

**OSTEOPATHIC MEDICAL
BOARD
OF CALIFORNIA**

**Board Meeting, Thursday, January 23, 2014
10:00 a.m.**

**Department of Consumer Affairs
Headquarters Building 2
1747 North Market Blvd.
Hearing Room
Sacramento, CA 95834**

OMBC Phone (916) 928-8390

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TABLE I



OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA
BOARD MEETING

Date: Thursday, January 23, 2014
Time: 10:00 a.m. – 5:00 p.m. (or until the end of business)
Location: Department of Consumer Affairs
Headquarters Building 2 (HQ2)
1747 North Market Blvd.
Hearing Room
Sacramento CA 95834
(916) 928-8390

AGENDA

(Action may be taken on any items listed on the agenda and may be taken out of order)

Open Session

1. Call to Order and Roll Call / Establishment of a Quorum
2. Election of Officers
3. Approval of Minutes – September 26, 2013 Board Meeting
4. Executive Director's Report – Angie Burton
 - Licensing
 - Staffing
 - Diversion Program
 - Budget
 - BreEZe
 - Enforcement Report / Discipline (Corey Sparks)
5. Diversion Program
 - Guest Speaker – Virginia L. Matthews (MAXIMUS)
6. **Closed Session**
 - Performance evaluation of the Executive Director pursuant to Government Code Section 11126(a)(1).
 - Deliberations on disciplinary or enforcement actions pursuant to Government Code Section 11126(c)(3).

Return to Open Session

7. Sunset Review Follow-up
 - Discussion and possible action to initiate a rulemaking related to a Code of Ethics for licensees.
 - Review and discussion of Internet Prescribing.
8. Update of Pain Management Task Force/ Guidelines – Dr. Connett
 - Summary review – Richard Reimer, D.O.
9. Regulations
 - Review and Discussion of the Uniform Standards Related to Substance Abuse (SB 1441) and Disciplinary Guidelines.
 - Review and Discussion of Consumer Protection Enforcement Initiative provisions (SB 1111).
10. Agenda Items for Next Meeting
11. Future Meeting Dates
12. Public Comment for Items Not on the Agenda

Note: The Board may not discuss or take action on any matter raised during this public comment section except to decide whether to place the matter on the agenda of a future meeting [Government Code Sections 11125, 11125.7(a)]
13. Adjournment

For further information about this meeting, please contact Machiko Chong at 916-928-7636 or in writing 1300 National Drive, Suite 150 Sacramento CA 95834. This notice can be accessed at www.ombc.ca.gov

The meeting facilities are accessible to the physically disabled. A person, who needs a disability-related accommodation or modification in order to participate in the meeting, may make a request by contacting Machiko Chong, ADA Liaison, at (916) 928-7636 or e-mail at Machiko.Chong@dca.ca.gov or send a written request to the Board's office at 1300 National Drive, Suite 150, Sacramento, CA 95834-1991. Providing your request at least five (5) business days before the meeting will help to ensure availability of the requested accommodation.

TABLE 2



DRAFT
BOARD MEETING
MINUTES

Thursday, September 26, 2013

BOARD MEMBERS PRESENT:

David Connett, D.O., President
Keith Higginbotham, Esq., Vice President
Michael Feinstein, D.O., Secretary Treasurer
Alan Howard, Board Member
James Lally, D.O., Board Member
Scott Harris, Esq., Board Member
Claudia Mercado, Board Member
Joseph Zammuto, D.O., Board Member

STAFF PRESENT:

Angelina Burton, Executive Director
Laura Freedman, Esq., Legal Counsel, DCA
Michael Santiago, Esq., Legal Counsel, DCA
Machiko Chong, Executive Analyst
Francine Davies, D.O., Assistant Executive Director
Donald Krpan, D.O., Medical Consultant
Corey Sparks, Lead Enforcement Analyst

The Board meeting of the Osteopathic Medical Board of California (OMBC) was called to order by President, David Connett, D.O. at 10:06 a.m. at the Department of Consumer Affairs (DCA), 1625 North Market Blvd., Suite N220, El Dorado Conference Room, Sacramento, CA 95834.

1. Roll Call:

Dr. Connett called roll and determined that a quorum was present.

2. Presidents Report:

Dr. Connett gave opening comments as the new president of the board and thanked the prior president Dr. Joseph Provenzano for his time spent serving the board as a member and President.

He informed the board that he attended the Prescribing Task Force meeting that was held on Monday September 23, 2013 and stated that the board would be working collaboratively with the Medical Board and all other boards that were in attendance to review and establish guidelines for opioid prescriptions, noting that he would be attending the next Task Force meeting scheduled in January 2014.

He updated the Board on the MOL Task Force and stated that the Federation of State Medical Board (FSMB) elected to make Dr. Geraldine O'Shea as the lead of the national Task Force that was created. In addition the MOL Task Force is set to come forth with new information in November 2013 regarding the priorities of the Task Force and MOL criteria.

Prior to completing his introduction he quickly went through the points that were discussed during the Sunset Review and noted that while it is important to work in collaboration with the Medical Board on many issues it is also important to keep in mind that there is a clear and distinctive difference as to what our physicians are able to provide in the practice of osteopathic medicine.

3. Approval of Minutes – May 2, 2013 Board Meeting:

Dr. Connett called for approval of the Board Meeting minutes of May 2, 2013. M – Zammuto, S – Higginbotham to approve the minutes with no additions or corrections. motion carried.

Approval of Minutes – June 12, 2013 Teleconference:

Dr. Connett called for approval of the teleconference minutes of June 12, 2013. M – Zammuto, S – Higginbotham to approve the minutes with no additions or corrections. motion carried.

4. Executive Director's Report:

Angie Burton updated the board regarding office staffing, board budget activity, and diversion program statistics. Mrs. Burton also noted that Laura Freedman, Esq. would no longer be serving as the board's legal counsel due to changes within the legal department and informed the board that it would now be working with Michael Santiago, Esq. on all future issues.

Mr. Awet Kidane, DCA Chief Deputy Director gave an update on the BreEZe system being implemented by Department of Consumer Affairs (DCA). He answered all budgetary and system concerns had by the board and gave them insight into what the new system will allow the Boards/Bureaus to achieve.

Enforcement/ Discipline - The boards Lead Enforcement Analyst Corey Sparks compiled and presented the report. Mr. Howard thanked Mr. Sparks for the report that was provided and made note that he would also like to see a more in-depth aging report for all enforcement cases that are being worked on in and out of office for possible review and comparison to the Medical Boards aging reports as well.

5. Administrative Hearing:

10:30 a.m. – Michael Duffy, D.O. – Petition for Early Termination of Probation.

The Office of Administrative Hearing (OAH) Administrative Law Judge Coren D. Wong conducted the above hearing

6. Closed Session

Deliberations on petition(s) for early termination of probation (Government Code Section 11126(c)(3).)

Return to Open Session

7. Guest Speaker – Richard Riemer, D.O.

Dr. Connett gave an introductory speech detailing why Dr. Richard Riemer was in attendance and explained why the board would be viewing a Presentation on the topic of chronic pain guidelines for the “Chronic Noncancer Pain.” He explained the importance of the Osteopathic Medical Board being in the forefront of opioid abuse epidemic and his desire to compile treatment and prescription guidelines that would be implemented and used by physicians statewide and possibly nationally.

Dr. Connett recommended that he felt that the best approach going forth would be to create a task force. M – Dr. Connett to discuss creation of a pain management task force by the board S – Higginbotham. Dr. Lally expressed concern regarding lack of funding that may be available to the board for creation of a task force in addition to staffing constraints that the board may face. Ms. Freedman advised that the board would be a paid per-diem for any time worked and teleconferences could be used to conduct meetings. Dr. Connett offered to organize meetings and teleconferences for the potential task force over the next few months to compile the framework for the guidelines. If a standard of practice is being developed for physicians to follow and be regulated by, than it would have to be supported through either completion of regulations or statute. Dr. Krpan made note that if a task force is created that effort should be made to reach out and include input from the osteopathic brethren at The Medical Board. The board was in favor and the motion carried.

8. Legislation

No action was taken regarding legislation and all documents provided were merely for informational purposes. However, the board was made aware that AB 1288 (Medical Board of California and Osteopathic Medical Board of California: Licensing: Application Process (Chapter 307)) was chaptered and that information regarding the definition of medically underserved areas would be made available to physicians via the board site. In addition there would also be instructions posted so that applicants would know how to

complete the application process when applying for licensure. The board members questioned whether we would be altering the application forms so that physicians would be able to appropriately indicate whether they qualified or not. Mrs. Burton stated that the board would discuss the best way to make the necessary changes on the application once the BreZE site went live.

9. Sunset Review:

CODE OF ETHICS:

Dr. Connett explained that along with Dr. Krpan they reviewed and crosswalked the American Osteopathic Association (AOA) Code of Ethics with the Professional and Business Standards for the State of California to ensure that the ethics standards meet California laws. Dr. Connett called for discussion of the Code of Ethics and editorial changes. The document provided to the board was reviewed by Kathleen Creason, Executive Director, Osteopathic Physicians and Surgeons of California (OPSC) who suggested that amendments be made to sections 4, 10, 11, and 12 of the proposed Code of Ethics. After further discussion by the board it was decided that the Code of Ethics would be used to create “Best Practices” for physicians to refer to making it accessible on the board site as opposed to something that would be enforced by the board requiring completion of regulations. Dr. Connett recommended he forward a copy of the Code of Ethics with edits to legal counsel for return of the final draft to be used as “Best Practices” M – Zammuto, S – Higginbotham, motion carried.

INTERNET PRESCRIBING:

Dr. Zammuto thanked Ms. Mercado for her input and suggestions, to create the draft and Dr. Krpan for all of the research that he completed. He explained that the document was composed using information obtained from their review of the Federation of State Medical Boards composite report of 50 state rules and regulations. The board discussed the difference between telemedicine and internet prescribing and where interplay occurred. The report was submitted for consideration by Dr. Zammuto. M - Dr. Connett S – Harris, to adopt this document to move forward with regulations, motion carried.

10. Agenda Items for Next Board Meeting:

- Code of Ethics Final Draft
- Internet Prescribing Final Draft
- Updated on Pain Management Task Force

11. Future Meeting Dates:

- Thursday, January 23, 2014 @ 10:00 am – Sacramento

12. Public Comments

There were no public comments.

13. Adjournment

There being no further business, the Meeting was adjourned at 3:50 p.m.

TABLE 3

DEPARTMENT OF CONSUMER AFFAIRS BreEze Database System

The BreEze database was launched on October 7, 2013, for the first release group. As you know, OMBC is in the first release. As with any new system, BreEze has many challenges, which we are still working around and learning as we move forward.

Our on-line license application and renewal functions have not yet been implemented and we hope to see this phase go-live this spring.

The enforcement reports currently created by BreEze accurately reflecting our enforcement statistic. The BreEZE team has been notified of this and we are currently working on a fix.

STAFFING

The Budget Change Proposal (BCP) submitted last year has been approved. We are approved to hire three fulltime Office Technician positions. This will allow us to convert the two Permanent Intermittent positions, who are currently working three days a week, to full time positions and bring in the third position as a cashier.

Additionally, we have recently filled our vacant position in licensing. Mr. Jaime Nichols, has joined our staff and will be working in our license renewal unit. He will be assisting our CME compliance coordinator in ensuring our physicians meet the CME requirement for re-licensure.

With the addition of the three positions approved by the BCP, in July 2014, the number of staff for OMBC will be at 11.4. This increase in number of positions has been long overdue and we are very excited to finally receive the staffing so desperately needed.

LICENSING

OMBC currently has approximately 250 applications in various stages of process.

The license application process has two steps. In the first step, applicants submit their completed renewal form and fee. Because of the new BreEze system, cashiering is currently being performed by the DCA cashiering unit. The fees and the application forms are forwarded to DCA cashiering unit to be processed. Once the fee is processed, the application forms are returned to our office. This process could anywhere between 7 days to 3 weeks. A few days later, we receive confirmation via the AAA9 accounting report that the money has been assigned to the application. The staff can then begin work on the application. Documents which are primary source verified, i.e., medical school transcripts, National Board of Osteopathic Medical Examiners, Inc (NBOME) COMLEX scores, other state license verifications, must be submitted to this office from the primary source. The staff then matches the documents from the primary source with the application, to create the applicant file. If the applicant is from out-

of-state, fingerprints are submitted on manual cards, which staff forwards to Department of Justice for clearance. If the applicants are in-state, they may utilize the live scan method. Applications cannot be approved until all documents are received, including the State and Federal level fingerprint clearances. Once the application file is complete, an OMBC analyst conducts a final review of the application. This starts the second step of the application process. OMBC licensing staff will send the licensing fee statement to the applicant. Once the licensing fee is received from the applicant, the fee again, must be forwarded to DCA cashiering unit to be processed. Once we receive the document and after the AAA9 accounting report is received from cashiering unit, OMBC staff can complete entering data into BreEZE, which provides the applicant with his/her license number. This information becomes immediately available on the board's website. The pocket license and wall certificates are then printed by METRO, the vendor contracted to print all DCA license materials. Wallet ID's are mailed out to the applicants within days of issuance of license. The engraved wall certificates are returned to the board office and on a monthly bases, forwarded to the board president and secretary for signatures. Once the signed certificates are received back in our office, staff will send them out via certified mail, to the new licensees.

This entire process minus the wall certificate, used to take two to four months to complete. Some of the processes are what we call "in our control", other processes are "out of our control". For instance, the time it takes the primary source documents to reach this board, the time it takes DOJ to provide us with fingerprint clearances, and the time it takes the applicants to send their licensing fee to the board, are "out of our control". Sometimes, these processes could delay our application processing time.

OMBC will be hiring our own cashiering staff, which will eliminate a minimum of three weeks of processing time and free up our licensing staff's time currently spent on preparing transmittals of fees forwarded to the DCA cashiering unit.

BUDGET

The budget report ending December 31, 2013 is included in the agenda packet. After six months, we have 53% of the budget remaining. We are in good shape and will have sufficient funds to finish this fiscal year without a large reversion.

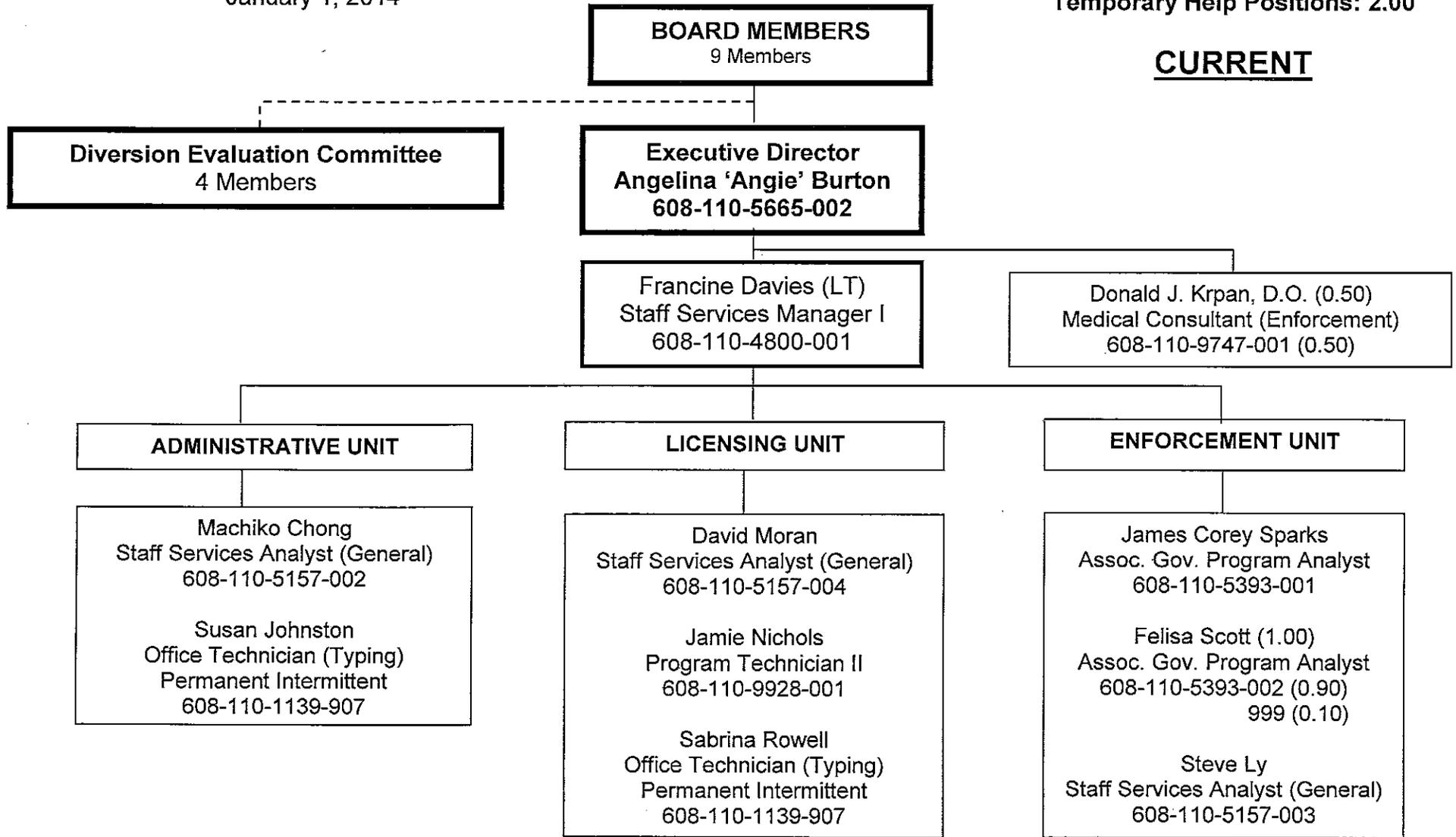
DIVERSION PROGRAM

The OMBC's Diversion Program currently has 13 participants. Of the 13, 7 are in the program through a probationary order; the remaining 6 are self-referred. The current contract between the seven DCA Boards and Maximus, Inc. is set to expire on December 31, 2014. The Diversion Program Managers are currently working on a Request for Proposal. OMBC is very pleased with our current program. There is frequent communication between our case manager, Ms. Mireles and myself and she is available to consult with at all times.

Department of Consumer Affairs
Osteopathic Medical Board of California
 January 1, 2014

FY 2013-14
 Authorized Positions: 8.40
 BL 12-03 (999 Blanket): 0.10
 Temporary Help Positions: 2.00

CURRENT



Angelina Burton, Executive Director

Date

Personnel Analyst

Date

DEPARTMENT OF CONSUMER AFFAIRS

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OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA

DESCRIPTION	BUDGET	CURR. MONTH	YR-TO-DATE	ENCUMBRANCE	YTD + ENCUMBRANCE	BALANCE	PCNT REMAIN
PERSONAL SERVICES							
SALARIES AND WAGES							
003 00 CIVIL SERVICE-PERM	452,850	32,951	191,125	0	191,125	261,725	
033 04 TEMP HELP (907)	0	3,913	21,458	0	21,458	(21,458)	
063 00 STATUTORY-EXEMPT	81,732	6,297	38,582	0	38,582	43,150	
063 01 BD/COMMSN (901,920)	2,800	0	200	0	200	2,600	
TOTAL SALARIES AND WAGES	537,382	43,161	251,365	0	251,365	286,017	53.22%
STAFF BENEFITS							
103 00 OASDI	871	2,440	13,915	0	13,915	(13,044)	
104 00 DENTAL INSURANCE	1,158	227	1,491	0	1,491	(333)	
105 00 HEALTH/WELFARE INS	82,503	3,610	20,893	0	20,893	61,610	
106 01 RETIREMENT	99,837	8,760	50,921	0	50,921	48,916	
125 00 WORKERS' COMPENSAT	12,626	0	0	0	0	12,626	
125 15 SCIF ALLOCATION CO	0	404	2,999	0	2,999	(2,999)	
134 00 OTHER-STAFF BENEFI	3,000	2,860	16,259	0	16,259	(13,259)	
134 01 TRANSIT DISCOUNT	0	65	390	0	390	(390)	
135 00 LIFE INSURANCE	0	11	60	0	60	(60)	
136 00 VISION CARE	1,032	43	259	0	259	773	
137 00 MEDICARE TAXATION	296	597	3,410	0	3,410	(3,114)	
TOTAL STAFF BENEFITS	201,323	19,018	110,597	0	110,597	90,726	45.06%
TOTAL PERSONAL SERVICES	738,705	62,179	361,962	0	361,962	376,743	51.00%
OPERATING EXPENSES & EQUIPMENT							
FINGERPRINTS							
213 04 FINGERPRINT REPORT	25,000	2,499	11,878	0	11,878	13,122	
TOTAL FINGERPRINTS	25,000	2,499	11,878	0	11,878	13,122	52.49%
GENERAL EXPENSE							
201 00 GENERAL EXPENSE	39,077	0	0	0	0	39,077	
205 00 DUES & MEMBERSHIPS	0	0	2,400	0	2,400	(2,400)	
206 00 MISC OFFICE SUPPLI	0	0	2,004	0	2,004	(2,004)	
213 02 ADMIN OVERHEAD-OTH	0	147	1,776	0	1,776	(1,776)	
TOTAL GENERAL EXPENSE	39,077	147	6,180	0	6,180	32,897	84.19%
PRINTING							
241 00 PRINTING	8,178	0	0	0	0	8,178	

