



July 29, 2019

The Honorable Charles Grassley
Chairman
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Senators Grassley and Wyden:

The Federation of State Medical Boards (FSMB) is pleased to respond to your letter of June 28, 2019 requesting information about the FSMB and its work in assisting state medical boards and other policymakers with their efforts to address the opioid crisis.

The FSMB and state medical boards agree that the abuse and misuse of opioids continues to be a serious national problem. In annual surveys, including those commissioned since 2012, state medical boards consistently cite the need to develop policies to address opioid prescribing and the creation of resources to assist the ability of state boards to respond. In 2018, 81% of responding state boards identified efforts to curb opioid abuse as a top priority.¹ In the interests of the public that the FSMB and state medical boards serve, the FSMB has worked with federal, state, and local governments, health systems, associations and provider groups, health education and accrediting institutions, pharmacies, payers, industry, public interest groups, and academia to collaborate and address the complex challenges of crafting model pain guidelines which result in the reduction of the abuse and diversion of opioids, while ensuring that patients who suffer from pain have access to needed treatment.

In October 2018, the National Academy of Medicine (NAM) launched an Action Collaborative to address the public health issues created by opioids. It invited the FSMB to serve as a participating member. At the time of the Collaborative's formation, NAM recognized that "[t]he complex drivers of the opioid epidemic make it impossible for any single organization or professional sector to make a significant impact on its own. This one-of-a-kind public-private partnership will bring stakeholders from government, academia, the health care industry, health education, and communities impacted by addiction under the same roof to build collective solutions and accelerate the pace of progress."² Admiral Brett Giroir, MD Assistant Secretary for Health and Senior Advisor for Mental Health and Opioid Policy in the U.S. Department of Health and Human Services, commented that this effort "brings the best from academia, industry, nonprofits, and public service to identify opportunities and recommend bold action plans to yield results."³

¹ Federation of State Medical Boards 2019 Annual Report, <http://www.fsmb.org/SysSiteAssets/advocacy/publications/fsmb-current-annual-report.pdf> (last accessed July 26, 2019).

² National Academy of Medicine Launches Action Collaborative to Counter Opioid Epidemic; Public-Private Partnership Will Coordinate Initiatives Across Sectors to Drive Collective Solutions, available at <https://nam.edu/national-academy-of-medicine-launches-action-collaborative-to-counter-opioid-epidemic-public-private-partnership-will-coordinate-initiatives-across-sectors-to-drive-collective-solutions/> (last accessed July 23, 2019).

³ Id.

It is in this spirit that the FSMB, together with state medical boards, crafted an appropriate patient-centered regulatory response to serious problems caused by opioid misuse. We look to continue our collaborative efforts, at both the state and federal level, on this important area of public health.

About the Federation of State Medical Boards

Established in 1912, the Federation of State Medical Boards is the national non-profit organization that represents the 70 medical and osteopathic boards of the United States and its territories. The FSMB promotes excellence in medical practice, licensure, and regulation and serves as a voice for state medical boards, supporting them through education, assessment, research and advocacy while providing services and initiatives that promote patient safety, quality health care and regulatory best practices. To assist its efforts, the FSMB launched the Federation of State Medical Boards Research and Education Foundation (FSMB Foundation) in 1980. The FSMB Foundation is a supporting non-profit organization to the FSMB that expands knowledge and awareness of issues of importance to state medical boards, the public and the medical profession.

The FSMB enhances the role of state medical boards in a dynamic health care environment by leading, anticipating and responding to trends in medical regulation; serving as an informational and educational resource for the boards; and assisting the boards in developing and using consistent standards, language, definitions, and tools to regulate the practice of medicine. The FSMB helps state medical boards adapt and respond as medicine evolves and various new issues emerge that impact the public. In the constantly changing environment of medical practice, the FSMB plays a key role as a thought leader and shaper of policy.

In drafting model policies and guidelines, the FSMB employs a deliberative and open drafting process that relies on the expertise of state medical boards and utilizes input from experts and observers that represent the views of other stakeholders that will be impacted by the policies. Proposals for model policies are received from state medical boards and refined in committees that produce proposals that are then discussed at reference committees. The reference committees solicit broad feedback and can make modifications to proposals as part of their review. The final recommendations are reported out of committee and are voted on by the FSMB House of Delegates, a deliberative body representing each one of the 70 state medical boards. The process of comment and review, which often lasts a year or longer, ensures that FSMB policies represent an objective view of an issue and provide states with practical solutions for consideration.

