or permitting any trainee, applicant, or registrant under supervision to perform, any professional services beyond the scope of the license authorized by this chapter.

(m) Failure to maintain confidentiality, except as otherwise required or permitted by law, of all information that has been received from a client in confidence during the course of treatment and all information about the client which is obtained from tests or other means.

(n) Prior to the commencement of treatment, failing to disclose to the client or prospective client the fee to be charged for the professional services, or the basis upon which that fee will be computed.

(o) Paying, accepting, or soliciting any consideration, compensation, or remuneration, whether monetary or otherwise, for the referral of professional clients. All consideration, compensation, or remuneration shall be in relation to professional clinical counseling services actually provided by the licensee. Nothing in this subdivision shall prevent collaboration among two or more licensees in a case or cases. However, no fee shall be charged for that collaboration, except when disclosure of the fee has been made in compliance with subdivision (n).

(p) Advertising in a manner that is false, fraudulent, misleading, or deceptive, as defined in Section 651.

(q) Reproduction or description in public, or in any publication subject to general public distribution, of any psychological test or other assessment device, the value of which depends in whole or in part on the naivete of the subject, in ways that might invalidate the test or device.

(r) Any conduct in the supervision of a registered intern, associate clinical social worker, or clinical counselor trainee by any licensee that violates this chapter or any rules or regulations adopted by the board.

(s) Performing or holding oneself out as being able to perform professional services beyond the scope of one's competence, as established by one's education, training, or experience. This

subdivision shall not be construed to expand the scope of the license authorized by this chapter.

(t) Permitting a clinical counselor trainee or intern under one's supervision or control to perform, or permitting the clinical counselor trainee or intern to hold himself or herself out as competent to perform, professional services beyond the clinical counselor trainee's or intern's level of education, training, or experience.

(u) The violation of any statute or regulation of the standards of the profession, and the nature of the services being rendered, governing the gaining and supervision of experience required by this chapter.

(v) Failure to keep records consistent with sound clinical judgment, the standards of the profession, and the nature of the services being rendered.

(w) Failure to comply with the child abuse reporting requirements of Section 11166 of the Penal Code.

(x) Failing to comply with the elder and dependent adult abuse reporting requirements of Section 15630 of the Welfare and Institutions Code.

(y) Repeated acts of negligence.

(z) (1) Engaging in an act described in Section 261, 286, 288a, or 289 of the Penal Code with a minor or an act described in Section 288 or 288.5 of the Penal Code regardless of whether the act occurred prior to or after the time the registration or license was issued by the board. An act described in this subdivision occurring prior to the effective date of this subdivision shall constitute unprofessional conduct and shall subject the licensee to refusal, suspension, or revocation of a license under this section.

(2) The Legislature hereby finds and declares that protection of the public, and in particular minors, from sexual misconduct by a licensee is a compelling governmental interest, and that the ability to suspend or revoke a license for sexual conduct with a minor occurring prior to the effective date of this section is equally important to protecting the public as is the ability to refuse a license for sexual conduct with a minor occurring prior to the effective date of this section.

(aa) Engaging in any conduct that subverts or attempts to subvert any licensing examination or the administration of an examination as described in Section 123.

(ab) Revocation, suspension, or restriction by the board of a license, certificate, or registration to practice as a professional clinical counselor, clinical social worker, educational psychologist, or marriage and family therapist.

(ac) Willful violation of Chapter 1 (commencing with Section 123100) of Part 1 of Division 106 of the Health and Safety Code.

SEC. 9. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to protect the health and safety of the public due to a lack of access to health care providers in rural and urban medically underserved areas of California, the increasing strain on existing providers expected to occur with the implementation of the federal Patient Protection and Affordable Care Act, and the assistance that further implementation of telehealth can provide to help relieve these burdens, it is necessary for this act to take effect immediately.

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL No. 1013

Introduced by Assembly Member Gomez

February 22, 2013

An act to amend Section 320 of the Business and Professions Code, relating to consumer affairs.

LEGISLATIVE COUNSEL'S DIGEST

AB 1013, as introduced, Gomez. Consumer affairs.

Under existing law, the Department of Consumer Affairs is comprised of boards that license and regulate various professions and vocations. Existing law provides that these boards are established to ensure that private businesses and professions are regulated to protect the people of this state. Existing law authorizes the director or the Attorney General to intervene in a matter or proceeding pending before any state commission, regulatory agency, department, or agency, or any court, which the director finds may affect substantially the interests of consumers within California, in any appropriate manner to represent the interests of consumers. Existing law also authorizes the director, or any officer or employee designated by the director for that purpose, or the Attorney General to thereafter present evidence and argument to the agency, court of department, as specified, for the effective protection of the interests of consumers.