DEPARTMENT OF CONSUMER AFFAIRS

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DESCRIPTION	BUDGET	CURR. MONTH	YR-TO-DATE	ENCUMBRANCE	YTD + ENCUMBRANCE	BALANCE	PCNT REMAIN
242 00 PAMPHLT/LEAFLT/BRO	0	0	26	0	26	(26)	
242 02 REPRODUCTION SVS	0	23	43	0	43	(43)	
242 03 COPY COSTS ALLO	0	0	165	0	165	(165)	
242 05 METRO PRINT/MAIL	0	240	240	0	240	(240)	
245 00 PRINTED FORM/STATN	0	18	18	0	18	(18)	
246 00 OFC COPIER SUPPLIE	0	0	0	74	74	(74)	
TOTAL PRINTING	8,178	281	492	74	566	7,612	93.08%
COMMUNICATIONS							
251 00 COMMUNICATIONS	11,511	0	0	0	0	11,511	
252 00 CELL PHONES,PDA,PA	0	0	1,226	0	1,226	(1,226)	
254 00 FAX	0	0	721	0	721	(721)	
257 01 TELEPHONE EXCHANGE	0	371	1,153	0	1,153	(1,153)	
TOTAL COMMUNICATIONS	11,511	371	3,099	0	3,099	8,412	73.08%
POSTAGE							
261 00 POSTAGE	22,034	0	0	0	0	22,034	
263 00 POSTAGE METER	0	14,400	14,400	340	14,740	(14,740)	
263 05 DCA POSTAGE ALLO	0	0	785	0	785	(785)	
TOTAL POSTAGE	22,034	14,400	15,185	340	15,525	6,509	29.54%
TRAVEL: IN-STATE							
291 00 TRAVEL: IN-STATE	18,852	0	0	0	0	18,852	
292 00 PER DIEM-I/S	0	0	46	0	46	(46)	
294 00 COMMERCIAL AIR-I/S	0	0	2,199	0	2,199	(2,199)	
296 00 PRIVATE CAR-I/S	0	0	455	0	455	(455)	
297 00 RENTAL CAR-I/S	0	44	117	0	117	(117)	
305 00 MGMT/TRANS FEE-I/S	0	0	60	0	60	(60)	
305 01 CALATERS SERVICE F	0	6	6	0	6	(6)	
TOTAL TRAVEL: IN-STATE	18,852	50	2,883	0	2,883	15,969	84.71%
TRAINING							
331 00 TRAINING	3,237	0	0	0	0	3,237	
TOTAL TRAINING	3,237	0	0	0	0	3,237	100.00%
FACILITIES OPERATIONS							
341 00 FACILITIES OPERATI	60,322	0	0	0	0	60,322	
343 00 RENT-BLDG/GRND(NON	0	6,430	38,275	38,581	76,856	(76,856)	
347 00 FACILITY PLNG-DGS	0	127	627	0	627	(627)	
TOTAL FACILITIES OPERATIONS	60,322	6,557	38,902	38,581	77,484	(17,162)	-28.45%

DEPARTMENT OF CONSUMER AFFAIRS

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C/P SVS - INTERDEPARTMENTAL							
382 00 CONSULT/PROF-INTER	106,644	333	1,667	2,333	4,000	102,644	
TOTAL C/P SVS - INTERDEPARTMENTAL	106,644	333	1,667	2,333	4,000	102,644	96.25%
C/P SVS - EXTERNAL							
402 00 CONSULT/PROF SERV-	110,638	0	0	0	0	110,638	
404 05 C&P EXT ADMIN CR C	0	0	0	21,000	21,000	(21,000)	
418 02 CONS/PROF SVS-EXTR	0	3,234	16,918	5,124	22,042	(22,042)	
TOTAL C/P SVS - EXTERNAL	110,638	3,234	16,918	26,124	43,042	67,596	61.10%
DEPARTMENTAL SERVICES							
424 03 OIS PRO RATA	82,270	0	41,136	0	41,136	41,134	
427 00 INDIRECT DISTRB CO	85,545	0	42,772	0	42,772	42,773	
427 30 DOI - PRO RATA	2,712	0	1,356	0	1,356	1,356	
427 34 PUBLIC AFFAIRS PRO	3,812	0	1,906	0	1,906	1,906	
427 35 CCED PRO RATA	3,247	0	1,624	0	1,624	1,623	
TOTAL DEPARTMENTAL SERVICES	177,586	0	88,794	0	88,794	88,792	50.00%
CONSOLIDATED DATA CENTERS							
428 00 CONSOLIDATED DATA	1,138	1,280	6,612	0	6,612	(5,474)	
TOTAL CONSOLIDATED DATA CENTERS	1,138	1,280	6,612	0	6,612	(5,474)	-481.03%
DATA PROCESSING							
431 00 INFORMATION TECHNO	1,950	0	0	0	0	1,950	
435 00 NOC-SERV-IT (SECUR	0	0	121	0	121	(121)	
436 00 SUPPLIES-IT (PAPER	0	0	407	0	407	(407)	
445 00 SOFTWARE-IT PURCH,	0	0	0	1,583	1,583	(1,583)	
TOTAL DATA PROCESSING	1,950	0	528	1,583	2,111	(161)	-8.26%
CENTRAL ADMINISTRATIVE SERVICES							
438 00 PRO RATA	109,971	0	54,986	0	54,986	54,986	
TOTAL CENTRAL ADMINISTRATIVE SERVICES	109,971	0	54,986	0	54,986	54,986	50.00%
MAJOR EQUIPMENT							
453 00 OFFICE EQPT-REPL	0	0	0	8,800	8,800	(8,800)	
472 00 ADDITIONAL EQUIPME	8,500	0	0	0	0	8,500	
TOTAL MAJOR EQUIPMENT	8,500	0	0	8,800	8,800	(300)	-3.53%
ENFORCEMENT							
396 00 ATTORNEY GENL-INTE	268,984	26,791	153,935	0	153,935	115,050	
397 00 OFC ADMIN HEARNG-I	18,527	3,119	7,646	0	7,646	10,881	

DEPARTMENT OF CONSUMER AFFAIRS

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414 31 EVIDENCE/WITNESS F	8,646	1,638	4,228	0	4,228	4,418	
414 34 EVIDENCE	0	0	24	0	24	(24)	
418 97 COURT REPORTER SER	0	234	384	0	384	(384)	
427 32 INVEST SVS-MBC ONL	124,000	7,122	19,009	0	19,009	104,991	
TOTAL ENFORCEMENT	420,157	38,903	185,225	0	185,225	234,932	55.92%
MINOR EQUIPMENT							
226 00 MINOR EQUIPMENT	1,500	0	0	0	0	1,500	
226 10 MIN EQPMT-GEN-ADD'	0	2,570	2,570	0	2,570	(2,570)	
226 15 MIN EQPMT-GEN-REPL	0	0	6,600	33	6,633	(6,633)	
226 40 MIN EQPMT-DP-ADD'L	0	0	686	0	686	(686)	
TOTAL MINOR EQUIPMENT	1,500	2,570	9,856	33	9,889	(8,389)	-559.27%
TOTAL OPERATING EXPENSES & EQUIPMEN	1,126,295	70,624	443,204	77,869	521,073	605,222	53.74%
TEOPATHIC MEDICAL BOARD OF CALIFORNIA	1,865,000	132,803	805,166	77,869	883,035	981,965	52.65%
	1,865,000	132,803	805,166	77,869	883,035	981,965	52.65%

DEPARTMENT OF CONSUMER AFFAIRS

THE OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA
 DISTRIBUTED-OSTEOPATHIC MEDICAL BOARD OF CA

BUDGET REPORT
 AS OF 12/31/2013

RUN DATE 1/13/2014

PAGE 1

FM 06

DIST - OSTEOPATHIC MEDICAL BOARD

DESCRIPTION	BUDGET	CURR. MONTH	YR-TO-DATE	ENCUMBRANCE	YTD + ENCUMBRANCE	BALANCE	PCNT REMAIN
INTERNAL COST RECOVERY							
INTERNAL COST RECOVERY							
912 00 INTERNAL COST RECO	(14,000)	0	0	0	0	(14,000)	
<u>TOTAL</u> INTERNAL COST RECOVERY	(14,000)	0	0	0	0	(14,000)	100.00%
<u>TOTAL</u> INTERNAL COST RECOVERY	(14,000)	0	0	0	0	(14,000)	100.00%
<hr/>							
DIST - OSTEOPATHIC MEDICAL BOARD	(14,000)	0	0	0	0	(14,000)	100.00%
<hr/>							
	(14,000)	0	0	0	0	(14,000)	100.00%
<hr/>							

DEPARTMENT OF CONSUMER AFFAIRS
ENCUMBRANCE REPORT

AS OF: 12/31/2013

FM 06

RUN DATE: 1/13/2014

14850 OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA

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DOCUMENT	VENDOR	ORIG. AMOUNT	ADJUSTMENTS	LIQUIDATIONS	BALANCE
GENERAL EXPENSE					
226 15 REQ00111-18	0000013683-00 PITNEY BOWES INC	\$6,632.61	\$0.00	(\$6,599.89)	\$32.72
TOTAL GENERAL EXPENSE					\$32.72
PRINTING					
246 REQ01134-1B	0000065283-00 SMILE BUSINESS PR	\$74.09	\$0.00	\$0.00	\$74.09
TOTAL PRINTING					\$74.09
POSTAGE					
263 REQ00115-91	0000013683-00 PITNEY BOWES INC	\$340.20	\$0.00	\$0.00	\$340.20
TOTAL POSTAGE					\$340.20
FACILITIES OPERATIONS					
343 5636-004-00	0000072629-00 ETHAN CONRAD	\$76,856.20	\$0.00	(\$38,275.00)	\$38,581.20
TOTAL FACILITIES OPERATIONS					\$38,581.20
C/P SVS - INTERDEPARTMENTAL					
382 REQ00069-65	0000020095-00 DEPT OF JUSTICE	\$4,000.00	\$0.00	(\$1,666.70)	\$2,333.30
TOTAL C/P SVS - INTERDEPARTMENTAL					\$2,333.30
C/P SVS - EXTERNAL					
404 05 REQ00828-5V	0000074019-01 ELAVON INC	\$20,000.00	\$0.00	\$0.00	\$20,000.00
404 05 REQ00828-8V	0000073449-00 AMERICAN EXPRESS	\$1,000.00	\$0.00	\$0.00	\$1,000.00
418 02 REQ03674-OS	0000069741-01 MAXIMUS HEALTH SE	\$22,042.08	\$0.00	(\$16,918.40)	\$5,123.68
TOTAL C/P SVS - EXTERNAL					\$26,123.68
DATA PROCESSING					
445 REQ00822-0F	0000052379-00 COMPUCOM SYSTEMS,	\$1,583.42	\$0.00	\$0.00	\$1,583.42
TOTAL DATA PROCESSING					\$1,583.42

DEPARTMENT OF CONSUMER AFFAIRS
ENCUMBRANCE REPORT

AS OF: 12/31/2013

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RUN DATE: 1/13/2014

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14850 OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA

DOCUMENT	VENDOR	ORIG. AMOUNT	ADJUSTMENTS	LIQUIDATIONS	BALANCE	
MAJOR EQUIPMENT						
453	REQ01134-1A 0000065283-00	SMILE BUSINESS PR	\$8,800.14	\$0.00	\$0.00	\$8,800.14
TOTAL	MAJOR EQUIPMENT					\$8,800.14

14850 OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA

\$77,868.75

CSTARH10 1110 (DEST: A1 CAL2) PM,C,6,5,4,0,
 FISCAL MONTH: 06 DECEMBER 6(INDEX) 5(PCAS) 4(AGYOBJ) 0(NOFUND) FUND(ALL) GL(ALL)
 DEPT OF CONSUMER AFFAIRS - REGULATORY BOARDS
 HISTORY FILE EXPENDITURE RECORDS SUPPORTING THE Q16 REPORT
 AS OF 12/31/13

***** RUN:01/13/14 TIME:18.33

***** PAGE 263

FFY: 13
 PCA: 70-01-000-000-14850 OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA

 SEC SS U SU SSU INDEX DESCRIPTION C OB OD AO DESCRIPTION

INVOICE	DOC DATE	REF DOC	SX CUR DOC	SX CLAIM NO	BATCH	HDR PR DATE	TC R	VENDOR NAME	CUR MONTH EXP
*TOTAL AGENCY OBJECT 00 FACILITY PLNG-DGS									126.67
17 10 00 00 00	1485	OSTEOPATHIC MEDICAL BOARD OF	C 3	25 382 00	CONSULT/PROF-INTERDEPT				
009462	12/20/13	REQ0006965	JUS0000785	13123107057	12/31/13 245	DEPT OF JUSTICE			333.34
*TOTAL AGENCY OBJECT 00 CONSULT/PROF-INTERDEPT									333.34
17 10 00 00 00	1485	OSTEOPATHIC MEDICAL BOARD OF	C 3	25 396 00	ATTORNEY GENL-INTERDEPT				
008903	12/20/13	JUS0000784	13123107054	01/02/14 242	DEPT OF JUSTICE				26,791.00
*TOTAL AGENCY OBJECT 00 ATTORNEY GENL-INTERDEPT									26,791.00
17 10 00 00 00	1485	OSTEOPATHIC MEDICAL BOARD OF	C 3	25 397 00	OFC ADMIN HEARNG-INTERDEPT				
2741920	12/11/13	10-2013 GS13001528	131203XE015	12/26/13 242	DEPT OF GENERAL SERVICES				3,118.75
*TOTAL AGENCY OBJECT 00 OFC ADMIN HEARNG-INTERDEPT									3,118.75
17 10 00 00 00	1485	OSTEOPATHIC MEDICAL BOARD OF	C 3	26 414 31	EVIDENCE/WITNESS FEES				
PD PREP/MEETIN	12/08/13	EOMB000010	1301446	14010304132	01/03/14 231	GEORGE M BIFANO			588.00
00-2012-3641	11/30/13	EOMB000006	1301446	14010304132	01/03/14 231	JOHN J KOWALCZYK			300.00
00-2013-3913	12/04/13	EOMB000015	1301389	13122004085	12/20/13 231	LORI BIRNDORF			750.00
*TOTAL AGENCY OBJECT 31 EVIDENCE/WITNESS FEES									1,638.00
17 10 00 00 00	1485	OSTEOPATHIC MEDICAL BOARD OF	C 3	26 418 02	CONS/PROF SVS-EXTRNL				
DIV-949	12/02/13	REQ03674OS REQ03674OS	1301377	13123003015	12/30/13 214	MAXIMUS HEALTH SERVICES INC			323.37
		REQ03674OS	1301377	13122304096	12/23/13 232	MAXIMUS HEALTH SERVICES INC			2,910.31
*TOTAL AGENCY OBJECT 02 CONS/PROF SVS-EXTRNL									3,233.68
17 10 00 00 00	1485	OSTEOPATHIC MEDICAL BOARD OF	C 3	26 418 97	COURT REPORTER SERVS				
140617	11/27/13	1301391	13122004087	12/20/13 231	KENNEDY COURT REPORTERS				83.50
69072	11/21/13	1301391	13122004087	12/20/13 231	DIAMOND COURT REPORTERS				150.00
*TOTAL AGENCY OBJECT 97 COURT REPORTER SERVS									233.50
17 10 00 00 00	1485	OSTEOPATHIC MEDICAL BOARD OF	C 3	27 427 32	INVEST SVS-MBC ONLY				
	12/16/13	NOV 201300	13121607031	12/16/13 242					7,122.00
*TOTAL AGENCY OBJECT 32 INVEST SVS-MBC ONLY									7,122.00
17 10 00 00 00	1485	OSTEOPATHIC MEDICAL BOARD OF	C 3	28 428 00	CONSOLIDATED DATA CENTRS				
DC1314050BX	12/16/13	IO13060265	14010607071	01/06/14 242	OFC OF THE ST CHIEF INFO-OCIO				1,279.52

CSTARH10 1110 (DEST: A1 CAL2) PM,C,6,5,4,0,
 FISCAL MONTH: 06 DECEMBER 6(INDEX) 5(PCA) 4(AGYOBJ) 0(NOFUND) FUND(ALL) GL(ALL)
 DEPT OF CONSUMER AFFAIRS - REGULATORY BOARDS
 HISTORY FILE EXPENDITURE RECORDS SUPPORTING THE Q16 REPORT
 AS OF 12/31/13

***** RUN:01/13/14 TIME:18.33

***** PAGE 264

FFY: 13
 PCA: 70-01-000-000-14850 OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA

 SEC SS U SU SSU INDEX DESCRIPTION C OB OD AO DESCRIPTION

INVOICE	DOC DATE	REF DOC	SX CUR	DOC SX	CLAIM NO	BATCH	HDR PR	DATE	TC	R	VENDOR NAME	CUR MONTH EXP
*TOTAL AGENCY OBJECT 00	CONSOLIDATED DATA CENTRS											1,279.52
*TOTAL INDEX 1485	OSTEOPATHIC MEDICAL BOARD OF C											132,802.77
*TOTAL PCA 14850	OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA											132,802.77

CSTARQ24 1110 (DEST: A1 CAL2) PM,C,6,5,2,0, ,6212,
 FISCAL MONTH: 06 DECEMBER 6(INDEX) 5(PCA) 2(AGYSRC) 0(NOFUND) FUND(ALL) GL(6212)
 DEPT OF CONSUMER AFFAIRS - REGULATORY BOARDS
 RECEIPTS BY ORGANIZATION AND SOURCE
 AS OF 12/31/13

***** RUN:01/13/14 TIME:18.33

***** PAGE 19

ENVY: 13 FFY: 13
 SECTION: 17 SECTION 17
 SUB-SECTION: 10 OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA
 UNIT: 00
 SUB-UNIT: 00
 SUB-SUB-UNIT: 00
 INDEX: 1485 OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA

PROGRAM
 PG EL CMP TSK PCA DESCRIPTION

REF	SOURCE	ASRC	DESCRIPTION	PLANNED RECEIPTS	ACTUAL CURRENT MONTH	RECEIPTS YEAR-TO-DATE	BALANCE
70 01 000 000	72640		REIMB - OSTEOPATHIC MEDICAL BOARD OF CA				
001 991937	01		FINGERPRINT REPORTS	25,000.00	539.00	17,022.00	7,978.00
001 991937	02		EXTERNAL/PRIVATE/GRANT	28,000.00	245.00	1,930.00	26,070.00
*TOTAL SOURCE 991937				53,000.00	784.00	18,952.00	34,048.00
001 995988	01		UNSCHED-INVESTIGATIVE COST RECOVER	0.00	1,000.00	16,386.00	16,386.00-
*TOTAL SOURCE 995988				0.00	1,000.00	16,386.00	16,386.00-
*TOTAL PROG 70				53,000.00	1,784.00	35,338.00	17,662.00
*TOTAL REFERENCE 001				53,000.00	1,784.00	35,338.00	17,662.00
70 01 000 000	82640		OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA				
980 125600	CW		PHYSICIAN/SURGEON-REINSTATEMENT F	0.00	0.00	2,742.00	2,742.00-
980 125600	CY		DUPLICATE CERTIFICATE-\$25.00	0.00	550.00	2,800.00	2,800.00-
980 125600	DA		ENDORSEMENT FEE-\$25.00	0.00	0.00	2,850.00	2,850.00-
980 125600	DD		LICENSE STATUS CHANGE FEE-VARIABL	0.00	0.00	250.00	250.00-
980 125600	00		OTHER REGULATORY FEES	32,000.00	0.00	0.00	32,000.00
*TOTAL SOURCE 125600				32,000.00	550.00	8,642.00	23,358.00
980 125700	B4		PHYSICIAN/SURGEON-ORIG APP FEE-\$2	0.00	2,000.00	70,010.00	70,010.00-
980 125700	B6		PHYSICIAN/SURGEON-LICENSE FEE-VAR	0.00	2,010.00	55,920.00	55,920.00-
980 125700	B9		FICTITIOUS NAME PERMIT APP FEE \$1	0.00	350.00	4,350.00	4,350.00-
980 125700	00		OTHER REGULATORY LICENSES AND PER	243,000.00	0.00	0.00	243,000.00
980 125700	90		OVER/SHORT FEES	0.00	0.00	2.00	2.00-
980 125700	91		SUSPENDED REVENUE	0.00	2,080.00	14,994.00	14,994.00-
*TOTAL SOURCE 125700				243,000.00	6,440.00	145,276.00	97,724.00
980 125800	BR		BIENNIAL TAX AND REGISTRATION FEE	0.00	23,750.00	598,100.00	598,100.00-

CSTARQ24 1110 (DEST: A1 CAL2) PM,C,6,5,2,0, ,6212,
 FISCAL MONTH: 06 DECEMBER 6(INDEX) 5(PCAS) 2(AGYSRC) 0(NOFUND) FUND(ALL) GL(6212)
 DEPT OF CONSUMER AFFAIRS - REGULATORY BOARDS
 RECEIPTS BY ORGANIZATION AND SOURCE
 AS OF 12/31/13

***** RUN:01/13/14 TIME:18.33

***** PAGE 20

ENY: 13 FFY: 13
 SECTION: 17 SECTION 17
 SUB-SECTION: 10 OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA
 UNIT: 00
 SUB-UNIT: 00
 SUB-SUB-UNIT: 00
 INDEX: 1485 OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA

PROGRAM
 PG EL CMP TSK PCA DESCRIPTION

REF	SOURCE	ASRC	DESCRIPTION	PLANNED RECEIPTS	ACTUAL RECEIPTS		BALANCE
					CURRENT MONTH	YEAR-TO-DATE	
980	125800	BS	BIENNIAL INACTIVE CERTIFICATION F	0.00	4,200.00	47,425.00	47,425.00-
980	125800	BT	ANNUAL RENEWAL-FICTITIOUS NAME PE	0.00	16,000.00	16,750.00	16,750.00-
980	125800	C1	AUTOMATED REVENUE REFUND CLAIM	0.00	100.00-	0.00	0.00
980	125800	00	RENEWAL FEES	1,303,000.00	0.00	0.00	1,303,000.00
*TOTAL SOURCE 125800				1,303,000.00	43,850.00	662,275.00	640,725.00
980	125900	A6	DELINQUENT TAX AND REGISTRATION F	0.00	300.00	2,425.00	2,425.00-
980	125900	A7	DELINQUENT INACTIVE RENEWAL-\$75.0	0.00	0.00	1,300.00	1,300.00-
980	125900	00	DELINQUENT FEES	8,000.00	0.00	0.00	8,000.00
*TOTAL SOURCE 125900				8,000.00	300.00	3,725.00	4,275.00
980	141200	00	SALES OF DOCUMENTS	0.00	0.00	205.00	205.00-
*TOTAL SOURCE 141200				0.00	0.00	205.00	205.00-
980	150300	00	INCOME FROM SURPLUS MONEY INVESTM	5,000.00	0.00	1,935.08	3,064.92
*TOTAL SOURCE 150300				5,000.00	0.00	1,935.08	3,064.92
980	161400	91	DISHONORED CHECK FEE-VAR	0.00	0.00	25.00	25.00-
*TOTAL SOURCE 161400				0.00	0.00	25.00	25.00-
*TOTAL PROG 70				1,591,000.00	51,140.00	822,083.08	768,916.92
*TOTAL REFERENCE 980				1,591,000.00	51,140.00	822,083.08	768,916.92
*TOTAL INDEX 1485				1,644,000.00	52,924.00	857,421.08	786,578.92
*TOTAL SBSEC 10				1,644,000.00	52,924.00	857,421.08	786,578.92

TABLE 4

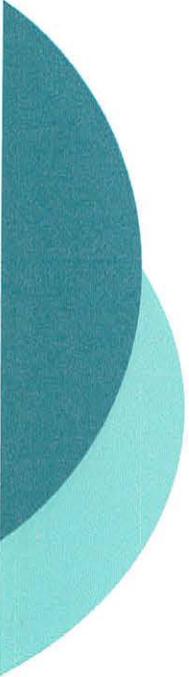


California Health Professionals Diversion Program

**Presented to the
Osteopathic Medical
Board of California**

January 23, 2014

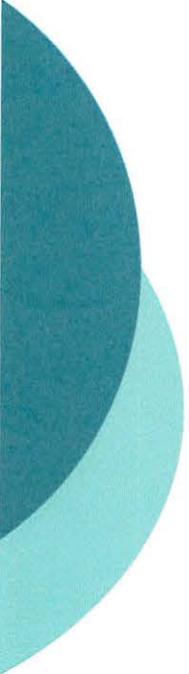
MAXIMUS HEALTH PROFESSIONALS
DIVERSION PROGRAM



Introductions

Virginia Matthews, RN, BSN, MBA
Project Manager

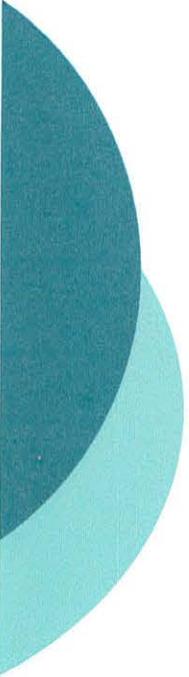
Anne Mireles, RN, BSN
Clinical Case Manager



Program Leadership

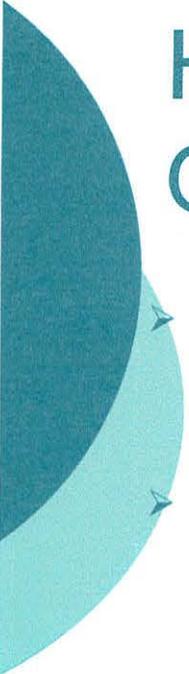
Virginia (Ginny) Matthews, RN, BSN, MBA

- ✓ More than 30 years of experience in the healthcare industry
- ✓ Nursing experience includes direct patient care in psychiatric and substance use disorder settings
- ✓ Leadership experience covers program and hospital administration in a variety of settings
- ✓ Current President of NOAP, the National Organization of Alternative Programs, a nationwide networking organization for health professional monitoring programs



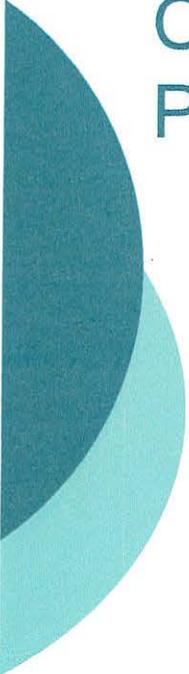
PROGRAM MISSION

- To protect the public
- To assist Health Professionals to return safely to practice



Health Professionals Monitoring Overview

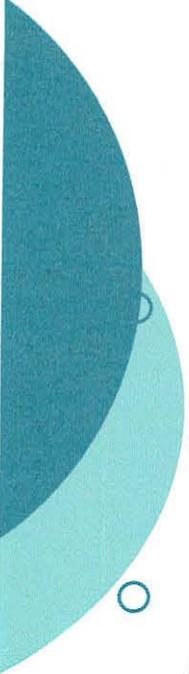
- California's program was one of the first Diversion/ Health Professional Monitoring Programs in the U.S., implemented in 1986 by the California Legislature
- The MAXIMUS California Diversion program is the only ISO-9000:2008 Certified program of this type in the world, demonstrating consistency, adherence to contract requirements and high quality standards
- MAXIMUS has partnered with California's Department of Consumer Affairs since 2003 to administer the program. The contract was renewed in 2010, and is currently in the first of two Option Years
- California's Program is one of the largest programs in the country, serving approximately 650 licensed Health Care Professionals from seven licensing boards, diagnosed with Substance Use Disorders and/or mental illness



California Health Professionals Diversion Program Overview

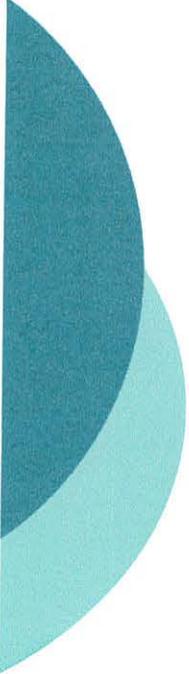
BOARD	PARTICIPANTS*
Board of Registered Nursing	490
Board of Pharmacy	70
Physical Therapy Board of California	15
Osteopathic Medical Board	12
Veterinary Medical Board	3
Physician Assistant Committee	15
Dental Board of California	35
Dental Hygiene Committee	2
TOTAL	655

*Numbers are Approximate



How the Diversion Program Achieves its Goals:

- Suspension of Practice upon enrollment to immediately provide for public protection (more effective alternative to the longer disciplinary process, which allows licensees to continue working)
- Return to full practice with supervision, coordinated monitoring, and communication with workplace
- Random Drug Testing via independent third party administrator
- Sophisticated Quality Assurance monitoring program incorporates continuous and intermittent internal audits and prompt feedback
- ISO 9000-2008 Certification, only program with this certification, ensures adherence to contract and quality standards



CONTRACTOR RESPONSIBILITIES

- Maintain toll-free telephone response system 24 hours/day, 7 days/week, crisis calls, assist with interventions
- Complete comprehensive intake and assessment of applicants
- Monitor applicants and participants
- Provide outreach and education

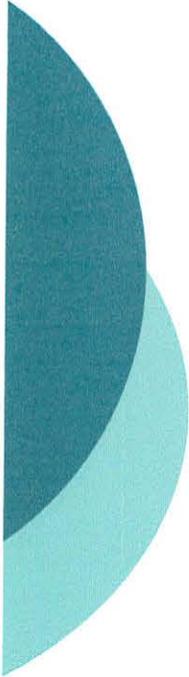
Program Components: DEC Model

Diversion Evaluation Committee (DEC) Model

- ✓ The State of California uses a unique model of participant review involving a committee appointed by the Licensing Boards
- ✓ Each Committee is composed of professionals with experience and training in Substance Use Disorders, and licensed in the profession of the licensee. *Each DEC group brings a cumulative 150 to 200 years of experience to the table*
- ✓ Example: a OMB DEC consists of three Osteopathic physicians, and a Public Member, and is attended by the Case Manager and a Board representative



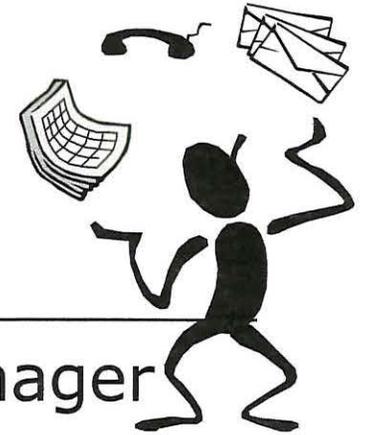
Each committee reviews its assigned participants **face-to-face**, 1 to 4 times per year. This allows the Board, the Case Manager and the Committee to assess the participant's progress in recovery and make informed decisions regarding changes to the plan



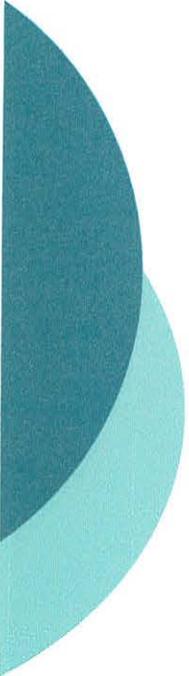
CASE MANAGER and DEC RESPONSIBILITIES AND DUTIES

- Determine appropriateness for acceptance into Program
- Determine readiness to return to work
- Determine rehabilitation/recovery plan
- Analyze compliance with program requirements (Drug Testing, Support Group attendance, 12-Step meeting attendance, Worksite Monitor, Treatment compliance)
- Determine completion (successful or unsuccessful)

How Program Participants are monitored:



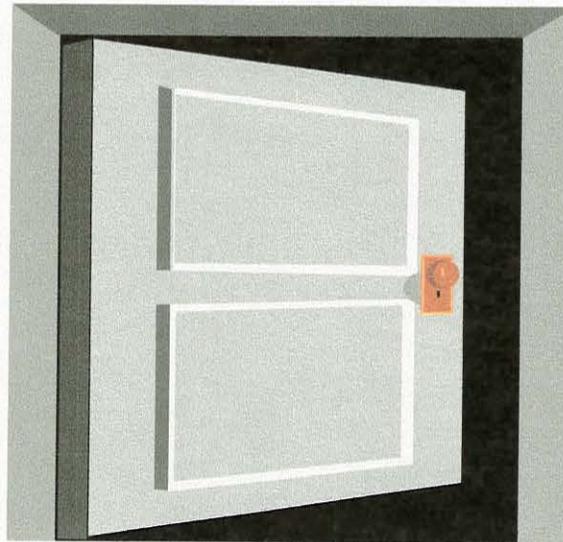
- Intake interview by MAXIMUS Case Manager
- Clinical assessment “in the field” by an evaluator, Licensed Clinician
- Reports from treatment facility, therapist, physician, etc.
- Random Drug Testing
- Monthly self-report
- Monthly report from Support Group Facilitator
- Attendance cards for 12-Step meetings
- Worksite monitor report monthly/quarterly
- Participant contact by phone weekly/monthly



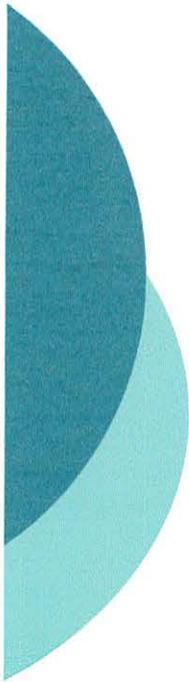
HEALTH SUPPORT GROUPS

- Approximately 30 Support Groups located throughout California, with Facilitators who are licensed clinicians approved by MAXIMUS
- Groups provide peer support regarding issues related to the process of recovery and re-entry into the workplace
- Facilitators see participants in-person, weekly or twice weekly, and are able to detect changes in behavior/signs of relapse, and quickly report to MAXIMUS

How does a Health Professional get into the Program?



- Self-referral
- Probation referral



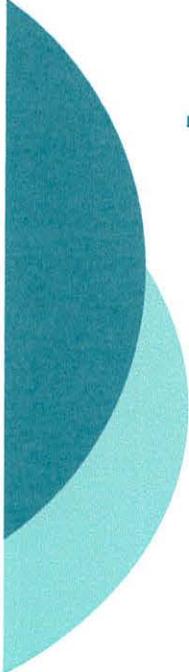
Typical Recovery Terms on Entry:

- Suspend practice (NOT suspending the license). Uniform Standards require 30 days of negative test results before being allowed to return to work.
- Treatment (in-patient, out-patient, etc.- treatment plan is individualized)
- Twelve step meetings - Daily (minimum 90/90 to start), include Caduceus meeting
- Health Support Group once or twice a week



Typical Recovery Terms on Entry:

- Random urine drug testing (52-104 times yearly).
- Hair, nail and other body fluid testing - longer period of detection.
- Complete abstinence from mind altering substances. If taking Rx, may not work
- Sponsor with five years sobriety.
- May not leave home area for >24 hours without program approval.

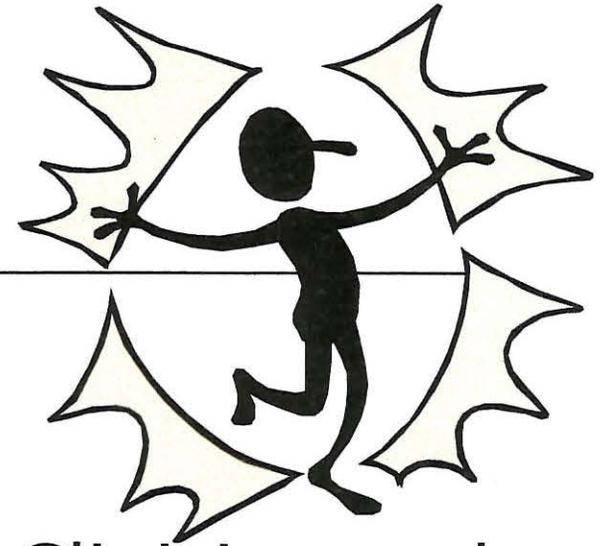


Typical Progression Through Program

Meetings:

- Begin with daily 12-Step meetings, reduce daily meetings slowly (over 1-2 years) to 3 to 5 meetings per week
 - PLUS twice-weekly Health Support Group
 - PLUS one year of weekly Aftercare
- Specific types of meetings (AA, NA, Women's, Men's, etc.) may be required--this is individualized to participant
- Same-gender sponsor with at least 5 years of sobriety

Typical Progression Through Program



Return to Practice:

- Initially suspend practice
- Assessment with a Licensed Clinician and Random Drug Testing at least 30 days of negative results before return to practice
- Positive drug test, missed call, missed test, or other major noncompliance results in immediate removal from practice
- Progression is individualized

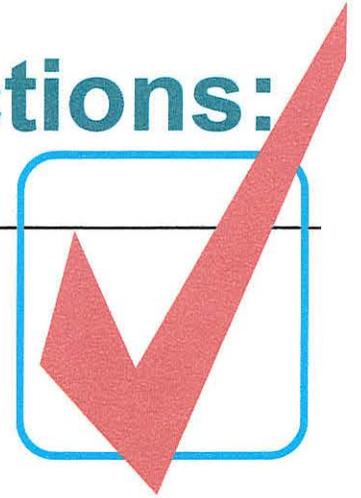


Requirements to Return to Practice:

- 30 days of negative drug test results
- Job description must be submitted and approved prior to returning to work
- Must obtain a Worksite Monitor who is in a supervisory position
- Must authorize communication between Worksite Monitor and MAXIMUS
- Worksite Monitor submits monthly reports for 3 months, then quarterly
- Worksite Monitor informed within 1 hour if participant is removed from work for positive result, missed call, or missed test

Examples of work restrictions:

- ✓ Restricted to 40 hours per week or less
- ✓ No night shifts
- ✓ No multiple work locations
- ✓ Must have contact with Worksite Monitor at least weekly, or more frequently if requested by the Board



Program Components: Drug Testing

- ✓ Drug testing is coordinated by an independent Third Party Administrator (TPA), enlisting an analytical lab with SAMHSA certification and extensive experience working with Professional Health Monitoring Programs, and a nationwide network of collection sites
- ✓ Drug testing program, utilizes the ***most comprehensive test panel among monitoring programs in the US, and low cutoff thresholds to support a total abstinence model***

TPA notifies the program

- the following business day of missed daily check-in with lab
- Failure to appear/missed test
- Non-Compliance with observed collection requirement

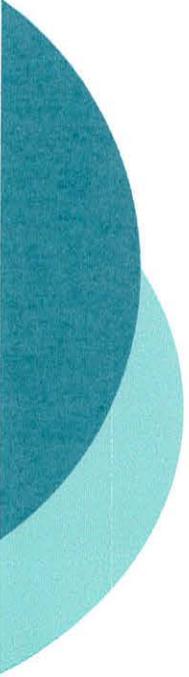
Quality Assurance process in place to monitor results for accuracy and timeliness



MAXIMUS

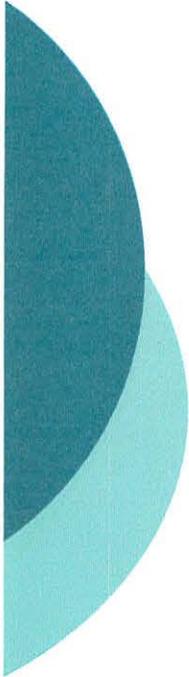
HEALTH PROFESSIONALS DIVERSION PROGRAM

20



Random Drug Testing

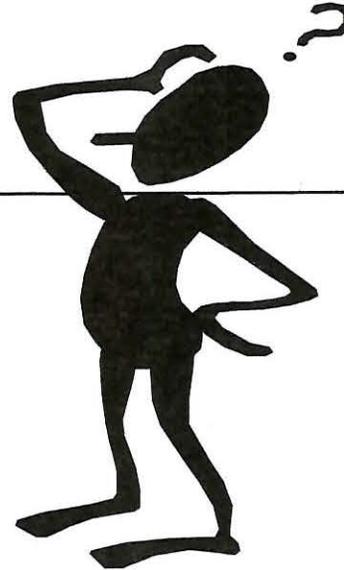
- Randomized testing, scheduled by computer
- Call-in or login each day, 7 days/week, between 5 a.m. – 8 p.m.
- Observed testing (Department of Transportation guidelines) performed at collection facilities throughout California
 - Same test panel each time, most extensive panel in the country, lowest cutoffs
 - Capability to add drug-specific test if needed
- Must test on same day as notified of selection unless Board approves cancellation or rescheduling of test
- No travel out of country allowed; must arrange test collection sites prior to travel within the U.S.



What is the cost to the Participant?

- Treatment costs, self-pay or insurance
- Random Drug Testing and collection costs - \$62.50 per test, plus cost of collection (ranges from \$15 to \$75 or more depending on collector and day of collection)
- Health Support Group - \$150 to \$400 per month, varies by group
- Healthcare costs associated with outpatient visits, psych exam, counseling, therapy, etc.
- Administrative fee co-pay -
Dental Board is \$100 per month

Diversion Program Questions



Ginny Matthews, RN, BSN, MBA
Program Manager
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TABLE 5

Osteopathic Medical Board of California-Code of Ethics - DRAFT

The Osteopathic Medical Board of California Code of Ethics is adapted from the American Osteopath Association code of Ethics annotated with corresponding section numbers from this document with enclosed crosswalks from the Business and Professions Standards in the laws relating to the practice of Osteopathic Medicine Edition 2005 or the California Code of Regulations specific to healthcare regulation. The code of ethics of the American Osteopathic Association was not adopted in its entirety due to conflicts with current state law or inability to enforce such a provision under California state law.

1. Section 1- The physician shall keep in confidence whatever he/she may learn about a patient in the discharge of professional duties. Information shall be divulged by the physician when required by law or when authorized by the patient. (Business and professional Code 2263, Violation of Professional Confidence-the willful, unauthorized violation of professional confidence constitutes unprofessional conduct.)
2. Section 2- The physician shall give a candid account of the patient's condition to the patient or to those responsible for the patient's care. (Business and Professional codes 2220.08 (B) A division of medical Quality: Authority; 2225.5 Records Requests compliance; 2261 Making False Statements; 2262.
3. Section 3- A physician-patient relationship must be founded on mutual trust, cooperation, and respect. The patient, therefore, must have complete freedom to choose his/her physician. The physician must have complete freedom to choose patients whom he/she will serve. However, the physician should not refuse to accept patients for reasons of discrimination, including, but not limited to, the patient's race, creed, color, sex, national origin, sexual orientation, gender identity or handicap. In emergencies, a physician should make his/her services available. (Business and Professional Code 125.6 Unprofessional Conduct-discrimination; 2395 – 98 Emergency Care- Scene of an Emergency, Emergency Care-Obstetrical Services, Emergency Care-Medical Complications, Emergency Care-Informed Consent, and Emergency Care-Athletic Events.
4. Section 4- A physician is never justified in abandoning a patient. The physician shall give a written ~~one-month's~~ notice to patients or to those responsible for the patient's care *by certified-return receipt 30 days before* when he/she withdraws from the case so that in other physician may be engaged.

5. Section 5- A physician shall practice in accordance with the body of systemized and scientific knowledge related to the healing arts. A physician shall maintain competence in such systemized and scientific knowledge through study and clinical applications. California Code of Regulations-CCRS Division 16, Article 9, Sections 1635-1641, Business and Professions Code 2454.5 Adoption and Administration of Continuing Education Standards, 2190.5 Continuing Medical Education-Pain Management.