In recent years, the FSMB has facilitated stronger ties and partnerships between state and federal leaders on important national health issues. The FSMB continues to be recognized as an organization that acts with integrity and efficacy to assist federal policymakers in anticipating impactful trends in medicine and shaping best practices and recommendations for the future safety of the public when receiving medical care.

License Mobility and Access to Care

State medical boards, with assistance from the FSMB, successfully implemented the Interstate Medical Licensure Compact, a key development in addressing the longstanding calls for enhanced license mobility, improved access to care, and the growing use and support of telemedicine. The Interstate Compact is now law in 29 states and 2 territories and has facilitated the expedition of over 6,000 medical licenses since 2017.

The successful implementation and growth of the Interstate Medical Licensure Compact can be attributed to on-going partnership between the FSMB and the U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA). Since 2012, the FSMB has been the recipient of multiple license-portability grants, authorized under the Public Health Service Act. These grant funds have allowed the FSMB to coordinate and expand multi-state cooperation between licensing boards in furtherance of national needs and priorities.

The ability of the FSMB to work collaboratively with a variety of stakeholders in furtherance of regulatory efficiency has not gone unnoticed by Congress and other federal policymakers. On January 9, 2014, a bi-partisan group of sixteen U.S.

Senators publicly commended state medical boards and the FSMB for their recent efforts to streamline the licensing process for physicians who wish to practice in multiple states. In the letter, the Senators noted that the proposed compact system retains important patient protection advantages of the current state-based medical licensing process. “We agree that allowing states to share information while allowing each state to retain jurisdiction over physicians who choose to practice in the state is in the best interest of both physicians and patients,” the letter said. The Senators noted that the new expedited licensure system would help ensure telemedicine is practiced in a “safe and accountable manner.”⁴ On February 26, 2014, Maureen K. Ohlhausen, Commissioner, Federal Trade Commission, offered the following statement: “In what I view as a positive development, a bipartisan group of sixteen U.S. Senators recently commended state medical boards and the Federation of State Medical Boards (FSMB) for their efforts to streamline the licensing process for physicians who wish to practice in multiple states.”⁵

Regenerative Medicine and Stem Cell Therapy

Recognizing rapidly evolving use of stem cell therapies requires consistent regulation to ensure patients are not being exploited or harmed, Senator Lamar Alexander, Chairman of the Senate Health, Education, Labor, and Pensions (HELP) Committee called upon the FSMB to lead efforts to develop recommendations for state medical boards in their pursuit to help protect patients from unproven or unethical stem cell treatments. Working fastidiously to address the issues raised by Senator Alexander, the FSMB’s Workgroup to Study Regenerative and Stem Cell Therapy Practices completed its report in April 2018. The report recommends best practices for regulating the promotion, communication and practices of treatments received at stem cell clinics in the United States. It raises awareness about these practices generally, outlines potential benefits and risks, as well as provides basic guidance for state medical boards and their licensees.

FSMB Activities Related to Treatment of Pain and the Misuse, Abuse and Diversion of Opioids

For over 20 years, state medical boards have struggled with a lack of consistent policies related to the treatment of pain, which contributed to the dual public health issues of the under-treatment of pain and the improper use of controlled substances in addressing pain. Increased public demand for improvement in the medical management of pain and advances in medical knowledge regarding the use of controlled substances (including opioids), combined with sometimes inadequate physician awareness of the practical implications, laws, and regulations governing the prescribing of these substances, has made initiatives related to opioids a continuing priority for the FSMB.

Since its first major initiative related to pain and opioid prescribing in 1997, the FSMB and its state medical board members have sought to balance efforts to ensure patient access to appropriate pain care with efforts to reduce the potential for prescription drug misuse, abuse and diversion. These multi-pronged efforts have included policy-making, educational outreach, and collaboration with key federal and state agencies, physician organizations, foundations, academia, and many other stakeholder groups. The goal of the FSMB has remained the same: engage all stakeholders to work towards development of policy frameworks that bring consistency to differing regulatory processes and to assist states in development of guidelines and laws addressing pain management and appropriate and responsible prescribing.

Federal officials who have made curbing opioid misuse a priority have recognized the ability of the FSMB to provide a thoughtful, unbiased forum in which to raise awareness of these issues and develop strategies aimed at addressing the misuse, abuse and diversion of all controlled substances. On several occasions, these leaders have engaged directly with the FSMB Board of Directors or used FSMB programs to address the state medical board community.