This bill would additionally authorize any employee designated by the Attorney General to make those presentations.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 320 of the Business and Professions Code is amended to read:

320. Whenever there is pending before any state commission, regulatory agency, department, or other state agency, or any state or federal court or agency, any matter or proceeding which the director finds may affect substantially the interests of consumers within California, the director, or the Attorney General, may intervene in such matter or proceeding in any appropriate manner to represent the interests of consumers. The director, or any officer or employee designated by the director for that purpose, or the Attorney General*, or any employee designated by the Attorney General for that purpose*, may thereafter present to ~~such~~ *that* agency, court, or department, in conformity with the rules of practice and procedure thereof, ~~such~~ *the* evidence and argument as he *or she* shall determine to be necessary, for the effective protection of the interests of consumers.

AMENDED IN ASSEMBLY APRIL 9, 2013

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL No. 1057

Introduced by Assembly Member Medina

February 22, 2013

An act to add Section 114.5 to the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

AB 1057, as amended, Medina. Professions and vocations: licenses: military service.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law authorizes a licensee or registrant whose license expired while the licensee or registrant was on active duty as a member of the California National Guard or the United States Armed Forces to, upon application, reinstate his or her license without penalty and without examination, if certain requirements are satisfied, unless the licensing agency determines that the applicant has not actively engaged in the practice of his or her profession while on active duty, as specified.

This bill would require each board, *commencing January 1, 2015,* to inquire in every application for licensure if the applicant is serving in, or has previously served in, the military.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 114.5 is added to the Business and Professions Code, to read:

114.5. ~~Each~~ *Commencing January 1, 2015, each* board shall inquire in every application for licensure if the applicant is serving in, or has previously served in, the military.

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AMENDED IN SENATE APRIL 15, 2013

SENATE BILL No. 305

Introduced by Senator Price
(Principal coauthor: Assembly Member Gordon)

February 15, 2013

An act to amend Sections 2450, 2450.3, *2569, 3010.5, 3014.6,* 3685, 3686, 3710, ~~and~~ 3716, *and 3765*of, *and to add Section 144.5 to,* the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 305, as amended, Price. Healing arts: boards.

Existing law requires specified regulatory boards within the Department of Consumer Affairs to require an applicant for licensure to furnish to the board a full set of fingerprints in order to conduct a criminal history record check.

This bill would additionally authorize those boards to request and receive from a local or state agency certified records of all arrests and convictions, certified records regarding probation, and any and all other related documentation needed to complete an applicant or licensee investigation and would authorize a local or state agency to provide those records to the board upon request.

Existing law, the Osteopathic Act, ~~establishes the Osteopathic Medical Board of California, which issues certificates to, and regulates, osteopathic physicians and surgeons.~~ *provides for the licensure and regulation of osteopathic physicians and surgeons by the Osteopathic Medical Board of California.*

This bill would require that the powers and duties of the board, as provided, be subject to review by the appropriate policy committees of the Legislature. The bill would require that *the* review be performed as

if ~~those~~ *these* provisions were scheduled to be repealed as of January 1, 2018.

Existing law, the Naturopathic Doctors Act, *until January 1, 2014,* provides for the licensure and regulation of naturopathic doctors by the Naturopathic Medicine Committee within the Osteopathic Medical Board of California. ~~Existing law repeals these provisions on January 1, 2014.~~ Existing law also specifies that the *repeal of the* committee ~~is subject~~ *subjects it* to review by the appropriate policy committees of the Legislature.

This bill would ~~instead repeal those provisions on January 1, 2018,~~ *extend the operation of these provisions until January 1, 2018,* and make conforming changes.

Existing law provides for the regulation of dispensing opticians, as defined, by the Medical Board of California.

This bill would require that the powers and duties of the board, as provided, be subject to review by the appropriate policy committees of the Legislature. The bill would require that the review be performed as if these provisions were scheduled to be repealed as of January 1, 2018.

Existing law*, the Optometry Practice Act, provides for the licensure and regulation of optometrists by the State Board of Optometry. The Respiratory Care Act* provides for the licensure and regulation of respiratory care practitioners by the Respiratory Care Board of California. ~~Existing law~~ *Each of those acts* authorizes the board to employ an executive officer. Existing law repeals these provisions on January 1, 2014 and subjects the ~~board~~ *boards* to review by the Joint ~~Sunset Review Committee~~ *Committee on Boards, Commissions, and Consumer Protection*.

This bill would ~~instead repeal those provisions on January 1, 2018,~~ *extend the operation of these provisions until January 1, 2018,* and provide that the ~~committee is subject to~~ *repeal of these provisions subjects the boards to* review by the appropriate policy committees of the Legislature.

The Respiratory Care Act also prohibits a person from engaging in the practice of respiratory care unless he or she is a licensed respiratory care practitioner. However, the act does not prohibit specified acts, including, among others, the performance of respiratory care services in case of an emergency or self-care by a patient.