6. Section 6-Under the law a physician may advertise, but no physician shall advertise or solicit patients directly or indirectly through the use of matters or activities which are false or misleading. Business and Professional Codes 651 Advertising, Advertising Without Use of Name, Employment of Carriers and Steerers.

7. Section 7-A physician shall not hold forth or indicate possession of any degree recognized as the basis for licensure to practice the healing arts unless he is actually licensed on the basis of that degree. A physician shall designate his/her osteopathic school of practice and all professional uses of his/her name. Indications of specialty practice, membership in professional societies, and related matters shall be governed by the rules promulgated by the American Osteopathic Association. Business and Professional Codes §2235 Procuring License by Fraud, §2274 – 76 Misuse of Titles, Election of M. D., §2288 – 89 Impersonation-Examination, Impersonation-Practice of Medicine, §2453.5 Board Certification.

8. Section 8-A physician should not hesitate to seek consultation whenever he/she believes it is advisable for the care of the patient.

9. Section 9-In any dispute between or among physicians regarding the diagnosis and treatment of a patient, the attending physician has the responsibility for the final decisions, consistent with any applicable hospital rules or regulations.

10. Section 10-Any fee charged by a physician shall compensate the physician for services actually rendered. There shall be no division of professional fees for

referrals of patients. Business and Professional Code §650 Consideration for Referrals Prohibited, §2284 Fee Sharing prohibited-Employment of Acupuncturists.

11. Section 11-A physician shall respect the law *abide by?*. When necessary a physician shall *may* attempt to help to formulate the law by all proper means in order to improve patient care and public health.

12. Section 12-It is considered sexual misconduct for a physician to have sexual contact with any current patient whom the ~~patient~~ *physician* has interviewed and/or upon whom a medical or surgical procedure has been performed. Business and professional codes §726 – 29 Sexual Relations with Patients, Evidentiary Rule, Psychotherapists-Knowledge of Sexual Conduct with Previous Psychotherapist, Psychotherapist Sexual Exploitation, §2246 Sexual Exploitation.

13. Section 13-Sexual-harassment by physician is considered unethical. Sexual harassment is defined as physical or verbal intimidation of a sexual nature involving a colleague or subordinate in the workplace or academic setting, when such conduct creates an unreasonable, intimidating, hostile or offensive workplace or academic setting. Business and professional codes §729 Psychotherapist Sexual Exploitation, §2246 Sexual Exploitation.

TABLE 6

**Model Policy on
the Use of Opioid
Analgesics in the
Treatment of
Chronic Pain**

July 2013

The recommendations contained herein were adopted as policy by the Executive Committee of the Federation of State Medical Boards of the United States, Inc., July 2013.

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MODEL POLICY ON THE USE OF OPIOID ANALGESICS IN THE TREATMENT OF CHRONIC PAIN

INTRODUCTION

The Federation of State Medical Boards (FSMB) is committed to assisting state Medical Boards in protecting the public and improving the quality and integrity of health care in the United States. In 1997, the FSMB undertook an initiative to develop model guidelines and to encourage state medical boards and other health care regulatory agencies to adopt policies encouraging safe and effective treatment of patients with pain, including, if indicated, the use of opioid analgesics. [1]. The FSMB updated its guidelines in 2003 [2] so that its Model Policy would reflect the best available evidence on management of pain and give adequate attention to both the undertreatment and overtreatment of pain and the inappropriate use of opioid analgesics.

Through these initiatives, the FSMB has sought to provide a resource for use by state medical boards in educating their licensees about cautious and responsible prescribing of controlled substances while alleviating fears of regulatory scrutiny. The FSMB recognizes that inappropriate prescribing can contribute to adverse outcomes such as reduced function, opioid addiction, overdose, and death [3-5]. By promulgating its Model Policies, the FSMB has sought to provide a framework for the legitimate medical use of opioid analgesics for the treatment of pain while emphasizing the need to safeguard against their misuse and diversion.

Since their publication, the 1998 and 2004 Model Policies have been widely distributed to state medical boards, medical professional organizations, other health care regulatory boards, patient advocacy groups, pharmaceutical companies, state and federal regulatory agencies, and practicing physicians and other health care providers. The policies have been endorsed by the American Academy of Pain Medicine, the Drug Enforcement Administration, the American Pain Society, and the National Association of State Controlled Substances Authorities. Many states have adopted all or part of the Model Policies.¹

The updated Model Policy presented here reflects the considerable body of research and experience accrued since the 2004 revision was adopted [2]. While recognizing that adequate evidence is currently lacking as to the effectiveness and safety of long-term opioid therapy, this Model Policy is designed to promote the public health by encouraging state medical boards to adopt consistent policy regarding the treatment of pain, particularly chronic pain, and to promote patient access to appropriate pain management and, if indicated, substance abuse and addiction treatment. The Model Policy emphasizes the professional and ethical responsibility of physicians to appropriately assess and manage patients' pain, assess the relative level of risk for misuse and addiction, monitor for aberrant behaviors and intervene as appropriate. It also includes references and the definitions of key terms used in pain management.

¹ As of March 7, 2012, 57 of 70 State Medical Boards have policy, rules, regulations or statutes reflecting the Federation's 1997 or 2004 *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*.

Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain

The FSMB encourages every state medical board to work with the state attorney general to evaluate the state's policies, regulations and laws in an effort to identify any barriers to the effective and appropriate use of opioids to relieve pain, while ensuring that adequate safeguards are in place to deter and rapidly detect those who would obtain opioid analgesics for nonmedical purposes [6-7].

The FSMB acknowledges with gratitude the efforts of the state board members and directors who collaborated to prepare this updated Model Policy, as well as the contributions of the independent experts and medical organizations that advised the drafting committee and reviewed its work. The FSMB also thanks SAMHSA for its support of this important project.

ISSUES ADDRESSED IN THE NEW MODEL POLICY

There is a significant body of evidence suggesting that many Americans suffer from chronic pain and much of that pain is inadequately or ineffectively treated [8-10]. Since the 2004 revision, evidence for risk associated with opioids has surged, while evidence for benefits has remained controversial and insufficient. Over the last decade, there has been a parallel increase in opioid sales and an increase in morbidity and mortality associated with these drugs. At the same time, approximately one in four patients seen in primary care settings suffers from pain so intense as to interfere with the activities of daily living [4]. Pain arises from multiple causes and often is categorized as either *acute pain* (such as that from traumatic injury and surgery) or *chronic pain* (such as the pain associated with terminal conditions such as cancer or severe vascular disease or with non-terminal conditions such as arthritis or neuropathy) [4,8]. This model policy applies most directly to the treatment of chronic pain and the use of opioid analgesics but many of the strategies to improve appropriate prescribing and mitigate risks can be applied to the use of other controlled medications and to the treatment of acute pain.

Undertreatment of pain is recognized as a serious public health problem that compromises patients' functional status and quality of life [4,9]. A myriad of psychological, social, economic, political, legal and educational factors—including inconsistencies and restrictions in state pain policies—can either facilitate or impede the ability and willingness of physicians to manage patients with pain [6,10-11].

While acknowledging that undertreatment of pain exists, it must be understood that chronic pain often is intractable, that the current state of medical knowledge and medical therapies, including opioid analgesics, does not provide for complete elimination of chronic pain in most cases, and that the existence of persistent and disabling pain does not in and of itself constitute evidence of undertreatment [4,8,12]. Indeed, some cases of intractable pain actually result from overtreatment in terms of procedures and medications.

Complicating the picture, adverse outcomes associated with the misuse, abuse and diversion of prescription opioids have increased dramatically since the FSMB's last review [3]. Physicians and other health care professionals have contributed—often inadvertently—to these increases.

Circumstances that contribute to both the inadequate treatment of pain and the inappropriate prescribing of opioids by physicians may include: (1) physician uncertainty or lack of knowledge as to prevailing best clinical practices; (2) inadequate research into the sources of and treatments for pain; (3) sometimes conflicting clinical guidelines for appropriate treatment of pain; (4) physician concerns that prescribing needed amounts of opioid analgesics will result in added scrutiny by regulatory authorities; (5) physician misunderstanding of causes and manifestations of opioid dependence and addiction; (6) fear on the part of physicians of causing addiction or being deceived by a patient who seeks drugs for purposes of misuse; (7) physicians practicing outside the bounds

Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain

of professional conduct by prescribing opioid analgesics without a legitimate medical purpose; and (8) inadequate physician education about regulatory policies and processes [3-4,12,14-20]. Inappropriate treatment also can result from a mistaken belief on the part of patients and their physicians that complete eradication of pain is an attainable goal, and one that can be achieved without disabling adverse effects. Additionally, treatment options may be limited based on availability and/or health plan policies on covered benefits or drug formularies.

Patients share with physicians a responsibility for appropriate use of opioid analgesics [21-22]. This responsibility encompasses providing the physician with complete and accurate information and adhering to the treatment plan. While many patients take their medication safely as prescribed and do not use opioids problematically, some patients—intentionally or unintentionally—are less than forthcoming or have unrealistic expectations regarding the need for opioid therapy or the amount of medication required. Other patients may begin to use medications as prescribed, then slowly deviate from the therapeutic regimen. Still others may not comply with the treatment plan because they misunderstood the physician's instructions. Some patients share their drugs with others without intending harm (a pattern of misuse that is seen quite often among older adults [15]). Then there are patients who deliberately misuse or are addicted to opioids, and who mislead, deceive or fail to disclose information to their physicians in order to obtain opioids to sustain their addiction and avoid withdrawal [19-23].

Patients often leave medications unsecured where they can be stolen by visitors, workers and family members, which is another important source of diversion. Thus a prescription that is quite appropriate for an elderly patient may ultimately contribute to the death of a young person who visits or lives in the patient's home. Therefore, the physician's duty includes not only appropriate prescribing of opioid analgesics, but also appropriate education of patients regarding the secure storage of medications and their appropriate disposal once the course of treatment is completed [18,23].

A more problematic individual is the criminal patient, whose primary purpose is to obtain drugs for resale. Whereas many addicted patients seek a long-term relationship with a prescriber, criminal patients sometimes move rapidly from one prescriber (or dispenser) to another. Such individuals often visit multiple practitioners (a practice sometimes characterized as "doctor shopping") and travel from one geographic area to another not for the purposes of relief of legitimate pain but in search of unsuspecting targets [19-21]. Physicians' attention to patient assessment and the routine use of state prescription drug monitoring programs (PDMPs), where available, have been cited as effective ways to identify individuals who engage in such criminal activities [20-23,45].

Conclusion: The goal of this Model Policy is to provide state medical boards with an updated guideline for assessing physicians' management of pain, so as to determine whether opioid analgesics are used in a manner that is both medically appropriate and in compliance with applicable state and federal laws and regulations. The revised Model Policy makes it clear that the state medical board will consider inappropriate management of pain, particularly chronic pain, to be a departure from accepted best clinical practices, including, but not limited to the following:

- **Inadequate attention to initial assessment to determine if opioids are clinically indicated and to determine risks associated with their use in a particular individual with pain:** Not unlike many drugs used in medicine today, there are significant risks associated with opioids and therefore benefits must outweigh the risks.
- **Inadequate monitoring during the use of potentially abusable medications:** Opioids may be associated with addiction, drug abuse, aberrant behaviors, chemical coping and other dysfunctional

behavioral problems, and some patients may benefit from opioid dose reductions or tapering or weaning off the opioid.

- **Inadequate attention to patient education and informed consent:** The decision to begin opioid therapy for chronic pain should be a shared decision of the physician and patient after a discussion of the risks and a clear understanding that the clinical basis for the use of these medications for chronic pain is limited, that some pain may worsen with opioids, and taking opioids with other substances or certain condition (i.e. sleep apnea, mental illness, pre-existing substance use disorder) may increase risk.
- **Unjustified dose escalation without adequate attention to risks or alternative treatments:** Risks associated with opioids increase with escalating doses as well as in the setting of other comorbidities (i.e. mental illness, respiratory disorders, pre-existing substance use disorder and sleep apnea) and with concurrent use with respiratory depressants such as benzodiazepines or alcohol.
- **Excessive reliance on opioids, particularly high dose opioids for chronic pain management:** Prescribers should be prepared for risk management with opioids in advance of prescribing and should use opioid therapy for chronic non-cancer pain only when safer and reasonably effective options have failed. Maintain opioid dosage as low as possible and continue only if clear and objective outcomes are being met.
- **Not making use of available tools for risk mitigations:** When available, the state prescription drug monitoring program should be checked in advance of prescribing opioids and should be available for ongoing monitoring.

In addition, the Model Policy is designed to communicate to licensees that the state medical board views pain management as an important area of patient care that is integral to the practice of medicine; that opioid analgesics may be necessary for the relief of certain pain conditions; and that physicians will not be sanctioned solely for prescribing opioid analgesics or the dose (mg./mcg.) prescribed for legitimate medical purposes. However, prescribers must be held to a safe and best clinical practice. The federal Controlled Substances Act [25] defines a “lawful prescription” as one that is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The use of opioids for other than legitimate medical purposes poses a threat to the individual and to the public health, thus imposing on physicians a responsibility to minimize the potential for misuse, abuse and diversion of opioids and all other controlled substances.

MODEL POLICY FOR THE USE OF OPIOID ANALGESICS IN THE TREATMENT OF CHRONIC PAIN

SECTION I: PREAMBLE

The (name of Board) is obligated under the laws of the State of (name of state) to protect the public health and safety. The (name of Board) recognizes that principles of high-quality medical practice dictate that the people of the State of (name of state) have access to appropriate, safe and effective pain management. The application of up-to-date knowledge and treatment modalities can help to restore function and thus improve the quality of life of patients who suffer from pain, particularly chronic pain [4,8,26].

This policy has been developed to articulate the Board's position on the use of controlled substances for pain, particularly the use of opioid analgesics and with special attention to the management of chronic pain. The policy thus is intended to encourage physicians to be knowledgeable about best clinical practices as regards the prescribing of opioids and be aware of associated risks. For the purposes of this policy, inappropriate treatment of pain includes non-treatment, inadequate treatment, overtreatment, and continued use of ineffective treatments.

The Board recognizes that opioid analgesics are useful and can be essential in the treatment of acute pain that results from trauma or surgery, as well as in the management of certain types of chronic pain, whether due to cancer or non-cancer causes [20,26,28]. The Board will refer to current clinical practice guidelines and expert reviews in approaching allegations of possible mismanagement of pain [8,10,12,14,26-41, 80].

Responsibility for Appropriate Pain Management: All physicians and other providers should be knowledgeable about assessing patients' pain and function, and familiar with methods of managing pain [4,16]. Physicians also need to understand and comply with federal and state requirements for prescribing opioid analgesics [3,12,19]. Whenever federal laws and regulations differ from those of a particular state, the more stringent rule is the one that should be followed [42].

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice, when current best clinical practices are met.

The Board will consider the use of opioids for pain management to be for a legitimate medical purpose if it is based on sound clinical judgment and current best clinical practices, is appropriately documented, and is of demonstrable benefit to the patient. To be within the usual course of professional practice, a legitimate physician-patient relationship must exist and the prescribing or administration of medications should be appropriate to the identified diagnosis, should be accompanied by careful follow-up monitoring of the patient's response to treatment as well as his or her safe use of the prescribed medication, and should demonstrate that the therapy has been adjusted as needed [7,38,43]. There should be documentation of appropriate referrals as necessary [36-37].

The medical management of pain should reflect current knowledge of evidence-based or best clinical practices for the use of pharmacologic and nonpharmacologic modalities, including the use of opioid analgesics and non-opioid therapies [14,16,27]. Such prescribing must be based on careful assessment of the patient and his or her pain (see the discussion on risk stratification, below) [33].

Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain

Pain should be assessed and treated promptly, and the selection of therapeutic modalities (including the quantity and frequency of medication doses) should be adjusted according to the nature of the pain, the patient's response to treatment, and the patient's risk level relative to the use of medications with abuse potential [8,10,12,14,26-38].

Preventing Opioid Diversion and Abuse: The Board also recognizes that individuals' use of opioid analgesics for other than legitimate medical purposes poses a significant threat to the health and safety of the individual as well as to the public health [3]. The Board further recognizes that inappropriate prescribing of controlled substances by physicians may contribute to drug misuse and diversion by individuals who seek opioids for other than legitimate medical purposes [5,19,44]. Accordingly, the Board expects physicians to incorporate safeguards into their practices to minimize the risk of misuse and diversion of opioid analgesics and other controlled substances [19-23,38,45-46].

Allegations of inappropriate pain management will be evaluated on an individual basis. The Board may use a variety of sources to determine the appropriateness of treatment including prescribing information obtained from the State Prescription Drug Monitoring Program. The Board will not take disciplinary action against a physician for deviating from this Model Policy when contemporaneous medical records show reasonable cause for such a deviation.

The Board will judge the validity of the physician's treatment of a patient on the basis of available documentation, rather than solely on the quantity and duration of medication administered. The goal is the management of the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors, and mitigating risk of misuse, abuse, diversion and overdose [4,29].

The Board will consider the unsafe or otherwise inappropriate treatment of pain to be a departure from best clinical practice, taking into account whether the treatment is appropriate to the diagnosis and the patient's level of risk.

SECTION II: GUIDELINES

The Board has adopted the following criteria for use in evaluating a physician's management of a patient with pain, including the physician's prescribing of opioid analgesics:

Understanding Pain: The diagnosis and treatment of pain is integral to the practice of medicine [4,34-37]. In order to cautiously prescribe opioids, physicians must understand the relevant pharmacologic and clinical issues in the use of such analgesics, and carefully structure a treatment plan that reflects the particular benefits and risks of opioid use for each individual patient. Such an approach should be employed in the care of every patient who receives chronic opioid therapy [4,8].

Patient Evaluation and Risk Stratification: The medical record should document the presence of one or more recognized medical indications for prescribing an opioid analgesic [7] and reflect an appropriately detailed patient evaluation [38]. Such an evaluation should be completed before a decision is made as to whether to prescribe an opioid analgesic.

The nature and extent of the evaluation depends on the type of pain and the context in which it occurs. For

Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain

example, meaningful assessment of chronic pain, including pain related to cancer or non-cancer origins, usually demands a more detailed evaluation than an assessment of acute pain. Assessment of the patient's pain typically would include the nature and intensity of the pain, past and current treatments for the pain, any underlying or co-occurring disorders and conditions, and the effect of the pain on the patient's physical and psychological functioning [31].

For every patient, the initial work-up should include a systems review and relevant physical examination, as well as laboratory investigations as indicated [33,36,48-53]. Such investigations help the physician address not only the nature and intensity of the pain, but also its secondary manifestations, such as its effects on the patient's sleep, mood, work, relationships, valued recreational activities, and alcohol and drug use.

Social and vocational assessment is useful in identifying supports and obstacles to treatment and rehabilitation; for example: Does the patient have good social supports, housing, and meaningful work? Is the home environment stressful or nurturing? [14].

Assessment of the patient's personal and family history of alcohol or drug abuse and relative risk for medication misuse or abuse also should be part of the initial evaluation [11,14,21-23,45], and ideally should be completed prior to a decision as to whether to prescribe opioid analgesics [56-58]. This can be done through a careful clinical interview, which also should inquire into any history of physical, emotional or sexual abuse, because those are risk factors for substance misuse [31]. Use of a validated screening tool (such as the Screener and Opioid Assessment for Patients with Pain [SOAPP-R; 48] or the Opioid Risk Tool [ORT; 49]), or other validated screening tools, can save time in collecting and evaluating the information and determining the patient's level of risk.

All patients should be screened for depression and other mental health disorders, as part of risk evaluation. Patients with untreated depression and other mental health problems are at increased risk for misuse or abuse of controlled medications, including addiction, as well as overdose.

Patients who have a history of substance use disorder (including alcohol) are at elevated risk for failure of opioid analgesic therapy to achieve the goals of improved comfort and function, and also are at high risk for experiencing harm from this therapy, since exposure to addictive substances often is a powerful trigger of relapse [11,31,45]. Therefore, treatment of a patient who has a history of substance use disorder should, if possible, involve consultation with an addiction specialist before opioid therapy is initiated (and follow-up as needed). Patients who have an active substance use disorder should not receive opioid therapy until they are established in a treatment/recovery program [31] or alternatives are established such as co-management with an addiction professional. Physicians who treat patients with chronic pain should be encouraged to also be knowledgeable about the treatment of addiction, including the role of replacement agonists such as methadone and buprenorphine. For some physicians, there may be advantages to becoming eligible to treat addiction using office-based buprenorphine treatment.

Information provided by the patient is a necessary but insufficient part of the evaluation process. Reports of previous evaluations and treatments should be confirmed by obtaining records from other providers, if possible. Patients have occasionally provided fraudulent records, so if there is any reason to question the truthfulness of a patient's report, it is best to request records directly from the other providers [54-55].

If possible, the patient evaluation should include information from family members and/or significant others [22-23,49-50]. Where available, the state prescription drug monitoring program (PDMP) should be consulted

Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain

to determine whether the patient is receiving prescriptions from any other physicians, and the results obtained from the PDMP should be documented in the patient record [34].

In dealing with a patient who is taking opioids prescribed by another physician—particularly a patient on high doses—the evaluation and risk stratification assume even greater importance [21-23]. With all patients, the physician's decision as to whether to prescribe opioid analgesics should reflect the totality of the information collected, as well as the physician's own knowledge and comfort level in prescribing such medications and the resources for patient support that are available in the community [21-23].