⁴ <https://www.thune.senate.gov/public/index.cfm/2013/3/thune-encourages-federation-of-state-medical-boards-to-develop-medical-licensure-portability-proposal>.

⁵ Maureen K. Olhausen, Beyond Law Enforcement: The FTC’s Role In Promoting Health Care Competition And Innovation, available at <http://healthaffairs.org/blog/2015/01/26/beyond-law-enforcement-the-ftcs-role-in-promoting-health-care-competition-and-innovation/> (last accessed July 26, 2019).

- In October 2012, Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control at the Drug Enforcement Agency (DEA) spoke to a joint meeting of the FSMB, the National Council of State Boards of Nursing (NCSBN) and the National Association of Boards of Pharmacy (NABP) and urged improved alignment between federal and state regulators on issue of diversion and prescription drug abuse.
- In October 2014, the FSMB Board of Director was addressed by Michael Botticelli, Director of the White House Office of National Drug Control Policy. Mr. Botticelli reviewed the Obama Administration’s National Drug Control Strategy that outlines innovative policies and programs and recognizes that substance abuse is not just a criminal justice issue but also a major public health concern. Mr. Botticelli praised the FSMB’s work in the area of opioid prescribing and addiction and encouraged the FSMB to notify the ONDCP of best practice results so that the office can amplify those accomplishments.
- In April 2015, Mr. Botticelli delivered the *Dr. Herbert Platter Lecture* at the FSMB’s annual meeting.
- In April 2016, U.S. Surgeon General Vivek Murthy, MD, served as a Keynote Speaker at the FSMB Annual Meeting and announced his intention to visit selected states to highlight the epidemic of deaths due to prescription opioids. He urged the FSMB to partner with him on efforts to mitigate the misuse, abuse, overdose and diversion of long-acting and extended-release prescription opioids. The FSMB assisted in this initiative to arrange representatives of state medical and osteopathic boards to personally join the Surgeon General across the country.
- In February 2019, Admiral Brett Giroir, MD Assistant Secretary for Health and Senior Advisor for Mental Health and Opioid Policy in the U.S. Department of Health and Human Services met with the FSMB Board of Director to provide a comprehensive update on the current state of opioid abuse and the status of the five-point strategy of the U.S. Department of Health and Human Services (HHS) to end the opioid addiction in America that was unveiled by the President in 2017. He reported how the HHS has expanded the scope of the strategy and is improving its effectiveness by using robust, scientific evidence as its foundation to set forth specific, concrete actions that can be taken by the Secretary and agencies within HHS to reduce opioid-related health harms. He called for continued collaboration with the FSMB and state medical boards and other stakeholders to opioid abuse and misuse.

Throughout its work on these issues, the FSMB has sought to raise awareness with physicians and the public of the risks that opioids pose – in addition to their benefits for patients in need – while striving to bolster safeguards for their appropriate use.

Guidelines for the Chronic Use of Opioid Analgesics (2013/2017)

As a result of increased scientific and clinical research on opioids and the ever-present need for evolving strategies aimed at addressing the misuse, abuse and diversion of opioids, the FSMB has revised its Model Guidelines for the Use of Controlled Substances for the Treatment of Pain in 2013 and 2017 and renamed the document Guidelines for the Chronic Use of Opioid Analgesics.

FSMB’s policies have never advocated for opioid therapy by physicians; rather, they offer a framework that ensures that physicians who choose to prescribe opioids do so responsibly and safely, and remain in compliance with legal requirements regarding their use. The FSMB firmly stands behind the integrity of the processes it uses to develop model policies. These policies are drafted by state medical boards and formulated with input from a diverse group of major stakeholders, including pain and addiction specialists, patient advocacy groups, professional medical societies and federal law enforcement agencies. This process resulted in guidelines that represent consensus from key national stakeholders on how best to address a complex issue and provided regulatory guidance that is designed to be both unbiased and thorough.

Since their adoption, the *Model Guidelines* have been extensively distributed to state medical boards, medical professional societies, other health care regulatory boards, and patient advocacy groups, as well as state and federal regulatory, law enforcement and other agencies, including the U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA) and U.S. Drug Enforcement Administration (DEA).

Copies of both policies, which include a roster of all members and participants of the committee are attached. Each member completed a conflict of interest and disclosure form as part of his or her service on the committee, as described in more detail in the answers provided below.