This bill would additionally authorize the performance of pulmonary function testing by persons who are currently employed by Los Angeles

county hospitals and have performed pulmonary function testing for at least 15 years.

This bill would make legislative findings and declarations as to the necessity of a special statute for the persons described above.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 144.5 is added to the Business and Professions Code, to read:

144.5. Notwithstanding any other law, a board described in Section 144 may request, and is authorized to receive, from a local or state agency certified records of all arrests and convictions, certified records regarding probation, and any and all other related documentation needed to complete an applicant or licensee investigation. A local or state agency may provide those records to the board upon request.

~~SECTION 1.~~

SEC. 2. Section 2450 of the Business and Professions Code is amended to read:

2450. There is a Board of Osteopathic Examiners of the State of California, established by the Osteopathic Act, which shall be known as the Osteopathic Medical Board of California which enforces this chapter relating to persons holding or applying for physician's and surgeon's certificates issued by the Osteopathic Medical Board of California under the Osteopathic Act.

Persons who elect to practice using the term of suffix "M.D.," as provided in Section 2275, shall not be subject to this article, and the Medical Board of California shall enforce the provisions of this chapter relating to persons who made the election.

Notwithstanding any other law, the powers and duties of the Osteopathic Medical Board of California, as set forth in this article and under the Osteopathic Act, shall be subject to review by the appropriate policy committees of the Legislature. The review shall be performed as if this chapter were scheduled to be repealed as of January 1, 2018.

~~SEC. 2.~~

SEC. 3. Section 2450.3 of the Business and Professions Code is amended to read:

2450.3. There is within the jurisdiction of the Osteopathic Medical Board of California a Naturopathic Medicine Committee authorized under the Naturopathic Doctors Act (Chapter 8.2 (commencing with Section 3610)). This section shall become inoperative on January 1, 2018, and, as of that date is repealed, unless a later enacted statute that is enacted before January 1, 2018, deletes or extends that date. Notwithstanding any other provision of law, the repeal of this section renders the Naturopathic Medicine Committee subject to review by the appropriate policy committees of the Legislature.

SEC. 4. Section 2569 of the Business and Professions Code is amended to read:

2569. ~~The~~ *Notwithstanding any other law, the* powers and duties of the board, as set forth in this chapter, shall be subject to ~~the~~ review ~~required by Division 1.2 (commencing with Section 473).~~ *by the appropriate policy committees of the Legislature.* The review shall be performed as if this chapter were scheduled to be repealed as of January 1, ~~2014, as described in Section 473.1.~~ *2018.*

SEC. 5. Section 3010.5 of the Business and Professions Code is amended to read:

3010.5. (a) There is in the Department of Consumer Affairs a State Board of Optometry in which the enforcement of this chapter is vested. The board consists of 11 members, five of whom shall be public members.

Six members of the board shall constitute a quorum.

(b) The board shall, with respect to conducting investigations, inquiries, and disciplinary actions and proceedings, have the authority previously vested in the board as created pursuant to Section 3010. The board may enforce any disciplinary actions undertaken by that board.

(c) This section shall remain in effect only until January 1, ~~2014,~~ *2018,* and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, ~~2014,~~ *2018,* deletes or extends that date. ~~The~~ *Notwithstanding any other law, the* repeal of this section renders the board subject to ~~the~~ review ~~required by Division 1.2 (commencing with Section 473).~~ *by the appropriate policy committees of the Legislature.*

SEC. 6. Section 3014.6 of the Business and Professions Code is amended to read:

3014.6. (a) The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter.

(b) This section shall remain in effect only until January 1, ~~2014,~~ *2018,* and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, ~~2014,~~ *2018,* deletes or extends that date.

~~SEC. 3.~~

SEC. 7. Section 3685 of the Business and Professions Code is amended to read:

3685. Notwithstanding any other law, the repeal of this chapter renders the committee subject to review by the appropriate policy committees of the Legislature.

~~SEC. 4.~~

SEC. 8. Section 3686 of the Business and Professions Code is amended to read:

3686. This chapter shall remain in effect only until January 1, 2018, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2018, deletes or extends that date.

~~SEC. 5.~~

SEC. 9. Section 3710 of the Business and Professions Code is amended to read:

3710. (a) The Respiratory Care Board of California, hereafter referred to as the board, shall enforce and administer this chapter.

(b) This section shall remain in effect only until January 1, 2018, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2018, deletes or extends that date. Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

~~SEC. 6.~~

SEC. 10. Section 3716 of the Business and Professions Code is amended to read:

3716. The board may employ an executive officer exempt from civil service and, subject to the provisions of law relating to civil service, clerical assistants and, except as provided in Section 159.5, other employees as it may deem necessary to carry out its powers and duties.