Development of a Treatment Plan and Goals: The goals of pain treatment include reasonably attainable improvement in pain and function; improvement in pain-associated symptoms such as sleep disturbance, depression, and anxiety; and avoidance of unnecessary or excessive use of medications [4,8]. Effective means of achieving these goals vary widely, depending on the type and causes of the patient's pain, other concurrent issues, and the preferences of the physician and the patient.

The treatment plan and goals should be established as early as possible in the treatment process and revisited regularly, so as to provide clear-cut, individualized objectives to guide the choice of therapies [38]. The treatment plan should contain information supporting the selection of therapies, both pharmacologic (including medications other than opioids) and nonpharmacologic. It also should specify the objectives that will be used to evaluate treatment progress, such as relief of pain and improved physical and psychosocial function [14,36,47].

The plan should document any further diagnostic evaluations, consultations or referrals, or additional therapies that have been considered [21-23,45].

Informed Consent and Treatment Agreement: The decision to initiate opioid therapy should be a shared decision between the physician and the patient. The physician should discuss the risks and benefits of the treatment plan (including any proposed use of opioid analgesics) with the patient, with persons designated by the patient, or with the patient's surrogate or guardian if the patient is without medical decision-making capacity [32,35]. If opioids are prescribed, the patient (and possibly family members) should be counseled on safe ways to store and dispose of medications [3,37].

Use of a written informed consent and treatment agreement (sometimes referred to as a "treatment contract") is recommended [21-23,35,38].

Informed consent documents typically address:

- The potential risks and anticipated benefits of chronic opioid therapy.
- Potential side effects (both short- and long-term) of the medication, such as constipation and cognitive impairment.
- The likelihood that tolerance to and physical dependence on the medication will develop.
- The risk of drug interactions and over-sedation.
- The risk of impaired motor skills (affecting driving and other tasks).
- The risk of opioid misuse, dependence, addiction, and overdose.
- The limited evidence as to the benefit of long-term opioid therapy.
- The physician's prescribing policies and expectations, including the number and frequency of prescription refills, as well as the physician's policy on early refills and replacement of lost or stolen medications.
- Specific reasons for which drug therapy may be changed or discontinued (including violation of the policies and agreements spelled out in the treatment agreement).

Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain

Treatment agreements outline the joint responsibilities of physician and patient [35-37] and are indicated for opioid or other abusable medications. They typically discuss:

- The goals of treatment, in terms of pain management, restoration of function, and safety.
- The patient's responsibility for safe medication use (e.g., by not using more medication than prescribed or using the opioid in combination with alcohol or other substances; storing medications in a secure location; and safe disposal of any unused medication).
- The patient's responsibility to obtain his or her prescribed opioids from only one physician or practice.
- The patient's agreement to periodic drug testing (as of blood, urine, hair, or saliva).
- The physician's responsibility to be available or to have a covering physician available to care for unforeseen problems and to prescribe scheduled refills.

Informed consent documents and treatment agreements can be part of one document for the sake of convenience.

Initiating an Opioid Trial: Generally, safer alternative treatments should be considered before initiating opioid therapy for chronic, non-malignant pain. Opioid therapy should be presented to the patient as a therapeutic trial or test for a defined period of time (usually no more than 90 days) and with specified evaluation points. The physician should explain that progress will be carefully monitored for both benefit and harm in terms of the effects of opioids on the patient's level of pain, function, and quality of life, as well as to identify any adverse events or risks to safety [51]. When initiating opioid therapy, the lowest dose possible should be given to an opioid naïve patient and titrate to affect. It is generally suggested to begin opioid therapy with a short acting opioid and rotate to a long acting/extended release if indicated.

A decision to continue opioid therapy beyond the trial period should reflect a careful evaluation of benefits versus adverse events [29]and/or potential risks.

Ongoing Monitoring and Adapting the Treatment Plan: The physician should regularly review the patient's progress, including any new information about the etiology of the pain or the patient's overall health and level of function [35,49-50]. When possible, collateral information about the patient's response to opioid therapy should be obtained from family members or other close contacts, and the state PDMP. The patient should be seen more frequently while the treatment plan is being initiated and the opioid dose adjusted [44-51]. As the patient is stabilized in the treatment regimen, follow-up visits may be scheduled less frequently. (However, if the patient is seen less than monthly and an opioid is prescribed, arrangements must be made for the patient to obtain a refill or new prescription when needed.)

At each visit, the results of chronic opioid therapy should be monitored by assessing what have been called the "5As" of chronic pain management; these involve a determination of whether the patient is experiencing a reduction in pain (Analgesia), has demonstrated an improvement in level of function (Activity), whether there are significant Adverse effects, whether there is evidence of Aberrant substance-related behaviors, and mood of the individual (Affect) [38,52]. Validated brief assessment tools that measure pain and function, such as the three-question "Pain, Enjoyment and General Activity" (PEG) scale [47] or other validated assessment tools, may be helpful and time effective.

Continuation, modification or termination of opioid therapy for pain should be contingent on the physician's evaluation of (1) evidence of the patient's progress toward treatment objectives and (2) the absence of substantial

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risks or adverse events, such as overdose or diversion [21-23,45]. A satisfactory response to treatment would be indicated by a reduced level of pain, increased level of function, and/or improved quality of life [29]. Information from family members or other caregivers should be considered in evaluating the patient's response to treatment [14,35-36]. Use of measurement tools to assess the patient's level of pain, function, and quality of life (such as a visual analog or numerical scale) can be helpful in documenting therapeutic outcomes [14,49].

Periodic Drug Testing: Periodic drug testing may be useful in monitoring adherence to the treatment plan, as well as in detecting the use of non-prescribed drugs [53-54]. Drug testing is an important monitoring tool because self-reports of medication use is not always reliable and behavioral observations may detect some problems but not others [55-59]. Patients being treated for addiction should be tested as frequently as necessary to ensure therapeutic adherence, but for patients being treated for pain, clinical judgment trumps recommendations for frequency of testing.

Urine may be the preferred biologic specimen for testing because of its ease of collection and storage and the cost-effectiveness of such testing [53]. When such testing is conducted as part of pain treatment, forensic standards are generally not necessary and not in place, so collection is not observed and chain-of-custody protocols are not followed. Initial testing may be done using class-specific immunoassay drug panels (point-of-care or laboratory-based), which typically do not identify particular drugs within a class unless the immunoassay is specific for that drug. If necessary, this can be followed up with a more specific technique, such as gas chromatography/mass spectrometry (GC/MS) or other chromatographic tests to confirm the presence or absence of a specific drug or its metabolites [53]. In drug testing in a pain practice, it is important to identify the specific drug not just the class of the drug.

Physicians need to be aware of the limitations of available tests (such as their limited sensitivity for many opioids) and take care to order tests appropriately [54]. For example, when a drug test is ordered, it is important to specify that it include the opioid being prescribed [53]. Because of the complexities involved in interpreting drug test results, it is advisable to confirm significant or unexpected results with the laboratory toxicologist or a clinical pathologist [59-60].

While immunoassay, point of care (POC) testing has its utility in the making of temporary and "on the spot" changes in clinical management, its limitations with regard to accuracy have recently been the subject of study. These limitations are such that the use of point of care testing for the making of more long term and permanent changes in management of people with the disease of addiction and other clinical situations may not be justified until the results of confirmatory testing with more accurate methods such as LC-MS/MS are obtained. A recent study on LC-MS/MS results following immunoassay POC testing in addiction treatment settings and found very high rates of "false negatives and positives" [53,81].

Test results that suggest opioid misuse should be discussed with the patient. It is helpful to approach such a discussion in a positive, supportive fashion, so as to strengthen the physician-patient relationship and encourage healthy behaviors (as well as behavioral change where that is needed). Both the test results and subsequent discussion with the patient should be documented in the medical record [53].

Periodic pill counting is also a useful strategy to confirm medication adherence and to minimize diversion (e.g., selling, sharing or giving away medications). As noted earlier and where available, consulting the state's PDMP before prescribing opioids for pain and during ongoing use is highly recommended. A PDMP can be useful in monitoring compliance with the treatment agreement as well as identifying individuals obtaining controlled substances from multiple prescribers [21-23,55,62].

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If the patient's progress is unsatisfactory, the physician must decide whether to revise or augment the treatment plan, whether other treatment modalities should be added to or substituted for the opioid therapy, or whether a different approach—possibly involving referral to a pain specialist or other health professional—should be employed [35-37,62-63].

Evidence of misuse of prescribed opioids demands prompt intervention by the physician [19,21-23,32,35]. Patient behaviors that require such intervention typically involve recurrent early requests for refills, multiple reports of lost or stolen prescriptions, obtaining controlled medications from multiple sources without the physician's knowledge, intoxication or impairment (either observed or reported), and pressuring or threatening behaviors [23]. The presence of illicit or unprescribed drugs, (drugs not prescribed by a physician) in drug tests similarly requires action on the part of the prescriber. Some aberrant behaviors are more closely associated with medication misuse than others [62-63]. Most worrisome is a pattern of behavior that suggests recurring misuse, such as unsanctioned dose escalations, deteriorating function, and failure to comply with the treatment plan [64].

Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors require a firm, immediate response [22-23,38,46]. Indeed, failure to respond can place the patient and others at significant risk of adverse consequences, including accidental overdose, suicide attempts, arrests and incarceration, or even death [23,65-67]. For this reason, physicians who prescribe chronic opioid therapy should be knowledgeable in the diagnosis of substance use disorders and able to distinguish such disorders from physical dependence—which is expected in chronic therapy with opioids and many sedatives.

Consultation and Referral: The treating physician should seek a consultation with, or refer the patient to, a pain, psychiatry, addiction or mental health specialist as needed [37-38]. For example, a patient who has a history of substance use disorder or a co-occurring mental health disorder may require specialized assessment and treatment, if available [31,66].

Physicians who prescribe chronic opioid therapy should be familiar with treatment options for opioid addiction (including those available in licensed opioid treatment programs [OTPs]) and those offered by an appropriately credentialed and experienced physician through office-based opioid treatment [OBOT]), so as to make appropriate referrals when needed [23,31,37,39].

Discontinuing Opioid Therapy: Throughout the course of opioid therapy, the physician and patient should regularly weigh the potential benefits and risks of continued treatment and determine whether such treatment remains appropriate [46].

If opioid therapy is continued, the treatment plan may need to be adjusted to reflect the patient's changing physical status and needs, as well as to support safe and appropriate medication use [22-23].

Reasons for discontinuing opioid therapy include resolution of the underlying painful condition, emergence of intolerable side effects, inadequate analgesic effect, failure to improve the patient's quality of life despite reasonable titration, deteriorating function, or significant aberrant medication use [38, 45].

If opioid therapy is discontinued, the patient who has become physically dependent should be provided with a safely structured tapering regimen. Withdrawal can be managed either by the prescribing physician or by referring the patient to an addiction specialist [63]. The termination of opioid therapy should not mark the end of

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treatment, which should continue with other modalities, either through direct care or referral to other health care specialists, as appropriate [21-23].

Additionally, providers should not continue opioid treatment unless the patient has received a benefit, including demonstrated functional improvement.

Medical Records: Every physician who treats patients for chronic pain must maintain accurate and complete medical records. Information that should appear in the medical record includes the following [22-23,38,43-44]:

- Copies of the signed informed consent and treatment agreement.
- The patient's medical history.
- Results of the physical examination and all laboratory tests.
- Results of the risk assessment, including results of any screening instruments used.
- A description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity).
- Instructions to the patient, including discussions of risks and benefits with the patient and any significant others.
- Results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement.
- Notes on evaluations by and consultations with specialists.
- Any other information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors [21-23,30,38,45,68]. These may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers.
- Authorization for release of information to other treatment providers.

The medical record must include all prescription orders for opioid analgesics and other controlled substances, whether written or telephoned. In addition, written instructions for the use of all medications should be given to the patient and documented in the record [25]. The name, telephone number, and address of the patient's pharmacy also should be recorded to facilitate contact as needed [23]. Records should be up-to-date and maintained in an accessible manner so as to be readily available for review [25].

Good records demonstrate that a service was provided to the patient and establish that the service provided was medically necessary. Even if the outcome is less than optimal, thorough records protect the physician as well as the patient [23,38,45,68].

Compliance with Controlled Substance Laws and Regulations: To prescribe, dispense or administer controlled substances, the physician must be registered with the DEA, licensed by the state in which he or she practices, and comply with applicable federal and state regulations [25].

Physicians are referred to the *Physicians' Manual of the U.S. Drug Enforcement Administration* (and any relevant documents issued by the state medical Board) for specific rules and regulations governing the use of controlled substances. Additional resources are available on the DEA's website (at www.deadiversion.usdoj.gov), as well as from (*any relevant documents issued by the state medical board*).

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SECTION III: DEFINITIONS

For the purposes of this Model Policy, the following terms are defined as shown.

Aberrant Substance Use Behaviors: Behaviors that are outside the boundaries of the agreed-upon treatment plan may constitute aberrant substance use behaviors [22-23]. For example, obtaining prescriptions for the same or similar drugs from more than one physician or other health care provider without the treating physician's knowledge is aberrant behavior, as is use of illicit drugs.

Abuse: Abuse has been described as a maladaptive pattern of drug use that results in harm or places the individual at risk of harm [29]. Abuse of a prescription medication involves its use in a manner that deviates from approved medical, legal, and social standards, generally to achieve a euphoric state (“high”) or to sustain opioid dependence that is opioid addiction or that is other than the purpose for which the medication was prescribed [28].

Addiction: A longstanding definition of addiction is that it is “a primary, chronic, neurobiologic disease, whose development and manifestations are influenced by genetic, psychosocial, and environmental factors” [28]. Addiction often is said to be characterized by behaviors that include impaired control over drug use, craving, compulsive use, and continued use despite harm [28].

A newer definition, adopted by the American Society of Addiction Medicine in 2011, describes addiction as “a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors. Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death” [40].

(As discussed below, physical dependence and tolerance are expected physiological consequences of extended opioid therapy for pain and in this context do not indicate the presence of addiction.)

Controlled Substance: A controlled substance is a drug that is subject to special requirements under the federal Controlled Substances Act of 1970 (CSA) [25], which is designed to ensure both the availability and control of regulated substances. Under the CSA, availability of regulated drugs for medical purposes is accomplished through a system that establishes quotas for drug production and a distribution system that closely monitors the importation, manufacture, distribution, prescribing, dispensing, administering, and possession of controlled drugs. Civil and criminal sanctions for serious violations of the statute are part of the government's control apparatus. The Code of Federal Regulations (Title 21, Chapter 2) implements the CSA.

The CSA provides that responsibility for scheduling controlled substances is shared between the Food and Drug Administration (FDA) and the DEA. In granting regulatory authority to these agencies, the Congress noted that both public health and public safety needs are important and that neither takes primacy over the other. To accomplish this, the Congress provided guidance in the form of factors that must be considered by the FDA and DEA when assessing public health and safety issues related to a new drug or one that is being considered for rescheduling or removal from control.

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The CSA does *not* limit the amount of drug prescribed, the duration for which it is prescribed, or the period for which a prescription is valid (although some states do impose such limits).

Most potent opioid analgesics are classified in *Schedules II or III* under the CSA, indicating that they have a significant potential for abuse and a currently accepted medical use in treatment in the U.S. (with certain restrictions), and that abuse of the drug may lead to severe psychological or physical dependence. Although the scheduling system provides a rough guide to abuse potential, it should be recognized that all controlled medications have some potential for abuse.

Dependence: Physical dependence is a state of biologic adaptation that is evidenced by a class-specific withdrawal syndrome when the drug is abruptly discontinued or the dose rapidly reduced, and/or by the administration of an antagonist [28]. It is important to distinguish addiction from the type of physical dependence that can and does occur within the context of good medical care, as when a patient on long-term opioid analgesics for pain becomes physically dependent on the analgesic. This distinction is reflected in the two primary diagnostic classification systems used by health care professionals: the *International Classification of Mental and Behavioural Disorders, 10th Edition* (ICD-10) of the World Health Organization [70], and the *Diagnostic and Statistical Manual (DSM)* of the American Psychiatric Association [71]. In the DSM-IV-TR, a diagnosis of “substance dependence” meant addiction. In the upcoming DSM V, the term *dependence* is reestablished in its original meaning of physiological dependence. When symptoms are sufficient to meet criteria for substance misuse or addiction, the term “substance use disorder” is used, accompanied by severity ratings [69].

It may be important to clarify this distinction during the informed consent process, so that the patient (and family) understands that physical dependence and tolerance are likely to occur if opioids are taken regularly over a period of time, but that the risk of addiction is relatively low, although estimates do vary. Discontinuing chronic opioid therapy may be difficult, even in the absence of addiction. According to the World Health Organization, “The development of tolerance and physical dependence denote normal physiologic adaptations of the body to the presence of an opioid” [70]. Consequently, physical dependence alone is neither necessary nor sufficient to diagnose addiction [71,72].

Diversion: Drug diversion is defined as the intentional transfer of a controlled substance from authorized to unauthorized possession or channels of distribution [73-74]. The federal Controlled Substances Act (21 U.S.C. §§ 801 et seq.) establishes a closed system of distribution for drugs that are classified as controlled substances. Records must be kept from the time a drug is manufactured to the time it is dispensed. Health care professionals who are authorized to prescribe, dispense, and otherwise control access to such drugs are required to register with the DEA [25,75].

Pharmaceuticals that make their way outside this closed distribution system are said to have been “diverted” [75], and the individuals responsible for the diversion (including patients) are in violation of federal law.

Experience shows that the degree to which a prescribed medication is misused depends in large part on how easily it is redirected (diverted) from the legitimate distribution system [17,19,74].

Misuse: The term *misuse* (also called *nonmedical use*) encompasses all uses of a prescription medication other than those that are directed by a physician and used by a patient within the law and the requirements of good medical practice [28].

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Opioid: An opioid is any compound that binds to an opioid receptor in the central nervous system (CNS) [4]. The class includes both naturally occurring and synthetic or semi-synthetic opioid drugs or medications, as well as endogenous opioid peptides [35].

Most physicians use the terms “opiate” and “opioid” interchangeably, but toxicologists (who perform and interpret drug tests) make a clear distinction between them. “Opioid” is the broader term because it includes the entire class of agents that act at opioid receptors in the CNS, whereas “opiates” refers to natural compounds derived from the opium plant but not semisynthetic opioid derivatives of opiates or completely synthetic agents. Thus, drug tests that are “positive for opiates” have detected one of these compounds or a metabolite of heroin, 6-monoacetyl morphine (MAM). Drug tests that are “negative for opiates” have found no detectable levels of opiates in the sample, even though other opioids that were not tested for—including the most common currently used and misused prescription opioids—may be present in the sample that was analyzed [53,59-260].

Pain: An unpleasant and potentially disabling sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Acute pain is the normal, predictable physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. Acute pain generally is time-limited, lasting six weeks or less [4].

Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury (e.g., more than three months). It may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over a period of months or years.

Chronic non-cancer related pain is chronic pain that is not associated with active cancer and does not occur at the end of life [4,76].

Opioid-induced hyperalgesia may develop as a result of long-term opioid use in the treatment of chronic pain. *Primary hyperalgesia* is pain sensitivity that occurs directly in the damaged tissues, while *secondary hyperalgesia* occurs in surrounding undamaged tissues. Human and animal studies have demonstrated that primary or secondary hyperalgesia can develop in response to both chronic and acute exposure to opioids. Hyperalgesia can be severe enough to warrant discontinuation of opioid treatment [77].

Prescription Drug Monitoring Program: Almost all states have enacted laws that establish prescription drug monitoring programs (PDMPs) to facilitate the collection, analysis, and reporting of information on the prescribing and dispensing of controlled substances. Most such programs employ electronic data transfer systems, under which prescription information is transmitted from the dispensing pharmacy to a state agency, which collates and analyzes the information [3,24].

After analyzing the efficacy of PDMPs, the GAO concluded that such programs have the potential to help law enforcement and regulatory agencies rapidly identify and investigate activities that may involve illegal prescribing, dispensing or consumption of controlled substances. Where real-time data are available, PDMPs also can help to prevent prescription drug misuse and diversion by allowing physicians to determine whether a patient is receiving prescriptions for controlled substances from other physicians, as well as whether the patient has filled or refilled an order for an opioid the physician has prescribed [24,78-79].

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Tolerance: Tolerance is a state of physiologic adaptation in which exposure to a drug induces changes that result in diminution of one or more of the drug's effects over time. Tolerance is common in opioid treatment, has been demonstrated following a single dose of opioids, and is not the same as addiction [28].

Trial Period: A period of time during which the efficacy of an opioid for treatment of an individual's pain is tested to determine whether the treatment goals can be met in terms of reduction of pain and restoration of function. If the goals are not met, the opioid dose may be adjusted, a different opioid substituted, an adjunctive therapy added, or use of opioids discontinued and an alternative approach to pain management selected [36].

Universal Precautions: The concept of *universal precautions* is borrowed from an infectious disease model of the same name to underscore its comparability to practices in other areas of medicine. The concept recognizes that all patients have a level of risk that can only be estimated initially, with the estimate modified over time as more information is obtained. The 10 essential steps of universal precautions can be summarized as follows [38]:

1. Make a diagnosis with an appropriate differential.
2. Conduct a patient assessment, including risk for substance use disorders.
3. Discuss the proposed treatment plan with the patient and obtain informed consent.
4. Have a written treatment agreement that sets forth the expectations and obligations of both the patient and the treating physician.
5. Initiate an appropriate trial of opioid therapy, with or without adjunctive medications.
6. Perform regular assessments of pain and function.
7. Reassess the patient's pain score and level of function.
8. Regularly evaluate the patient in terms of the "5 A's": Analgesia, Activity, Adverse effects, Aberrant behaviors, and Affect.
9. Periodically review the pain diagnosis and any comorbid conditions, including substance use disorders, and adjust the treatment regimen accordingly.
10. Keep careful and complete records of the initial evaluation and each follow-up visit.