Model Policy Guidelines for Opioid Addiction Treatment in the Medical Office (2013)

The use of buprenorphine for the treatment of opioid addiction is governed by the federal Drug Addiction Treatment Act of 2000, commonly referred to as "DATA 2000" (Public Law 106-310, Title XXXV, Sections 3501 and 3502). This legislation is of particular interest to state medical boards because, for the first time in almost a century, it allows physicians to treat opioid addiction with FDA-approved controlled drugs in office-based settings. Specifically, DATA 2000 allows physicians to use buprenorphine and other controlled substances in CSA Schedules III, IV, and V, which have been approved by the FDA for the treatment of opioid dependence, to treat patients in office-based settings, provided certain conditions are met. DATA 2000 thus has enlarged treatment capacity by lifting the requirement that patients who need opioid agonist treatment can receive such treatment only in specially licensed opioid treatment programs (OTPs), often referred to as "methadone clinics." Implementation of DATA 2000 required changes in the oversight systems within the Department of Health and Human Services (HHS) and the DEA. The Secretary of HHS delegated authority in this area to the Center for Substance Abuse Treatment (CSAT) of SAMHSA.

The use of opioid agonist medications to treat opioid-addicted patients in the offices of individual physicians significantly increased the role of state medical boards in overseeing such treatment. Recognizing that prior policies were outdated and did not reflect current best practices, SAMHSA, in 2011, sought out the assistance from the FSMB to develop model guidelines for use by state medical boards in regulating office-based treatment of addiction.

After a comprehensive review and drafting process, the revised Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office was adopted as policy by the House of Delegates of the FSMB in April 2013.

Responsible Opioid Prescribing: A Clinician's Guide

Among the FSMB's educational initiatives, facilitated through efforts of the FSMB Foundation, has been the development and distribution of guidebooks intended to help physicians recognize the risks of opioids and follow responsible and safe prescribing standards. The book distills the principles of FSMB's *Model Policy for the Use of Controlled Substances for the Treatment of Pain*. The guidelines offered a balanced approach to opioid prescribing, acknowledging the legitimate medical uses of controlled substances for patients in need, while stressing the critical responsibility that physicians have in safeguarding against abuse and diversion.

The first edition of *Responsible Opioid Prescribing: A Physician's Guide* was released in 2007. The book was authored by Scott M. Fishman, MD and developed with the assistance of an advisory board, which included a diverse range of physicians, academicians and health-policy experts who reviewed its content. This first edition was accredited, in compliance with applicable standards set by the ACCME, by the University of Wisconsin School Of Medicine and Public Health and designated for 7.25 AMA PRA Category 1 Credits™.

In April 2012, recognizing the continuing growth of the nation's prescription drug abuse epidemic, the FSMB Foundation, through funding from SAMHSA, commissioned an updated version of the guidebook, now titled *Responsible Opioid Prescribing: A Clinician's Guide*, which was published, with updated approaches to addressing pain management and opioid addiction. The second edition was accredited by the University of Nebraska Medical Center for 7.25 AMA PRA Category 1 Credits™.

The expanded 2012 edition of the book closely aligned with two important federal initiatives: (1) the FDA's proposed Risk Evaluation and Mitigation Strategies (REMS) for Long-Acting/Extended-Release Opioid Class-Wide content guidelines for prescriber education and (2) the ONDCP's action plan to address the national prescription drug abuse epidemic, adopted in

2011. Among its recommended strategies, the ONDCP's action-plan called for a collaborative effort with state medical boards to raise awareness of the safe and appropriate use of opioids to treat pain, while minimizing the risk of addiction and substance abuse, as a part of continuing medical education and instruction in health professional schools. Recommendations in the book addressed the key elements of these federal initiatives, including support of prescription drug monitoring programs (PDMPs), more effective disposal methods of unused medications, improved education for healthcare providers and patients, and reducing the prevalence of "pill mills" and doctor shopping through enforcement efforts.

National Collaboration to Better Utilize Health Information Technology Related to Prescribing

In 2012, the FSMB participated in a collaborative effort with the Office of the National Coordinator for Health Information Technology, ONDCP, SAMHSA, major pharmacy chains, and other stakeholder organizations to promote the use of health information technology to reduce prescription drug abuse. Under this project, the FSMB partnered with these organizations to improve access to database information on prescribers and dispensers of controlled substances found in PDMPs. The project emphasized timely access to PDMP data at the point of care, at the point of dispensing, and in hospital emergency departments.