This section shall remain in effect only until January 1, 2018, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2018, deletes or extends that date.

SEC. 11. Section 3765 of the Business and Professions Code is amended to read:

3765. This act does not prohibit any of the following activities:

(a) The performance of respiratory care that is an integral part of the program of study by students enrolled in approved respiratory therapy training programs.

(b) Self-care by the patient or the gratuitous care by a friend or member of the family who does not represent or hold himself or herself out to be a respiratory care practitioner licensed under the provisions of this chapter.

(c) The respiratory care practitioner from performing advances in the art and techniques of respiratory care learned through formal or specialized training.

(d) The performance of respiratory care in an emergency situation by paramedical personnel who have been formally trained in these modalities and are duly licensed under the provisions of an act pertaining to their speciality.

(e) Respiratory care services in case of an emergency. "Emergency," as used in this subdivision, includes an epidemic or public disaster.

(f) Persons from engaging in cardiopulmonary research.

(g) Formally trained licensees and staff of child day care facilities from administering to a child inhaled medication as defined in Section 1596.798 of the Health and Safety Code.

(h) The performance by a person employed by a home medical device retail facility or by a home health agency licensed by the State Department of Health Services of specific, limited, and basic respiratory care or respiratory care related services that have been authorized by the board.

(i) The performance of pulmonary function testing by persons who are currently employed by Los Angeles county hospitals and have performed pulmonary function testing for at least 15 years.

SEC. 12. The Legislature finds and declares that a special law, as set forth in Section 11 of this act, is necessary and that a general law cannot be made applicable within the meaning of Section 16 of Article IV of the California Constitution because of the unique circumstances relating to persons who are currently employed by

Los Angeles county hospitals and have performed pulmonary function testing for at least 15 years.

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SENATE BILL No. 690

Introduced by Senator Price

February 22, 2013

An act to amend Section 23.7 of the Business and Professions Code, relating to licenses.

LEGISLATIVE COUNSEL'S DIGEST

SB 690, as introduced, Price. Licenses.

Existing law provides for the licensing of various professions and vocations by boards within the Department of Consumer Affairs. Existing law defines license to mean a license, certificate, registration, or other means to engage in a business or profession, as provided.

This bill would expand the definition of license to include a permit.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 23.7 of the Business and Professions Code is amended to read:

23.7. Unless otherwise expressly provided, "license" means license, certificate, registration, *permit,* or other means to engage in a business or profession regulated by this code or referred to in Section 1000 or 3600.

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RESPIRATORY CARE BOARD COMMITTEES

(Updated May 2013)

The Board has established committees to enhance the efficacy, efficiency and prompt dispatch of duties upon the Board. They are as follows:

Executive Committee

Members of the Executive Committee include the Board's president and vice-president. As elected officers, this Committee makes interim (between Board meetings) decisions as necessary. This Committee is responsible for making recommendations to the Board with respect to legislation impacting the Board's mandate. This Committee also provides guidance to administrative staff for the budgeting and organizational components of the Board and is responsible for directing the fulfillment of recommendations made by legislative oversight committees.

President: Charles B. Spearman, MSEd, RCP

Vice-President: Mark Goldstein, BS, RRT, RCP

Enforcement Committee

Members of the Enforcement Committee are responsible for the development and review of Board-adopted policies, positions and disciplinary guidelines. Although members of the Enforcement Committee do not typically review individual enforcement cases (if they do they recuse themselves from any further proceedings), they are responsible for policy development of the enforcement program, pursuant to the provisions of the Administrative Procedure Act (APA).

Chair: ***Vacant***

Member: Murray Olson, RCP, RRT-NPS, RPFT

Outreach Committee

Members of the Outreach Committee are responsible for the development of consumer outreach projects, including the Board's newsletter, website, e-government initiatives and outside organization presentations. These members act as goodwill ambassadors and represent the Board at the invitation of outside organizations and programs.

Chair: ***Vacant***

Member: ***Vacant***

Professional Qualifications Committee

Members of the Professional Qualifications Committee are responsible for the review and development of regulations regarding educational and professional ethics course requirements for initial licensure and continuing education (CE) programs. Essentially, they monitor various education criteria and requirements for licensure, taking into consideration new developments in technology, managed care, and current activity in the healthcare industry.

Chair: Mark Goldstein, BS, RRT, RCP

Member: Charles B. Spearman, MSEd, RCP

Disaster Preparedness Committee

The Disaster Preparedness Committee is a one-person committee responsible for keeping the Board abreast of issues regarding disaster preparedness and facilitating communication between the Board, respiratory therapists, and public and private agencies regarding related matters.

Chair: Alan Roth, MS, MBA, RRT-NPS, FAARC