By acknowledging the fact that there are no signs that invariably point to substance use disorder [41], the universal precautions encourage a consistent and respectful approach to the assessment and management of pain patients, thereby minimizing stigma, improving patient care, and reducing overall risk [38].

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Coffin 2013 Annals of IM Dueling obligations of opioid stewardship

The Dueling Obligations of Opioid Stewardship

The United States leads the developed world in drug poisonings, a title earned through vastly increased opioid analgesic use (1). Overdoses involving opioid analgesics killed almost 17 000 persons in 2010—nearly as many as car accidents—and the number of people with opioid analgesic use disorders has increased to nearly 2 million. As a medical community, we have an ethical obligation to use our resources not only to reduce the incidence of opioid use disorders but also to provide optimum care to patients who have developed disorders due, at least in part, to our prescribing practices. Equally important, medical organizations have an imperative to advocate for changes in policy and practice that are cautious but sufficient to stave off the punitive policies emerging across the nation.

The American College of Physicians (ACP) position paper that appears in this issue (2) provides a thorough historical review of increased opioid prescribing, including the adoption of pain as the “5th vital sign” and the advent of novel opioid formulations. Other factors, most notably welfare and health care reform in the 1990s, also played into overreliance on opioids. Welfare restrictions are believed to have fueled disability claims for persons unable to find work, frequently because of difficulties with chronic pain. Managed care organizations, recognizing that opioids were less expensive than the comprehensive pain management clinics that once existed at many medical centers, stopped reimbursement for those services (3). In fact, many public insurers, whose clients include many at risk for adverse opioid-related events, no longer reimburse for non-medication services, such as physical therapy. Thus, primary care providers who were instructed to treat pain were seeing more chronic pain complaints, increasingly available opioid medications, and payers unwilling to cover non-pharmacologic interventions, leaving opioids as one of the few therapeutic options, if not the only one.

We have since moved through 3 stages of thinking about opioid medications, from the early hypothesis that treating pain with opioids resulted in addiction among less than 3% of patients (4), to the hope that opioid medication problems were due to “bad apples” who could be weeded out through screening, to a recent recognition that the problem is due to “risky drugs, not risky patients” (5). The era of “bad apples” has an unfortunate legacy apparent in the literature and many policy statements. First, “doctor shoppers” make up only 0.7% of persons receiving opioid prescriptions and receive only 1.9% of prescriptions (6), suggesting that these patients represent a small piece of the overall problem. Second, recognizing that many people suffer from iatrogenic opioid use disorders, we must also recognize that many patients who would not have met risk criteria when opioid therapy was initiated subsequently developed use disorders. Thus, these screening criteria may miss patients that will be harmed by opioids. Finally, we

should rarely have to “screen out” patients if we are prescribing opioids only when necessary and for proper indications.

While we rein in our use of opioids for less appropriate indications like chronic lower back pain (an approach to reforming prescribing practices not specifically addressed in the ACP policy paper), we must care for patients directly or indirectly harmed by opioid prescribing and diversion. Data indicate some users of opioid analgesics will transition to heroin or other illicitly obtained opioids, and we have witnessed increased overdose death coincident with prescribing restrictions (7). In addition, as we know from opioid maintenance treatment, even dose reductions motivated by practice or policy changes may be hazardous, possibly increasing mortality even among patients who don’t seek illicit opioids (8). At the same time, if we fail to act decisively and promote substantial changes, we risk stewardship and legislative efforts that could drive physicians back to the era of “opiophobia” and result in serious morbidity and even mortality among our patients currently receiving opioids.

The dual goals of reducing iatrogenic opioid use disorders and protecting our ability to care for existing patients lead us to suggest several adjustments to opioid prescribing practice. First, we should limit the *reasons* we prescribe opioid medications. Long-term opioids for chronic nonmalignant pain may not improve and may in fact worsen functional status (9). Patients should be aware that medications are rarely the best option for many types of pain. Even acute pain may not warrant opioids. Second, clinicians should rely on functional status, rather than reported pain, as the metric of success for management of chronic, nonmalignant pain. Third, we need to rebuild the infrastructure of nonopioid pain management. Services such as geographically and financially accessible physical and occupational therapy would go a long way toward improving management of many pain syndromes. Unfortunately, building infrastructure takes time and payers may balk at upfront costs. However, in the context of medical homes and total cost containment, such approaches may again become plausible economically. Fourth, we should consider buprenorphine for chronic pain in certain circumstances. Notwithstanding some well-publicized risks for diversion, buprenorphine has a “ceiling effect,” very low risk of overdose, and early evidence of efficacy for pain control in patients transitioned from other opioids (10). The cost is lower now that generics are available, and the even less costly monoformulated product may be sufficient for patients with no history of injection. Finally, we propose that clinicians prescribe the short-acting opioid antagonist naloxone to all patients receiving chronic opioids. Naloxone has been given to tens of thousands of patients for lay overdose reversal with no reported adverse medical events

and is associated with a relative risk for opioid overdose death of 0.53 (11). The U.S. Army's Fort Bragg gave naloxone to pain patients receiving opioid analgesics and witnessed a decrease from 8 overdoses each month to none. Naloxone prescribed to patients may not only be used to reverse overdose but may also be a powerful opportunity to show patients that the opioids they are taking carry serious risks.

The ethical imperative to safely treat patients harmed by our opioid prescribing practices rises to that which a surgeon has for operative complications. This also means taking a proactive role in policy development that satisfies the perceived need to reduce opioid prescribing while protecting our ability to treat those patients already using opioids. The ACP statement includes many important recommendations, yet we remain concerned that those supporting burdensome and punitive policies may not be swayed.

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Kirschner N 2013 prescription drug abuse exec summary policy position paper
ACP

Prescription Drug Abuse: Executive Summary of a Policy Position Paper From the American College of Physicians

Neil Kirschner, PhD; Jack Ginsburg; Lois Snyder Sulmasy, JD, for the Health and Public Policy Committee of the American College of Physicians*

The inappropriate use and abuse of prescription drugs is a serious public health problem. The Centers for Disease Control and Prevention (CDC) has declared that the United States is in the midst of an epidemic of deaths from prescription drug overdose (1). The CDC reports that drug overdose, particularly due to the increase in nonmedical use of prescription pain relief (opioid) drugs, is the second leading cause of deaths from unintentional injuries in the United States, exceeded only by motor vehicle fatalities (2). A recent analysis of preliminary CDC data suggests that drug overdose may now be the leading cause of such deaths (3).

Prescription drug abuse is found throughout all aspects of our population. Physicians and other health professionals with prescribing privileges are entrusted with the authority to use medications in the treatment of their patients and therefore have an important role to play in helping to ensure safe and effective use of this treatment option and the deterrence of its abuse. The American College of Physicians (ACP) developed this position paper to provide guidance to prescribers and policymakers regarding measures to effectively address the problem of prescription drug abuse. This Executive Summary provides a synopsis of the full position paper (see the Appendix, available at www.annals.org).

BACKGROUND

A 2010 Substance Abuse and Mental Health Services Administration survey found that 16 million Americans age 12 years and older had taken a prescription pain reliever, tranquilizer, stimulant, or sedative for nonmedical purposes at least once in the previous year; 7.0 million (2.7%) had used psychotherapeutic drugs nonmedically within the past month. Of these drug abusers, 55.0% said they obtained the drug they most recently used from a friend or relative for free (4). Another 17.3% reported that they got the drug from one doctor. Only 4.4% obtained them from a drug dealer or other stranger, and only 0.4% bought them on the Internet. The survey noted, "Among those who reported getting the pain reliever from a friend or relative for free, 79.4% reported in a follow-up question that the friend or relative had obtained the drugs from just one doctor." Another study found that more than 50% of teens obtained prescription drugs from their own family's

medicine cabinet (5). Also in 2010, there were 2.4 million opioid abusers in the United States—with 60% of abused opioids obtained directly or indirectly through a doctor's prescription (6). Furthermore, the Substance Abuse and Mental Health Services Administration 2010 survey indicated that 2 million people reported using prescription painkillers nonmedically for the first time within the last year (4).

The full position paper (see the Appendix) includes a definition of drug abuse, information about prescription drug abuse in different age groups, variation by geographic area, prescription drug abuse and fraud in Medicare, and factors contributing to the dramatic rise in the availability and misuse of prescription drugs.

Key measures of abuse of opioid drugs increased from 2003 to 2009 (4). The largest increases were in measures of adverse health consequences, such as emergency department visits, substance abuse treatment admissions, and unintentional overdose deaths (1). The adverse consequences of prescription drugs abuse are serious, and the costs are substantial. Commonly abused prescription drugs fall into 3 categories: pain relievers (opioids), sedatives and tranquilizers (central nervous system depressants), and stimulants (7).

The National Institute on Drug Abuse (NIDA) warns that opioids can be highly addictive and can depress respiration and lead to death, and that injecting opioids with unsterile or shared equipment increases the risk for HIV infection and other infectious diseases. Unintentional overdose deaths involving prescription opioids have quadrupled since 1999 and now outnumber those from heroin and cocaine combined. The number of overdose deaths involving opioid analgesics was more than 16 600 according to a recent report from the CDC (8). The National Survey on Drug Use and Health estimates that about 1.9 million people in the United States abuse or are dependent on prescription opioids (4). The potential for abuse is enormous because roughly 116 million patients in the United States have chronic pain (9). The NIDA provides a listing of commonly abused prescription drugs at www.drugabuse.gov/drugs-abuse/commonly-abused-drugs/commonly-abused-prescription-drugs-chart. Each year, drug abuse and addiction cost taxpayers nearly \$534 billion in pre-

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ventable health care, law enforcement, crime, and other costs (10).

The full position paper (see the Appendix) includes details about the types of drugs that are abused and summarizes the current regulatory framework within the U.S. Food and Drug Administration (FDA) and the Drug Enforcement Agency. It also discusses issues related to Medicare and Medicaid, programs that provide coverage for medically necessary prescription drugs, including opioids and other pain medications, and are dealing with the problem of increasing prescription drug abuse. It also discusses approaches taken by various state legislatures and medical boards to address this issue.

THE CHALLENGE FOR PHYSICIANS AND PUBLIC POLICYMAKERS

The challenge for physicians and public policymakers is how to deter prescription drug abuse while maintaining patient access to appropriate treatment. The physician must be up to date on the proper use of medications and treatments, including pain medications. Physicians have an ethical obligation to manage and relieve pain yet to do so responsibly and in accord with scientific evidence (11). Improvement in function through the short-term use of opioids and related substances to treat acute pain and their use to ease suffering at the end of life are well-accepted medical practices. However, long-term opioid use for chronic pain is controversial because of concerns about addiction, overuse, misuse, and adverse effects. Long-term use can also lead to opioid-induced hyperalgesia, which in turn leads to increased doses of opioids, further escalating sensitivity to pain. Furthermore, evidence for long-term efficacy is lacking (12). Concerns about pain being underdiagnosed and undertreated remain, particularly for ethnic and racial minorities (13). The result is needless suffering for patients, complications that cause further injury or death, and unnecessary treatment costs. Controlled substances include medications to treat not only pain but also sleep disorders, nerve conditions, weight loss, and other conditions. However, prescribing controlled substances, which can be addictive or abused, can subject physicians to substantial regulatory and administrative burdens. Physicians face criminal and civil penalties, including loss of licensure (and consequent inability to practice) for failure to comply with state and federal laws regulating controlled substances. On the other hand, failure to adequately medicate a patient can expose a physician to malpractice charges of negligence. Physicians can also be sued for overmedication that results in addiction or serious adverse effects (14). State medical boards also report addressing complaints for both overtreatment and undertreatment of pain.

METHODS

The decision to develop this policy paper was made by ACP's Health and Public Policy Committee, which is

charged with addressing issues affecting the health care of the U.S. public and the practice of internal medicine and its subspecialties. Recommendations developed were informed through a literature review and input from the various College constituencies and nonmember experts in the field. The policy paper and related recommendations were reviewed and approved by the College's Governing Board in July 2013.

ACP POSITION STATEMENTS AND RECOMMENDATIONS

The following statements represent the official policy positions and recommendations of the ACP. The rationale for each is provided in the full position paper (see the Appendix).

1. ACP supports appropriate and effective efforts to reduce all substance abuse. These include educational, prevention, diagnostic, and treatment efforts. As physicians dealing with the health effects of this condition, we also support medical research on addiction and its causes and treatment.
2. ACP supports a comprehensive national policy on prescription drug abuse containing education, monitoring, proper disposal, and enforcement elements.
3. ACP supports the consideration by physicians of the full array of treatments available for the effective treatment and management of pain.
4. ACP supports the establishment of a national Prescription Drug Monitoring Program (PDMP). Until such a program is implemented, ACP supports efforts to standardize state PDMPs through the federal National All Schedules Prescription Electronic Reporting (NASPER) program. Prescribers and dispensers should check PDMPs in their own and neighboring states (as permitted) prior to writing and filling prescriptions for medications containing controlled substances. All PDMPs should maintain strong protections to assure confidentiality and privacy.
5. ACP supports efforts to educate physicians, patients, and the public on the appropriate medical uses of controlled drugs and the dangers of both medical and nonmedical use of prescription drugs.
6. ACP favors a balanced approach to permit safe and effective medical treatment utilizing controlled substances and efforts to reduce prescription drug abuse. However, educational, documentation, and treatment requirements toward this goal should not impose excessive administrative burdens on prescribers or dispensers.
7. ACP recognizes that defined maximum dosage (i.e., morphine equivalent) and duration of therapy limitations are not applicable to every clinical encounter. ACP favors establishment of evidence-based, nonbinding guidelines regarding recommended maximum dosage and duration of therapy that a patient taking controlled substance medications may receive.
8. Patients identified by Medicare, Medicaid, private insurance plans, or law enforcement authorities as being at significant risk of prescription drug abuse may be required to

participate in a drug monitoring program and undergo random drug testing. Physicians may be required to report suspected cases of drug abuse, but should not be mandated to conduct random drug testing without the patient's consent. The financial cost of mandatory drug testing should be borne by the authority requiring the testing; neither the patient nor the physician should bear the financial cost of random drug testing mandated by a third-party authority.

9. ACP recommends the consideration of patient-provider treatment agreements between physician and patients as a tool for the treatment of pain.

10. ACP recommends the passage of legislation by all 50 states permitting electronic prescription for controlled substances (EPCS).

CONCLUSION

The goal of this paper is to provide physicians and policymakers with a set of recommendations to address the significant human and financial costs related to prescription drug abuse. The recommendations address detection and deterrence, as well as treatment, of this condition, and also discuss the need for increased educational efforts on the issue of prescription drug abuse both for the patient population and the physicians who treat them. They touch on the importance of maintaining patient involvement, dignity, and privacy and the importance of limiting third-party administrative and regulatory mandates on physicians attempting to provide care and address this issue. These recommendations offered by the College aim to form a framework for patients to receive the care they require while effectively accounting for the problems associated with the use of prescription drugs—specifically, those with a significant potential for abuse.

From the American College of Physicians, Philadelphia, Pennsylvania.

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APPENDIX: PRESCRIPTION DRUG ABUSE: A POLICY POSITION PAPER FROM THE AMERICAN COLLEGE OF PHYSICIANS

Executive Summary

Prescription drug abuse is found throughout all aspects of the U.S. population and is a serious public health problem. Phy-

sicians and other health professionals with prescribing privileges are entrusted with the authority to use medications in the treatment of their patients and therefore have an important role in helping to ensure safe and effective use of this treatment option and the deterrence of its abuse. This paper is intended to provide guidance to prescribers and policymakers regarding measures to effectively address the problem of prescription drug abuse and offers the following recommendations:

1. *ACP supports appropriate and effective efforts to reduce all substance abuse. These include educational, prevention, diagnostic, and treatment efforts. As physicians dealing with the health effects of this condition, we also support medical research on addiction and its causes and treatment.*

2. *ACP supports a comprehensive national policy on prescription drug abuse containing education, monitoring, proper disposal, and enforcement elements.*

3. *ACP supports the consideration by physicians of the full array of treatments available for the effective treatment and management of pain.*

4. *ACP supports the establishment of a national Prescription Drug Monitoring Program (PDMP). Until such a program is implemented, ACP supports efforts to standardize state PDMPs through the federal National All Schedules Prescription Electronic Reporting (NASPER) program. Prescribers and dispensers should check PDMPs in their own and neighboring states (as permitted) prior to writing or filling prescriptions for medications containing controlled substances. All PDMPs should maintain strong protections to assure confidentiality and privacy.*

5. *ACP supports efforts to educate physicians, patients, and the public on the appropriate medical uses of controlled drugs and the dangers of both medical and nonmedical use of prescription drugs.*

6. *ACP favors a balanced approach to permit safe and effective medical treatment utilizing controlled substances and efforts to reduce prescription drug abuse. However, educational, documentation, and treatment requirements toward this goal should not impose excessive administrative burdens on prescribers or dispensers.*

7. *ACP recognizes that defined maximum dosage (i.e., morphine equivalent) and duration of therapy limitations are not applicable to every clinical encounter. ACP favors establishment of evidence-based, nonbinding guidelines regarding recommended maximum dosage and duration of therapy that a patient taking controlled substance medications may receive.*

8. *Patients identified by Medicare, Medicaid, private insurance plans, or law enforcement authorities as being at significant risk of prescription drug abuse may be required to participate in a drug monitoring program and undergo random drug testing. Physicians may be required to report suspected cases of drug abuse, but should not be mandated to conduct random drug testing without the patient's consent. The financial cost of mandatory drug testing should be borne by the authority requiring the testing; neither the patient nor the physician should bear the financial cost of random drug testing mandated by a third-party authority.*

9. *ACP recommends the consideration of patient-provider treatment agreements between physician and patients as a tool for the treatment of pain.*

10. ACP recommends the passage of legislation by all 50 states permitting electronic prescription for controlled substances.

Introduction

The inappropriate use and abuse of prescription drugs is a serious public health problem. The Centers for Disease Control and Prevention (CDC) has declared that the United States is in the midst of an epidemic of prescription drug overdose deaths (1). The CDC reports that drug overdose, particularly due to nonmedical use of prescription pain relief (opioid) drugs, is the second leading cause of deaths from unintentional injuries in the United States, exceeded only by motor vehicle fatalities (2). A recent analysis of preliminary CDC data suggests that prescription drug overdose may now be the leading cause of such deaths (3). This paper uses the National Institute on Drug Abuse (NIDA) definition of drug abuse, which is “the *intentional* use of a medication without a prescription; in a way other than as prescribed; or for the experience or feeling it causes” (15). The literature reflects an attempt to differentiate between prescription drug misuse (for example, nonsanctioned therapeutic use) and abuse (for example, specific use for recreational/intoxicating purposes) without consensus (16); thus, our use of the term “prescription drug abuse” will include both these important components.

Methods

The decision to develop this policy paper was made by the American College of Physicians’ (ACP’s) Health and Public Policy Committee, which is charged with addressing issues affecting the health care of the U.S. public and the practice of internal medicine and its subspecialties. Recommendations developed were informed through a literature review and input from the various College constituencies and nonmember experts in the field. The policy paper and related recommendations were reviewed and approved by the College’s Governing Board in July 2013.

Background

Population at Risk

A survey in 2010 by the Substance Abuse and Mental Health Services Administration (SAMHSA) found that 16 million Americans age 12 years and older had taken a prescription pain reliever, tranquilizer, stimulant, or sedative for nonmedical purposes at least once in the previous year; 7.0 million (2.7%) had used psychotherapeutic drugs nonmedically within the past month. Of these drug abusers, 55.0% said they obtained the drug they most recently used from a friend or relative for free. Another 17.3% reported they got the drug from one doctor. Only 4.4% obtained the drug from a drug dealer or other stranger, and only 0.4% bought such drugs on the Internet. The survey noted, “Among those who reported getting the pain reliever from a friend or relative for free, 79.4% reported in a follow-up question that the friend or relative had obtained the drugs from just one doctor” (4). Another study found that more than 50% of teens obtained prescription drugs from their own family’s medicine cabinet (5).

The 2010 SAMHSA survey indicated that there were 2.4 million opioid abusers in the United States, with 60% of abused

opioids obtained directly or indirectly through a doctor’s prescription. Furthermore, 2 million people reported using prescription painkillers nonmedically for the first time within the past year (4).

Abuse by the Young

The 2010 SAMHSA survey indicated that individuals age 12 to 25 years report the highest rates of nonmedical use of prescription drugs. The rate of abuse of prescription drugs was 5.9% among young adults age 18 to 25 years. The survey showed that 2.7% of 8th graders, 7.7% of 10th graders, and 8.0% of 12th graders had abused Vicodin during the previous year. In addition, the survey showed that 2.1% of 8th graders, 4.6% of 10th graders, and 5.1% of 12th graders had used OxyContin for nonmedical purposes (4). Other than marijuana, prescription and over-the-counter (OTC) medications account for most of the commonly abused drugs by high school seniors (7).

Recent data from the 2011 National Survey on Drug Use and Health (17) indicates a decline in prescription drug abuse by young adults age 18 to 25 years. The number reporting that they had used prescription drugs for nonmedical purposes in the past month declined by 14%—from 2 million in 2010 to 1.7 million in 2011. The survey also found an overall 12% decline in the number of Americans abusing prescription drugs (18).