Efforts to Reduce Fraud and Improve DEA Monitoring of Controlled Substances

In accordance with the Controlled Substances Act, the DEA registers individuals and entities authorized to manufacture, distribute, or dispense controlled substances and seeks to ensure that only authorized individuals handle controlled substances. As part of this process, the DEA must rely upon state medical board licensure and disciplinary data to properly determine which health-care professionals are permitted to handle or prescribe controlled substances.

In May 2016, the United States Government Accountability Office issued recommendations designed to improve the ability of the DEA to monitor physician eligibility to handle controlled substances. Among the recommendations was a recommendation that the DEA identify and implement a cost-effective approach to monitor state licensure and disciplinary actions taken against registrants in the controlled substance database. DEA partnered with the FSMB to obtain physician licensure and disciplinary data in a format that allows real-time access to the data and which can accommodate the large numbers of applicants for DEA Registrations. This partnership highlights the role of the FSMB as a bridge between state and federal regulators in furtherance of policy that reduces the frequency of fraud and abuse related to opioids and other prescription drugs.

Educational Partnerships with DEA

Starting in 2018, the DEA partnered with the FSMB to develop and host live continuing medical education programs designed to educate licensed physicians and physician assistants on current trends involving pharmaceutical controlled substances, including the potential for controlled substance diversion. During these one-day regional conferences, attendees are presented with the current laws and regulations concerning valid controlled substance prescriptions as well as key federal and states resources available to them. Information on how to help patients and their family members overcome controlled substance addiction are discussed. Conferences are open to all DEA registered physicians, physician assistants, veterinarians, dentists and nurse practitioners.

These educational activities are planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education ("ACCME") through the joint sponsorship of the FSMB and the DEA. The FSMB is accredited by the ACCME to provide continuing medical education for physicians.

List of Conferences

Date	Location
May 5-6, 2018	Orlando, FL
August 6-7, 2018	Louisville, KY
September 29-30, 2018	Charleston, WV
November 9, 2018	Detroit, MI
November 18-19, 2018	Nashville, TN
December 17-18, 2018	Hershey, PA
February 4-5, 2019	Anaheim, CA
March 18-10, 2019	Cleveland, OH
May 5-6, 2019	Norman, OK
June 3-4, 2019	Dover, DE
June 14, 2019	Grand Rapids, MI
July 19-20, 2019	Phoenix, AZ
July 22-23, 2019	Indianapolis, IN
August 19-20, 2019	Manchester, NH

Additional Opioid Initiatives with Federal Agencies and Other Organizations

An integral component of the FSMB's efforts related to opioid prescribing and the under-treatment of pain is its collaboration with various government agencies and other stakeholder organizations. Among the organizations the FSMB has worked with are SAMHSA's Center for Substance Abuse Treatment, the DEA the FDA, ONDCP, and the National Institute on Drug Abuse – all of which assisted the FSMB in updating and revising its Model Policy for the Use of Controlled Substances for the Treatment of Pain.

- In March 2012, FSMB senior staff served as faculty for a DEA training program, Pharmaceutical Investigations and Prosecution Seminar, in Philadelphia, PA.
- In 2011-2012, the FSMB continued to participate in SAMHSA's Center for Substance Abuse Treatment Open Dialogue Meetings, a forum to discuss the non-therapeutic use of prescription medications, and strategies to reduce their misuse. Among the participants were experts from the medical community, federal agencies, consumer organizations, and the pharmaceutical industry.
- The FSMB continued to serve as a member of the FDA Opioid Patient Prescriber Pain Treatment Agreement Working Group, assisting with the development of model provider patient agreements for long-term opioid therapy as well as other prescriber resources.

Turning to the information requested in your June 28, 2019 letter, and to the best of our knowledge, after reasonable due diligence and good faith efforts and to comply with the information requested, the following is provided in response to the questions contained in that letter.

Question 1:

Please provide complete Form 990s that your organization has filed with the Internal Revenue Service for each year from 2012 to the present. In your submission, please also provide complete Schedule Bs.

Answer 1:

The requested Form 990s are attached for both the FSMB and the FSMB Foundation. The Form 990s for each respective organization cover the years of FY2012-FY2017 and are submitted in full form.

Question 2:

Please provide a detailed accounting of all payments/transfers (including but not limited to contributions, grants, advertising, program sponsorship, and other revenue or remuneration) received from any manufacturer of drugs, devices, biologicals or medical supplies and individuals that produce, market, or promote products on these entities' behalf. Please provide this information in hard copy, PDF, and in a Microsoft Excel workbook. For each payment identified, provide:

- a. Date of payment.
- b. Source or entity making the payment.
- c. Payment description (general support, project specific etc.).
- d. Amount of payment.
- e. Year-end or year-to-date payment total and cumulative total payments for each organization or individual.
- f. For each year a payment was received, the percentage of funding from organizations identified above relative to total revenue.