Abuse by the Elderly

Persons aged 65 years and older make up only 13% of the population yet account for more than one third of total outpatient spending on prescription drugs in the United States. Recent data also reflect that the dispensing of opioid medication has significantly increased in the past 5 years for individuals 60 years or older (19). Although illicit drug use is low in this population, the prevalence of prescription drug abuse may be as high as 11%, with female sex, social isolation, depression, and history of substance abuse increasing risk (20, 21). Older patients often are being treated for comorbid illnesses and are more likely to be prescribed long-term and multiple prescriptions, including opioid medications for pain. The elderly also are susceptible to age-related changes in drug metabolism and potential drug interactions and also use OTC medicines and dietary supplements, which (in addition to alcohol) could compound any adverse health consequences resulting from prescription drug abuse. As a result of the above, the NIDA notes that prescription drug abuse may therefore be more dangerous in the elderly than in younger populations (21). Some older persons improperly use prescriptions because of cognitive impairment. It is also possible that retirees on a fixed income may abuse leftover medications of a spouse or another person in order to save money.

The Centers for Medicare & Medicaid Services (CMS) has estimated that in 2011 as many as 225,000 Medicare Part D beneficiaries (0.7% of the Part D population) who did not have cancer and were not in hospice received high dosages (more than 120 mg daily) of morphine equivalent dose (MED) for at least 90 consecutive days in 2011, and thus could be at risk for being addicted to or abusing these drugs (22).

Abuse May Be Different in Rural Areas

Prescription drug abuse is a problem throughout the United States. From 1999 to 2003, the rate of increase was higher in rural areas than in urban areas. A study of deaths in rural western Virginia between 1997 and 2003 found a 300% increase in the number of deaths in which drugs, including prescription medications, were determined to be related or contributory causes of death. The rate of death from drugs in rural areas increased steadily over that period. In 58% of the cases, the deaths involved polydrugs (more than one drug or medication). Prescription opioids were identified in 74% of the cases. Although national data indicate the highest rates of prescription drug abuse among persons younger than age 25 years, this study indicated disproportionately higher rates of death from prescription drug abuse in rural areas in an older population (age 35 to 45 years). The authors (23) concluded:

Given the identification of older decedents in our study and nationally, this population may not be taking these medications as directed or may be abusing or addicted to prescription medications, instead of illicit drugs. As policymakers and researchers formulate a response to the increase in nonmedical use of prescription medications, an older population should be targeted for education as well as youths. We should educate all patients, and their families, about taking medication only as prescribed, only by the individual for whom it is intended, and the dangers of combining medications without prescriber knowledge.

It is also notable that prescription drugs have replaced heroin and cocaine as the leading drugs involved in fatal drug overdoses in all urban–rural categories (24).

Prescription Drug Abuse and Fraud in Medicaid

Widespread cases of fraud also have been uncovered in the Medicaid program. In a review of 5 states (California, Illinois, New York, North Carolina, and Texas) in 2009, the Government Accountability Office (GAO) found 65,000 instances of Medicaid beneficiaries improperly obtaining potentially addictive drugs at a cost of about \$63 million during 2006 and 2007. The GAO also found a disturbing amount of fraud, involving thousands of prescriptions written for dead patients or by people posing as doctors (10, 25).

The 65,000 Medicaid beneficiaries identified by GAO had acquired the same type of controlled substances from at least 6 different medical practitioners during fiscal years 2006 and 2007; most had “doctor shopped” to obtain prescriptions from 6 to 10 medical practitioners. At least 400 Medicaid beneficiaries had visited 21 to 112 medical practitioners and up to 46 different pharmacies for the same controlled substances. The GAO acknowledged that although some beneficiaries may have justifiable reasons for receiving prescriptions from multiple medical practitioners, such as visiting specialists or several doctors in the same medical group, others “were likely seeing several medical practitioners to support and disguise their addiction or to obtain drugs to fraudulently sell” (10).

Causes and Contributing Factors

Multiple factors are believed to account for the rise in prescription drug abuse in the United States. Motivations to purposely abuse drugs include the desire to become intoxicated; to counter anxiety, pain, or sleep problems; and to enhance cognition. Unintended misuse can be due to misperceptions about drug safety, use of medications other than as prescribed, and dosage errors due to cognitive decline or impairment.

Contributing to the problem is the dramatic rise in the availability and prescription of drugs. From 1999 to 2009, the number of prescriptions increased 39% (from 2.8 billion to 3.9 billion), compared with a U.S. population growth of 9%. The average number of retail prescriptions per capita increased from 10.1 in 1999 to 12.6 in 2009. Between 1991 and 2010, prescriptions for stimulants increased from 5 million to nearly 45 million and for opioid analgesics from about 75.5 million to 209.5 million (26). High-dose opioids also became more readily available as opioids were reformulated as extended-release medications to allow longer dosing intervals for treating patients in pain (27). After reviewing the significant growth in prescribed controlled drugs in recent years and its correlation with increases in abuse and overdose, Alexander and coworkers posited that the substantial increase in the nonmedical use of opioids and related drugs is a predictable adverse effect of substantial increases in the extent of prescriptive use (28). Furthermore, they questioned the extent to which such campaigns as “Pain as the 5th Vital Sign” (29) and other initiatives to improve the treatment of pain, the establishment of specific pain treatment professional guidelines, and the aggressive marketing of pain drugs by pharmaceutical companies have also, either directly or indirectly, contributed to this current problem.

Overprescribing of medication by physicians for treatment of limited acute or postsurgical pain is also a contributing factor (30). The surplus medications, coupled with inadequate instructions for disposal, serve as a ready source for drugs to abuse or divert for profit.

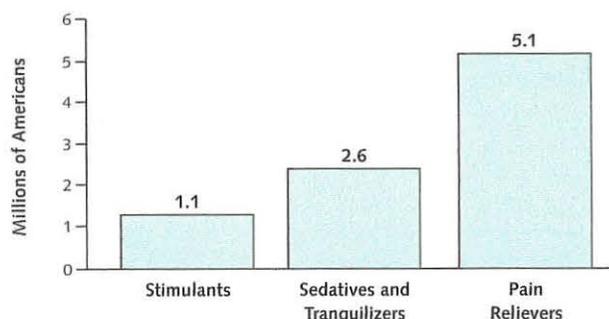
Society and the medical profession also need to reexamine how we view pain and pain relief (16, 16). As summarized by some experts: “The problem facing the United States now is how to change the culture into one that recognizes pain without conflating pain relief with opioid therapy. The treatment of pain with any number of approaches other than opioids can be held up as compassionate care. But most of them require more time than writing a prescription” (31). The profession needs to have a broader therapeutic toolkit that starts with strong patient–physician relationships and supportive systems of care.

Adverse Consequences

Key measures of abuse of pain-relieving opioid drugs increased from 2003 to 2009. The largest increases were in measures of adverse health consequences, such as emergency department visits, substance abuse treatment admissions, and unintentional overdose deaths (1).

The adverse consequences of prescription drugs abuse are serious, and the costs are substantial. Prescription drug abuse is

Figure. 2010 past-month use of prescription drugs for nonmedical uses.



common among both the young and the elderly, and it affects urban as well as rural areas. In 2010, about 7 million Americans reported past-month use of prescription drugs for nonmedical purposes. Commonly abused prescription drugs fall into 3 categories (Figure): pain relievers (opioids), sedatives and tranquilizers (central nervous system depressants), and stimulants (7).

NIDA warns that prescription opioids act on the same receptors of the brain as heroin and can be highly addictive. They also can depress respiration and lead to death. It further advises that injecting opioids increases the risk for HIV infection and other infectious diseases through use of unsterile or shared equipment. Unintentional overdose deaths involving prescription opioids have quadrupled since 1999 and now outnumber those from heroin and cocaine combined. The number of overdose deaths involving opioid analgesics was more than 16,600 according to a recent report from the CDC (8). The National Survey on Drug Use and Health estimates that about 1.9 million people in the United States abuse or are dependent on prescription opioids (15). The potential for abuse is enormous as there are roughly 116 million patients in the United States who have chronic pain (9).

In addition to the costs of treating the addiction and other adverse health consequences associated with prescription drug abuse, there are also other costs to consider. These include not only the actual cost of drug purchases but also the costs of the doctor and emergency department visits that precede the dispensing of these medications. There is also the economic cost of death and lost productivity. As noted by the GAO, "Unlike addiction to heroin and other drugs that have no accepted medical use, addiction to some controlled substances can be financed by insurance and public programs such as Medicaid." Each year, drug abuse and addiction cost taxpayers nearly \$534 billion in preventable health care, law enforcement, crime, and other costs (10).

The Challenge for Physicians and Public Policymakers

The physician must be up to date on the proper use of medications and treatments, including pain medications. Physi-

cians have an ethical obligation to manage and relieve pain yet to do so responsibly and in accord with scientific evidence (11). Improvement in function through the short-term use of opioids and related substances to treat acute pain and their use to ease suffering at the end of life are well-accepted medical practices. However, long-term opioid use for chronic pain is controversial because of concerns about addiction, overuse, misuse, and adverse effects. Long-term use can also lead to opioid-induced hyperalgesia, which in turn leads to increased doses of opioids, further escalating sensitivity to pain. Furthermore, evidence for long-term efficacy is lacking (12). Concerns about pain being underdiagnosed and undertreated remain, particularly for ethnic and racial minorities (13). The result is needless suffering for patients, complications that cause further injury or death, and unnecessary treatment costs. Controlled substances include medications to treat not only pain but also sleep disorders, nerve conditions, weight loss, and other conditions. However, prescribing controlled substances, which can be addictive or abused, can subject physicians to substantial regulatory and administrative burdens. There are criminal and civil penalties, including loss of licensure (and consequent inability to practice) for failure to comply with state and federal laws regulating controlled substances. On the other hand, failure to adequately medicate a patient can expose a physician to malpractice charges of negligence. Physicians can also be sued for overmedication that results in addiction or serious adverse effects (14). State medical boards also report addressing complaints for both overtreatment and undertreatment of pain.

The challenge for physicians and public policymakers is how to deter prescription drug abuse while maintaining patient access to appropriate treatment.

Current Regulatory Framework

The Food and Drug Administration

The U.S. Food and Drug Administration (FDA) is responsible for ensuring the safety and effectiveness of medicines, including prescription drugs, generic drugs, and OTC medications. It has oversight for approval of new prescription drugs, labeling of OTC and prescription drugs, and drug manufacturing standards. It also has regulatory authority over the manufacturing, marketing, and labeling of biological products, medical devices, vaccines, food, cosmetics, and products that emit radiation. It is "responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health" (32).

The FDA provides the public with important drug safety information that is easy to read and is in an interactive format. It maintains a webpage that contains the most recent Drug Safety Communications from the FDA and maintains an Index to Drug-Specific Information. The FDA shares information in the interest of informing doctors and patients about the issues that are under review and when FDA experts anticipate completing their review. The Healthcare Professional Information (33) sheet is for doctors, pharmacists, nurses, and other health care profes-

sionals. It contains an “alert” (a summary of the new safety information), detailed information about the safety issue, factors to consider when making treatment decisions, information for health care professionals to discuss with patients about their roles in reducing the risks from the drug, and a summary of the facts or data that serve as the basis for the information in the sheet.

In July 2012, the FDA approved a risk evaluation and mitigation strategy (REMS) for extended-release and long-acting opioids as part of a federal initiative to address the prescription drug abuse and related overdose epidemic (34). The REMS introduces new safety measures designed to reduce risks and improve the safe use of extended-release/long-acting opioids while ensuring access to needed medications for patients in pain. More specifically, the new REMS for extended-release/long-acting opioids will affect more than 20 companies that manufacture these opioid analgesics. These companies will be required to make education programs available to prescribers on the basis of an FDA blueprint. It is expected that companies will meet this obligation by providing educational grants to continuing education providers, who will develop and deliver the training. Physician participation in this training would be voluntary. In addition, physicians will be required to make available FDA-approved patient education materials on the safe use of these drugs. The companies will be required to periodically assess the implementation of the REMS and the success of the program in meeting its goals. In June 2013 ACP, along with its curriculum partner Pri-Med, launched an online training program on safe opioid prescribing consistent with the FDA blueprint and funded by industry (35).

Drug Enforcement Administration

Under the Controlled Substances Act of 1970, the Drug Enforcement Administration (DEA) established a system for controlling the manufacture, distribution, and dispensing of controlled substances. This legislation requires any person who manufactures, dispenses, imports, exports, or conducts research with controlled substances to register with DEA (unless exempt), keep track of all stocks of controlled substances, and maintain records to account for all controlled substances received, distributed, or disposed. All registrants are required by the DEA to maintain records of controlled substance transactions. Pharmacies are required to maintain records but are not required to report dispensing information at the patient level to the DEA (10).

The DEA classifies controlled substances into 5 schedules on the basis of their currently accepted medical use and potential for abuse and dependence: Schedule I drugs—including heroin, and hallucinogens such as LSD—have a high potential for abuse, and no currently accepted medical uses in treatment in the United States. It should be noted that marijuana, which traditionally is included under Schedule I, has been approved for medical use in several states. Schedule II drugs have currently accepted medical uses but have a high potential for abuse and can lead to severe psychological or physical dependence. They include stimulants, such as *methylphenidate*, and opiates, such as morphine and oxycodone. Drugs on Schedules III through V have medical uses and progressively lower potentials for abuse and dependence. All

drugs except those in Schedule I are legally available to the public with a prescription (10).

Physicians must register with the DEA to prescribe any medications that are controlled substances. The DEA maintains an online listing of criminal investigations of physicians that have resulted in arrest and prosecution. Also online is a list of administrative actions, including judicial decisions and orders.

On 31 March 2010, the DEA issued an Interim Final Rule with Request for Comment titled “Electronic Prescriptions for Controlled Substances” (EPCS). The rule revises DEA regulations to permit physicians to write prescriptions for controlled substances electronically. The regulations also permit pharmacies to receive, dispense, and archive these electronic prescriptions. The rule became effective 1 June 2010 (36).

To help deter abuse of prescription drugs, the DEA sponsors a National Prescription Drug Take-Back Day, the most recent of which was on 26 October 2013. A DEA press release (37) reported that at a similar event on 28 April 2012, citizens turned in a record-breaking 552,161 pounds (276 tons) of unwanted or expired medications for safe and proper disposal at the 5,659 take-back sites that were available in all 50 states and U.S. territories. When the results of the four Take-Back Days to date are combined, the DEA and its state, local, and tribal law-enforcement and community partners have removed over 1.5 million pounds (774 tons) of medication from circulation.”

As noted above, many of the drugs abused come from family, friends, and the home medicine cabinet.

In December 2012, the DEA released a proposed rule (38) that attempts to address the issue of safe disposal of unused controlled substances. More specifically, these proposed regulations contain specific provisions that continue to allow law enforcement agencies to voluntarily conduct take-back events, administer mail-back programs, and maintain collection boxes; allow authorized manufacturers, distributors, reverse distributors, and retail pharmacies to voluntarily administer mail-back programs and maintain collection boxes; and allow authorized retail pharmacies to voluntarily maintain collection boxes at long-term care facilities.

Medicare and Medicaid

Medicare and Medicaid provide coverage for medically necessary prescription drugs, including opioids and other pain medications. Both programs also are dealing with the problem of increasing prescription drug abuse.

CMS has developed daily MED criteria to identify potential cases of opioid overdose and risks for adverse drug reactions. Citing findings from a study in Washington State, CMS determined that “the total daily dose of opioids should not be increased above 120 mg oral MED without either the patient demonstrating improvement in function and pain or first obtaining a consultation from a practitioner qualified in chronic pain management.” CMS then examined claims for Medicare beneficiaries enrolled in Part D at any time in 2011, excluding claims for cancer and hospice beneficiaries. CMS found that 8.8 million of these beneficiaries (28% of all Part D beneficiaries) used opioids

in 2011 and that 1.765 million (5.6% of Part D beneficiaries) exceeded the MED threshold for at least 1 day. In addition, 225 000 beneficiaries (0.71% of all Part D beneficiaries) exceeded the threshold for 90 or more consecutive days and were considered to be “at high risk for potential adverse effects and have a high likelihood of inappropriately using opioids.” Further refinements indicated a population of 22 222 noncancer and nonhospice beneficiaries (0.071% of all Part D beneficiaries) for further utilization review, who received opioid prescriptions exceeding 120 mg daily for 90 or more consecutive days from at least 4 prescribers and at least 4 pharmacies (22).

Using these findings, CMS established a case management pilot program to identify potentially unsafe and inappropriate use of opioids and to detect fraudulent prescriptions. Under this program, the MED clinical thresholds and prescription patterns are used to trigger case management of opioid overutilizers. Written communications are sent to physicians about the appropriateness, medical necessity, and safety of high opioid dosages being prescribed for specific patients under their care. The letters also indicate that, if the patient has opiate prescriptions from multiple prescribers or pharmacies, the physician must then confirm that the opioid medications and the cumulative dosage of opioid medications being prescribed are appropriate, medically necessary, and safe for the patient. When multiple prescribers are involved, the case manager will seek to facilitate a consensus.

On 31 August 2012, CMS issued a memorandum informing Medicare Part D sponsors about the case management pilot program and urging them to be on the lookout for duplicative opioid drug use by identifying beneficiaries with high dosage, sustained use, and multiple providers. CMS also provides Medicare Part D prescription drug plans a MED analysis tool to help plans identify potential overuse (22). CMS supplied supplemental information providing guidance on how to improve drug utilization reviews on 6 September 2012.

Prescription Drug Monitoring Programs

Prescription Drug Monitoring Programs (PDMPs) are state-wide electronic databases that compile information from pharmacies on dispensed prescriptions for controlled substances. Information typically includes the medicine, dose, date dispensed, patient, prescriber, and pharmacy. States vary widely with regard to who is permitted to receive the data and under what conditions. The information is stored in central databases that can be accessed only by authorized users, which include health professional prescribers and pharmacists, but may also include licensure boards, law enforcement and drug control agencies, public and private third-party payers, medical examiners, drug courts, addiction treatment programs, and other public health and safety agencies. These programs are designed to detect and prevent prescription drug abuse by identifying individuals who seek to obtain prescriptions for addictive medications from multiple physicians for themselves or to sell (39).

In 2005, President George W. Bush signed the National All Schedule Prescription Electronic Reporting (NASPER) program. Under this program, federal grants were authorized for states to establish or enhance PDMPs. Review of the efficacy of these

programs indicated that PDMPs are effective in reducing inpatient admissions for prescription opioid abuse and had “a negligible chilling effect on physician prescribing” (40).

However, funding for NASPER was initially delayed and has been inconsistent. Much of the funding for state PDMPs has come from state governments, the Bureau of Justice Assistance of the U.S. Department of Justice, and Purdue Pharma (the manufacturer of OxyContin). By June 2012, 49 states and 1 territory had passed legislation creating PDMPs, and 41 states had operating programs (40). Recently, the Department of Veterans Affairs (VA) amended its regulations to allow participation in state PDMPs (41).

State Medical Boards and the Federation of State Medical Boards

Prescribing authority in each state is under the authority of the state medical board. The Federation of State Medical Boards (FSMB) is a national nonprofit organization representing the 70 medical and osteopathic boards of the United States and its territories. The FSMB leads by promoting excellence in medical practice, licensure, and regulation as the national resource and voice on behalf of state medical and osteopathic boards in their protection of the public. As part of this mission, the FSMB undertook an initiative to develop model guidelines and to encourage state medical boards and other health care regulatory agencies to adopt policies encouraging safe and effective treatment of patients with pain, including, if indicated, the use of opioid analgesics. These guidelines were most recently updated in July 2013 (42).

Recent Legislation and Regulatory Actions *Proposed Federal Legislation*

Senator Rockefeller introduced a bill (S. 348) in February 2013 to require education courses for all prescribers registering with the DEA to prescribe controlled substances. The bill would require the Department of Health and Human Services to establish a mandatory and comprehensive practitioner education program for methadone and other opioids, in collaboration with relevant professional societies (43). The FDA also supports a mandatory training program on responsible opioid prescribing practices that would be linked to DEA registration (44).

The ACP and other medical societies signed a 2009 letter opposing mandatory educational requirements but favoring voluntary efforts. The letter expressed support for adopting positive incentives to encourage physicians to complete educational requirements, such as a waiver of the \$550 DEA registration fee for those who complete a voluntary course on pain management and the recognition of substance use disorders.

On 19 July 2012, Congresswoman Mary Bono Mack (CA-45) and Congressman Bill Keating (MA-10) introduced a bill, the Stop Tampering of Prescription Pills (STOPP) Act (HR 6160), to require manufacturers to formulate tamper-proof versions of their prescription opiate painkillers. The legislation would require drug makers to produce tamper-resistant versions of their opioid pain drugs that cannot be crushed. The legislation is intended to deter people from getting high from crushing opiate pain medications into powder, chewing them, dissolving

them in water, or by injecting them (45). The bill was not brought out of committee review. Nonetheless, at least 2 manufacturers already have voluntarily developed tamper-resistant versions of their pain-relief medications (46).

Recent State Legislative/Regulatory Initiatives

Many states, in recognition of the growing problem of prescription drugs abuse, have recently taken actions to address this problem and also serve as a laboratory for new approaches. Recent legislative/regulatory efforts at the state level have included the following:

1. Implementation of, improvements to, and expanded physician and dispenser duties related to prescription drug monitoring programs (for example, in Kentucky [47], Massachusetts [48], Tennessee [49], and New York [50]).

2. The defining in law of clinical documentation and treatment requirements when scheduled medications are used, which may include patient education, counseling, mandatory urine samples, and the use of so-called pain contracts (for example, in Florida [51], Kentucky [47], and Washington [52]).