Answer 2:

In short, since 2012, the FSMB has received no funding from any manufacturer of drugs, devices, biologicals, or medical supplies or any individuals that produce, market, or promote products on these entities' behalf.

Direct Payments or Transfers

The requested payments/transfers received by the Federation of State Medical Boards (FSMB) and the Federation of State Medical Boards Research and Education Foundation (FSMB Foundation) from 2012 to the present are:

Payer Organization	Recipient Organization	Date	Payment Description	Amount	Percentage of Revenue
FSMB Foundation	Endo Pharmaceuticals	6/11/2012	Return of Funds Grant for Proposed CME Activity Related to FDA Opioid REMS	(\$106,817.73)	N/A
FSMB Foundation	Covidien	6/11/2012	Return of Funds Grant for Proposed CME Activity Related to FDA Opioid REMS	(\$76,500.00)	N/A
		Total For 2012		(\$183,317.73)	0.00%
		Total for 2013		\$0.00	0.00%
		Total for 2014		\$0.00	0.00%
		Total for 2015		\$0.00	0.00%
		Total for 2016		\$0.00	0.00%
		Total for 2017		\$0.00	0.00%

		Total for 2018		\$0.00	0.00%
		Total for 2019 (as of July 29, 2019)		\$0.00	0.00%
Totals				(\$183,317.73)	

In 2010, in anticipation of the FDA Opioid Prescribing REMS, the FSMB Foundation joined with a number of other organizations, including the American Pain Foundation, to work collaboratively to prepare for educational modules which would qualify under the then expected REMS. Both Endo Pharmaceuticals and Covidien supported this effort with an educational grant that was intended to support these efforts. These contributions were previously disclosed by the FSMB to the U.S. Senate Committee on Finance as part of its response to the Committee's 2012 inquiry into opioid prescribing.

After unexpected delays in the release of FDA REMS, the FSMB Foundation learned that the REMS participation restricted any use or inclusion of materials that existed prior to the issuances of the REMS, thereby disqualifying the FSMB's prior effort. Additionally, as a matter of sound public policy, the FSMB Foundation adopted a policy in early 2012 which precluded its acceptance of any grants or funding from pharmaceutical companies. Also of relevance, the American Pain Foundation terminated its corporate existence in May 2012. Given the change in circumstances, the FSMB Foundation believed that maintaining the funds would be inconsistent with its understanding of prospective REMS requirements and would undermine its role as an objective source of public information on many of the complex issues surrounding opioid prescribing. Accordingly, these funds were returned.

Annual Meeting Registration Fees

Each year, the FSMB hosts an Annual Meeting for its membership, which serves as the premier educational forum offered to the medical regulatory community. The FSMB Annual Meeting is open to any individual who pays the registration fee. On average, approximately 450 individuals attend the Annual Meeting. While the FSMB is unable to determine if registration fees are paid on personal or corporate credit cards, or the full relationship between any individual attendee and the entities indicated in this request, the following information is provided in interest of full disclosure. This information was also previously provided to Senator Claire McCaskill on October 11, 2017 in response to a letter of requesting information similar in nature to the information requested by this Committee.

Individual	Organization	Fee Paid	Date of Payment	Description
Ann Rule	Purdue Pharma, L.P.	\$595	3/7/2012	Registration for 2012 FSMB Annual Meeting
Kristi Dover	Purdue Pharma, L.P.	\$595	3/14/2012	Registration for 2012 FSMB Annual Meeting
J. David Haddox	Purdue Pharma, L.P.	\$770	04/03/2017	Registration for 2017 FSMB Annual Meeting, including \$75 CME fee
Matthew O'Donnell	Purdue Pharma, L.P.	\$695	04/03/2017	Registration for 2017 FSMB Annual Meeting

Question 3:

In addition to financial support, identify and describe any collaborative activity between your organization and the entities identified in Question 2 from 2012 to the present and the timeframe in which such activity took place.

Answer 3:

While there are divergent views within medical, scientific, pharmaceutical and policymaker communities on the best way forward to address issues related to opioid abuse, the FSMB has engaged with all of these communities to help ensure that patient safety and the role of the state medical boards are part of a shared understanding of how best to address evolving trends in pain management.