3. A requirement for physicians who prescribe scheduled substances to demonstrate competence in the area; take related continuing medical education courses; or, under certain conditions, consult a recognized authority (for example, in Kentucky [47], Wisconsin [52], Georgia [53]).

4. Removal of dispensing privileges for scheduled drugs from physicians (for example, in Florida [51]).

5. Mandating the electronic prescribing (e-prescribing) for all controlled substances (for example, in New York [50]).

Penalties for failure to adhere to defined physician obligations under these regulations vary with each state and may include monetary penalties, criminal charges, and/or suspension or loss of medical license.

Although the medical community has generally been supportive of state efforts to address this growing problem, various physicians and medical societies have expressed concerns that excessive documentation, reporting, and treatment requirements may have the adverse effects of discouraging the appropriate use of these medications and/or patients deciding not to seek needed care (54).

ACP Policy Positions

1. *ACP supports appropriate and effective efforts to reduce all substance abuse. These include educational, prevention, diagnostic, and treatment efforts. As physicians dealing with the health effects of this condition, we also support medical research on addiction and its causes and treatment.*

Since 1998, ACP has advocated for a medical model, as opposed to the criminal justice approach focused on interdiction and incarceration, to address the problem of drug abuse. The medical model favored by ACP focuses on addiction as the underlying pathophysiology of the problem. ACP found that treatment and prevention are cost-effective ways to combat the drug abuse epidemic. Interdiction and incarceration are expensive and yield only minimal results. ACP concluded that treatment and, most of all, prevention are essential to eradicating drug abuse in our society. The College has advocated for development of treat-

ment guidelines to provide the best-quality treatment of all who need it. ACP has recognized that addiction is a chronic condition that must be treated continuously throughout the life of the abuser. Aftercare and other support are crucial to keeping people off drugs. Adequate funding must be provided to ensure that treatment is available. Public perceptions of the drug user must be changed. As the society for internists, ACP seeks to educate our members to ensure that they recognize the signs of substance abuse, are prepared to appropriately counsel and treat their patients, and support public and patient education (55). Furthermore, the College supports research efforts toward meeting all of these goals—including the development of guidelines on how to best provide needed care to patients with a high potential for abuse.

For fiscal year 2012, about \$25.2 billion was provided for drug control programs across 17 federal departments and independent agencies, an increase of \$5.9 billion (about 31%) from 2004. Of these funds, \$10.1 billion was allocated by federal agencies for drug abuse prevention and treatment programs. Approximately 14% of this, or almost \$1.4 billion, was allocated for drug abuse prevention services, and more than 86% of these funds, or greater than \$8.7 billion, for drug abuse treatment services (56).

ACP is pleased to see that NIDA is supporting research to better understand how to effectively treat people with chronic pain because they may be predisposed to addiction to prescription pain relievers. NIDA research is also exploring ways to prevent addiction among those at risk and is leading efforts to develop pain medications that have less potential for abuse, such as those that bypass the reward system of the brain (56). The College is concerned that recent budget cuts mandated by the Budget Control Act of 2011 will adversely affect these efforts (57).

2. *ACP supports a comprehensive national policy on prescription drug abuse containing education, monitoring, proper disposal, and enforcement elements.*

ACP has been a long-time supporter of a comprehensive national policy on drug abuse. National Drug Control Strategies have been produced annually since 1989, and ACP formally supported the goals of the 1998 National Drug Control Strategy (55).

The Office of National Drug Control Policy (ONDCP) was established in the executive branch by the Anti-Drug Abuse Act of 1988 to enhance national drug control planning and coordination. It provides advice and government-wide oversight of federal drug programs and is responsible for coordinating drug control activities. The Office is required annually to develop the National Drug Control Strategy, which sets forth a plan to reduce illicit drug use through prevention, treatment, and law enforcement programs. The first strategy was issued for 2010. It sought to provide “a comprehensive approach to drug policy, including an emphasis on drug abuse prevention and treatment efforts and the use of evidence-based practices—approaches to prevention or treatment that are based in theory and have undergone scientific evaluation” (56).

The Obama Administration developed a Prescription Drug Abuse Prevention Plan in 2011 that expands on the National

Drug Control Strategy. Under the plan, action is to be taken in 4 major areas to reduce prescription drug abuse: education, monitoring, proper disposal, and enforcement. Education will seek to increase awareness about the dangers of prescription drug abuse. Education will be directed at parents, youth, patients, and health care providers. Education of health professionals will include information on ways to appropriately dispense, store, and dispose of controlled substance medications. Drug monitoring programs will be enhanced to help identify “doctor shoppers” and detect therapeutic duplication and drug–drug interactions. Consumer-friendly and environmentally responsible prescription drug disposal programs will be developed to reduce abuse of prescription drugs obtained from family and friends. The plan also includes support for law enforcement agencies in their efforts to shut down “pill mills” and to stop “doctor shoppers” (58). The College supports this and similar comprehensive efforts to address prescription drug abuse.

3. ACP supports the consideration by physicians of the full array of treatments available for the effective treatment and management of pain.

The literature reflects (6, 31), as a result of cultural trends, patient demands, and the time restraints of a typical patient visit, the observation that many physicians tend to respond too quickly to patient pain relief with the use of controlled substances, particularly opioid medications. The College encourages physicians to consider the broad set of therapies available for the effective treatment and management of pain. This “toolkit” starts with strong patient–physician relationships and supportive systems of care, and further can include nonaddictive medications (such as acetaminophen, nonsteroid anti-inflammatory drugs, and antidepressants); controlled medications; physical therapy; psychotherapy and counseling; mind–body approaches (such as relaxation therapy, biofeedback, hypnosis, and yoga); and various alternative therapies (such as acupuncture).

4. The ACP supports the establishment of a national Prescription Drug Monitoring Program (PDMP). Until such a program is implemented, ACP supports efforts to standardize state PDMPs through the federal National All Schedules Prescription Electronic Reporting (NASPER) program. Prescribers and dispensers should check PDMPs in their own and neighboring states (as permitted) prior to writing or filling prescriptions for medications containing controlled substances. All PDMPs should maintain strong protections to assure confidentiality and privacy.

ACP encourages physicians to use screening tools to identify possible drug abuse in their patients and to voluntarily use PDMP databases. Physicians should check before writing initial prescriptions for medications containing controlled substances. To deter prescription drug abusers from obtaining prescriptions from multiple physicians, pharmacies should be required to check the database before filling any prescriptions for controlled substances. A national PDMP structured under NASPER could be much more effective in addressing prescription drug abuse than programs administered by the states, which are not accessible to pharmacies or prescribers in other states and have different as well as redundant reporting requirements. A national program could be standardized so that data would be uniformly reported

to a single secure database that would be accessible across state lines to pharmacies, prescribers, and researchers on a confidential basis with appropriate privacy protections. Data on controlled medications dispensed by the VA should be included in the national database to detect potential drug abuse among the large population of veterans who are treated with them. As noted above, the VA recently modified its regulations to allow participation in state PDMP programs (41). Data in a national PDMP should be highly secure, with protections for confidentiality and privacy and strong penalties for violations or misuse. Funding for the national program should also be more stable than funding has been for the state-administered NASPER program and should include data for all states and the VA.

A national PDMP program would facilitate detection of attempts by drug dealers and drug abusers seeking to obtain controlled substances from multiple sources, including in different states, and would eliminate the administrative burden of checking multiple state databases for physicians and pharmacies.

Prescription data, particularly sensitive information on use of controlled substances, must be securely protected from violations of confidentiality. Access must be limited to those with legitimate needs for the data and must strictly adhere to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule requirements. Physicians, as well as anyone with access to confidential data in PDMP databanks, have an ethical obligation to “follow appropriate security protocols for storage and transfer of patient information to maintain confidentiality, adhering to best practices for electronic communication and use of decision-making tools” (11).

In states where physicians are mandated to check or report on PDMP databases when prescribing a controlled substance, efforts should be made to limit the administrative burden of this task. These efforts can include allowing the physician to delegate this responsibility to designated staff, defining reasonable exceptions to this mandate (for example, exempt mandate for patients receiving end-of-life care) and limiting when such checks are required to be made during a course of care (for example, limit to initial prescription and any new controlled substance prescription provided after 18 months).

The capability of electronic medical records systems to be connected to PDMPs and automatically check and report to these databases would also facilitate physician participation in these programs. The recent approval by the DEA of the electronic prescribing of controlled substances (36) (discussed below) makes this a viable goal.

5. ACP supports efforts to educate physicians, patients, and the public on the appropriate medical uses of controlled drugs and the dangers of both medical and nonmedical use of prescription drugs.

Drug abuse or misuse can be challenging to detect. Resources and education for better management of drug addiction and misuse should be part of any comprehensive plan for appropriate use and prescribing of controlled substances. Physicians must learn to recognize the signs of drug abuse and addiction. Protocols should be developed for the diagnosis and treatment of the conditions, including how to successfully wean patients off addictive medications.

ACP advocates development of evidence-based clinical guidelines and other tools to facilitate appropriate opioid prescribing (55).

Drugs that are classified by the DEA as controlled substances are particularly dangerous, and physicians should be cautious in prescribing them. In ordering any prescription drug, the prescriber must be knowledgeable about the drug's properties, potential benefits, efficacy, dosages, adverse effects, and potential drug interactions. To provide palliative care, physicians must be up to date on the proper use of opioids and the legality and propriety of using high doses of opioids as necessary to relieve suffering (11).

ACP encourages physicians, medical students, and residents to become well informed about the appropriate use and dangers of abuse of prescription drugs, particularly concerning controlled substances, and relevant training and learning opportunities should be available at all levels of practice. Medical school curricula, residency education and service obligations, and physician requirements for continuing medical education teach physicians about pharmacology and how to safely and appropriately prescribe medications. Medical education and training are comprehensive and continue throughout a physician's career.

Prescription drug abuse has only recently been recognized as a national crisis, so many physicians may not have received formal and systematic training regarding drug abuse and controlled substances. The prevention, identification, and treatment of prescription drug abuse take time, and the significant extra time required to adequately perform this task is not reimbursed. Although the College encourages physicians to voluntarily seek to update their knowledge about prescription drug abuse and responsible prescribing practices for controlled substances (particularly opioids), it does not support additional legislative mandates or DEA registration prerequisites specifying education requirements regarding prescribing controlled substances.

Public education should emphasize that all prescription drugs, especially those containing opioids and other controlled substances, should not be used for anything other than medical purposes. Public education should also include warnings not to take medications that are prescribed for someone else. Although patients may have similar ailments, self-medicating with someone else's unused medications, such as leftover drugs from a friend or deceased spouse, can be very dangerous. Patients should not use drugs that are not specifically prescribed for them by a physician who is knowledgeable about other drugs that they are taking, determines appropriate dosages, and is aware of potential for drug interactions. Perhaps most important, public education must raise awareness to approaches to pain management other than drugs.

This public education effort should also focus on ways to safeguard (for example, lock up) medications in use and how to dispose of medications no longer being prescribed.

6. *ACP favors a balanced approach to permit safe and effective medical treatment utilizing controlled substances and efforts to reduce prescription drug abuse. However, educational, documentation, and treatment requirements toward this goal should not impose excessive administrative burdens on prescribers or dispensers.*

ACP is particularly concerned that some current state drug abuse programs involve excessive practice requirements and enforcement methods. In addition to federal penalties that involve loss of DEA licensure and state disciplinary actions that can result in suspension or loss of medical licensure, some states impose criminal sanctions for failure to comply with documentation and treatment requirements. Excessive administrative/regulatory requirements create substantial and costly unfunded burdens for prescribers and pharmacies and can have the further unintended negative effect of interfering in effective delivery of care.

Sedatives, tranquilizers, stimulants, and pain relievers should be available for appropriate treatment of all patients as needed. Yet overly burdensome regulatory requirements may deter some physicians and other prescribers from using the most appropriate medications, causing patients to endure avoidable pain and unnecessary suffering.

7. *ACP recognizes that defined maximum dosage (i.e., morphine equivalent) and duration of therapy limitations are not applicable to every clinical encounter. ACP favors establishment of evidence-based, nonbinding guidelines regarding recommended maximum dosage and duration of therapy that a patient taking controlled substance medications may receive.*

Physicians must be responsive to the specific and unique needs of their patients. They must be able to adjust medication dosages according to individual needs that may vary over time and are not the same for all patients. Consequently, ACP opposes arbitrary maximum dosages by payers and health plans. These guidelines are instructive, but like any guidelines, they should not be rigidly applied and there must be some flexibility to allow adjustments in determining dosages and length of treatment reflecting physician judgment.

The FDA, in an effort to combat the "crisis of misuse, abuse, addiction, overdose, and death" from extended-release and long-acting opioid analgesics, recently narrowed their indicated use to the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate (59). The FDA regulates drug companies, not clinicians and their prescribing, so this does not prohibit physician judgment in prescribing decisions. It does prohibit off-label promotion that is inappropriate given current evidence and that may be encouraging overprescribing.

There has also been controversy over funding of educational efforts around pain management by industry and links between industry and pain groups. ACP favors establishment of evidence-based, nonbinding guidelines, including on recommended maximum dosage and duration of therapy for controlled substances, by unbiased bodies. Physicians should practice with consideration of such guidelines.

ACP does not oppose establishing criteria for targeting efforts to identify potential cases of drug abuse or risks for adverse drug reactions, such as the case management pilot program using MED criteria being tested by CMS to identify potential cases of opioid overdoses and risks for adverse drug reaction (22). These approaches should be coupled with research to assess their effectiveness.

8. *Patients identified by Medicare, Medicaid, private insurance plans, or law enforcement authorities as being at significant risk of drug abuse may be required to participate in a drug monitoring program and undergo random drug testing. Although physicians may be required to report suspected cases of drug abuse, they should not be mandated to conduct random drug testing without the patient's knowledge or consent. The financial cost of mandatory drug testing should be borne by the authority requiring the testing; neither the patient nor the physician should bear the financial cost of random drug testing mandated by a third-party authority.*

The epidemic of prescription drug abuse necessitates that physicians cooperate with efforts by health insurers and government entities to identify and thwart attempts to obtain prescriptions for drugs that will be abused or used illicitly. Programs in some states require patients identified as being at "high risk" for drug abuse to submit to random drug testing. Physicians are mandated to order these random drug tests for patients suspected of being drug abusers because of repeated requests for early refills, requests to replace multiple lost prescriptions, and unauthorized dose escalation. When a physician is mandated to order random drug testing or suspects that a patient is abusing drugs, the patient should first be informed that testing will occur on a random basis, patient consent should be obtained, and the procedure should be implemented in a manner that helps maintain the patient's dignity. The participating physician should also be aware of the limitations of the monitoring procedure used and how various factors (such as a patient's physical condition and use of other medications) can affect the validity of the findings.

Drug testing can cost patients up to several hundred dollars for each episode, and some states require multiple random tests a year. These costs may not be covered by insurance because they are not generally considered medically necessary (60). The costs of mandatory drug testing can thus be high for patients and possibly for the uncompensated physicians who order the tests. When drug testing is mandated by legal authorities, health insurers, or government programs, that authority should bear the cost of the tests.

This recommendation is focused on the specific situation when a third party mandates urine testing (or other forms of monitoring), rather than a situation in which a physician includes monitoring (with consent) as part of an overall treatment plan developed to meet the evaluated needs of a given patient.

9. *ACP recommends the consideration of patient-provider treatment agreements between physicians and patients as a tool for the treatment of pain.*

The use of patient-provider pain treatment agreements, also referred to in the literature as pain management agreements, opioid treatment agreements, and pain medication contracts, have become common in the field of pain management. The FSMB recommends that physicians consider using these agreements (42).

A growing number of states (such as Florida and Washington) currently require physicians to use these treatment agreements under specified conditions. Few evidence-based data reflect the overall effectiveness of these pain agreements or the most effective provisions to include (42, 61). Benefits attributed to use

include facilitating patient understanding regarding the risks and benefits of treatment—particularly when controlled substances are part of the treatment plan—and facilitating increased adherence through an explicit statement of expectations and responsibilities of both the patient and physician during the treatment process.

A review of the opioid agreements used at 38 major academic pain centers contained the following general elements: terms of treatment, prohibited behaviors, points of termination, patient responsibilities, issues about education, addiction treatments, emergency issues, goals, prescription limitations, legal considerations, discouraged behavior, and responsibilities of staff (62).

Recent literature has raised concerns regarding potential negative unintended consequences and ethics and legal concerns regarding the use of these agreements—particularly when the agreements are imposed on the patient as opposed to being developed in coordination with the patient in a manner that recognizes the patient's individual needs and preferences. These consequences/concerns include erosion of the patient-physician relationship as well as the promotion of an environment that discourages patients from seeking pain treatment or physicians from using controlled substances within the treatment plan (63). An ACP article titled "The Difficult Patient: Should You End the Relationship?" (64) addresses issues related to the use of these agreements, including treatment termination provisions, and highlights the ethical and legal obligations related to avoiding patient abandonment.

10. *The ACP recommends the passage of legislation by all 50 states permitting the electronic prescription of all scheduled controlled substances.*

The literature is replete with the benefits of electronic prescribing (e-prescribing) compared with traditional paper prescriptions and includes a seminal report recommending full adoption throughout health care by the Institute of Medicine (65). Benefits purported include improved safety, quality, efficiency, and patient/consumer convenience. These benefits are highlighted when related to the prescribing of controlled substances. The benefits of electronic prescribing of controlled substances include the following:

A. Improved safety in the delivery of these medications when connected with clinical decision support technology. Prescribing physicians can receive at the site of care real-time, drug-drug interaction, drug-allergy interaction, dosing, and clinical guideline information to ensure the appropriateness of the prescription. The physician's history of prescribing for this patient is also readily obtainable.

B. Facilitated real-time communication with payers and pharmacies to help ensure safe and appropriate prescribing of these substances. Prescribers can receive up-to-date system-wide information regarding the patient's medication history, including his or her receipt of prescriptions for controlled substances from other physicians, and safety and potential abuse information derived from REMS and Drug Utilization Review Controls used by payers and pharmacists.

C. Facilitated real-time communication with state (and potentially nationwide) controlled-substance monitoring systems to ensure the safe and appropriate prescribing of these substances.

D. Decreased likelihood of diversion resulting from the security features embedded in the DEA final rule permitting EPCS (summarized below).

Recent surveys reflect significant increases in adoption of EPCS capability throughout the health care system. The Office of the National Coordinator for Health Information recently published a report (66) indicating that 48% of physicians are currently e-prescribing. This report only included physicians doing so through an electronic medical record system. A second survey (67) found that 58% of office-based physicians were e-prescribing, either through an electronic medical record or a stand-alone system, by the end of 2011. A significant impetus for increased implementation of e-prescribing is the use of incentive and penalty initiatives by the federal government—particularly the Medicare eRx and the Medicare and Medicaid “Meaningful Use” electronic medical record programs.

Beginning with the Medicare Modernization Act of 2003, the federal government provided support for the general development of an e-prescribing infrastructure and encouraged implementation of this technology for noncontrolled medications. In contrast, the EPCS has been prohibited by the DEA until recently. The DEA contended that as a result of the increased likelihood of abuse and diversion of controlled substances (compared with other prescription medications), additional safeguards needed to be included within systems before the e-prescribing of these medications could be approved. As noted above, in 2010 the DEA released an interim final rule that defined an approved set of regulations for e-prescribing of controlled substance (36). Safeguards to decrease the likelihood of abuse and diversion include use of a certified e-prescribing application; prescriber identity proofing (that is, an approved credential issuer validates sufficient information to uniquely identify a person applying for the privilege); a 2-factor authentication procedure (the prescriber re-

quires 2 different forms of identification to e-prescribe the controlled substance—for example, password and thumbprint); defined local access procedures; and use of a certified, secure transmission network.

The DEA regulations permitting EPCS do not exempt existing related state laws. An informal survey by Surescripts (68), a provider of secure e-transmission information and e-prescribing networks, indicates that more than 40 states have laws consistent with ECPS, although they vary regarding approval of the ECPS of Schedule II through V or III through V medications. The College historically has supported the concept of e-prescribing and as a result of the recently approved DEA regulations (with embedded safeguards) recommends the passage by all 50 states of legislation permitting e-prescribing of all scheduled medications. Progress remains to be made toward the development of required infrastructure, ready availability of certified e-prescribing systems and modules, and expansion of pharmacies capable of receiving these electronically transmitted controlled substance prescriptions.

Conclusion

The goal of this paper is to provide physicians and policymakers with a set of recommendations to address the significant human and financial costs related to prescription drug abuse. The recommendations address detection and deterrence, as well as treatment, of this condition, and also discuss the need for increased educational efforts on the issue of prescription drug abuse both for the patient population and the physicians who treat them. They touch on the importance of maintaining patient involvement, dignity, and privacy and the importance of limiting third-party administrative and regulatory mandates on physicians attempting to provide care and address this issue. These recommendations offered by the College aim to form a framework for patients to receive the care they require while effectively accounting for the problems associated with the use of prescription drugs—specifically, those with a significant potential for abuse.

TABLE 7

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TAB 8

Osteopathic Medical Board

Future Agenda Items

Agenda Item	Requestor

TABLE 9

Osteopathic Medical Board

Future Meeting Dates

Date	Place	Time

**Please note that all meetings should be held in the best interest of the Board. Meetings in resorts or vacation areas should not be made. Using Conference areas that do not require contracts and or payment is the best option for the Board. No overnight travel. If an employee chooses a mode of transportation which is more costly than another mode, a Cost Comparison form must be completed. Reimbursement by the State will be made at the lesser of the two costs. Taxi Service should be used for trips within but not over a 10-mile radius. Receipts are required for taxi expenses of \$10.00 and over. Tips are not reimbursable.*