Pain Care Forum

The FSMB has participated with the Pain Care Forum from 2006, and still receives periodic communications from the Pain Care Forum about its activities that are monitored for issues of interest to state medical boards. However, the FSMB substantially decreased its involvement in recent years and rarely attends meetings.

Participants in the Pain Care Forum represented diverse viewpoints, and included individuals from pharmaceutical industry as well as groups such as the American Cancer Society, the Partnership for a Drug Free America, and several professional societies which represented physicians and other allied healthcare professionals. The FSMB viewed the opportunity to attend and participate in meetings and activities of this group as consistent with its overall public policy goals related to the study and drafting of model pain polices and as a means to ensure representation of the perspectives of the state medical board community in industry-wide discussions about pain care. FSMB participation also provided perspectives on patient safety and the growing issues faced by state regulators in addressing issues of opioid abuse and

diversion. The FSMB shared these perspectives on various subgroups within the Pain Care Forum that were studying federal legislation and providing comments focused on engaging the public.

Additionally, the meetings hosted by the Pain Care Forum allowed the FSMB to hear from leading policymakers in pain management and to call for further collaboration between state medical boards, federal agencies, and other interested stakeholders. For example, by attending and participating in Pain Care Forum programs, the FSMB was able to hear presentations from individuals such as:

- Douglas Throckmorton MD, Deputy Director, CDER, presentation entitled FDA Policies and Actions Related to the Development and Use of Opioids to Treat Pain (May 12, 2016)
- Michael Botticelli, Deputy Director of the Office of National Drug Control Policy (March 14, 2013)
- Story Landis and Linda Porter from National Institutes of Health, presenting materials from the Institute of Medicine and the Interagency Pain Research Coordinating Committee (IPRCC), which is a federal advisory committee created by the Department of Health and Human Services (December 13, 2012)
- Andrew Kolodny, MD, President, Physicians for Responsible Opioid Prescribing (September 20, 2012)

While this list is not exhaustive of all presentations or topics discussed, engagement with the Pain Care Forum allowed for exposure to a range of viewpoints that enhanced the ability of the FSMB to educate state medical boards. These meetings also allowed the FSMB to engage in dialogue with an eye towards creation of thoughtful and balanced public policy.

Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances

The National Association of Boards of Pharmacy hosted a coalition of stakeholders representing medicine, law enforcement, pharmacy and the supply chain spectrum over the course of several months. The FSMB, as well as representatives from the Ohio and Texas medical boards, participated. The purpose of the coalition was to address prescribing and dispensing of controlled substances and to provide clarification around federal law pertaining to pharmacist “corresponding responsibility” in the dispensing of controlled substances.

One of these meetings was the creation of ‘Stakeholders’ Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances’—a document that illustrated the challenges and the “red flag” warning signs related to the prescribing and dispensing of controlled substances. The goal of this resource was to provide prescribers and dispensers with a better understanding of their shared responsibility to ensure that all controlled substances are prescribed and dispensed for a legitimate medical purpose and to provide guidance as to the warning signs that warrant further scrutiny.

The FSMB approved this document in July 2015. In addition to the FSMB, the following participating organizations approved or endorsed the document: American College of Emergency Physicians; American Medical Association; American Osteopathic Association; American Pharmacists Association; American Society of Anesthesiologists; American Society of Health System Pharmacists; Cardinal Health; CVS Health; Healthcare Distribution Management Association; National Association of Boards of Pharmacy; National Association of Chain Drug Stores; National Community Pharmacists Association; Pharmaceutical Care Management Association; Purdue Pharma L.P.; Rite Aid; and Walgreen Co.

Question 4:

Does your organization maintain a conflict of interest policy? If so, please provide us a copy of the current policy and tell us how long this policy has been in effect. In addition, please describe any additional mechanisms your organization uses to police conflicts of interest and to promote transparency of funding sources.

Answer 4:

Throughout its history, the FSMB has instituted corporate best practices corporate governance policies and guidelines for workgroups and committees. As an organization that represents the state regulators who are charged by state law to develop standards for the practice of medicine, the FSMB demands high standards of ethical and honest behavior from its board members, staff, and those whom it calls upon to serve the organization in a variety of advisory capacities.

The FSMB has a conflict of interest policy that is enforced across the organization. Compliance with organizational policies and continual reaffirmation of commitment to these values is essential for the FSMB to serve as voice for both its member state medical boards and for the public. The Board of Directors maintains a list of disclosed affiliations that is included as part of the materials distributed in advance of each Board of Directors meeting. Any additions or changes to this list are called for by the Chair prior to commencing with the business agenda. Similarly, conflicts disclosed by committee or workgroup members are distributed and updated as part of regular business.

As part of its annual review of governance documents, the Governance Committee of the FSMB met in Spring 2019 and amended the definition of ‘Key Person’ in the conflict of interest policy to apply to any individual appearing before the FSMB where matters of public policy are discussed. The FSMB Board of Directors approved these recommended changes at its July 2019 meeting.

A copy of both the prior conflict of interest policy, which was in effect from July 2010 to July 2019, and as well as the recently amended version are attached to this response. Additionally, FSMB Board Members are subject to a Code of Conduct and Ethics Policy which is also attached to this response.

As an accredited provider of continuing medical education credits, the FSMB must also comply with ACCME Standards for Commercial Support. These standards require anyone in a position to control the content of an educational activity or involved in the planning of the educational content including faculty, abstract reviewers, paper presenters/authors, planning committee members, and these individuals to disclose all relevant financial relationships with commercial interests prior to the start of the activity. Disclosures are provided as part of any CME program hosted by the FSMB as well as included in all printed program materials.

A copy of the ACCME Policy on Identification, Resolution and Disclosure of Conflicts of Interest is attached.

Also attached is a roster of participants and any disclosed conflicts of interest for all FSMB programming since 2012 addressing opioids or model pain policies.

Question 5:

Regarding involvement with the Federal government:

- a. Has your organization received any funding from the Federal government since 2012? If yes, please list the year, amount, and purpose of this funding in hard copy, PDF, and in a Microsoft Excel workbook.

Answer 5a:

Since 2012, the FSMB has been the recipient of several grant awards from the Department of Health and Human Services, Health Resources and Services Administration (HRSA). The grants have been used by the FSMB to assist state medical boards in their efforts to improve license portability, expand access to health care, especially to those in rural and underserved areas of the country, and facilitate the use of telemedicine technologies in the delivery of health care.

Grant Funding from the Federal Government

FSMB Fiscal Year	Agency or Department	Amount	Purpose
2012	Department of Health and Human Services, Health Resources and Services Administration (HRSA)	\$449,004	The FSMB received funds from HRSA as part of a grant program addressing license portability. The grant allowed the FSMB to utilize funds to offset internal costs associated with the development and deployment of the Uniform Application for physician licensing and for the support of existing and creation of new committees to address issues of license portability and expedited licensure.
2013	Department of Health and Human Services, Health Resources and Services Administration (HRSA)	\$409,351	Includes second installment of grant awarded in 2012.
2014	Department of Health and Human Services, Health Resources and Services Administration (HRSA)	\$468,065	Includes third installment of grant awarded in 2012.
2015	Department of Health and Human Services, Health Resources and Services Administration (HRSA)	\$243,793	Grant supported the efforts of state medical and osteopathic boards to operationalize and to administer the Interstate Medical Licensure Compact. Funding supported the development of specifications for a technical infrastructure to support the expedited licensing process and facilitate greater information sharing among participating state medical boards.
2016	Department of Health and Human Services, Health Resources and Services Administration (HRSA)	\$261,112	Second installment of grant awarded in 2015 to support the Interstate Medical Licensure Compact.
2017	Department of Health and Human Services, Health Resources and Services Administration (HRSA)	\$234,830	Third installment of granted awarded in 2015 to support the Interstate Medical Licensure Compact.

Data Agreements

The FSMB Physician Data Center (PDC) is a central repository of license and disciplinary data for more than 1 million physicians and physician assistants. As noted in the previous discussion regarding the partnership with the DEA that allows the DEA to harness FSMB data to reduce fraud and improve monitoring of controlled substances prescribing, federal agencies, including the Department of Veterans Affairs (VA), Federal Aviation Authority (FAA), and Office of the Inspector General (OIG) have come to recognize the PDC as a premier source of information that is vital to their regulatory mandates.

The Department of Veterans Affairs utilizes two services provided through the PDC. The first service, which is a disciplinary alert service, cross-references VA rosters of health practitioners with PDC files to alert the VA to any adverse actions taken against healthcare providers in their system. The second service consists of transactional queries performed at the request of each of the VA's 143 medical credentialing centers for the purpose of obtaining

full PDC Profile Reports about individual health care practitioners. This PDC Profile Report is a comprehensive document identifying any previously recorded disciplinary actions taken by PDC reporting agencies in addition to a medical licensure history and a listing of currently active licenses held by the physician. In the time period of 2012-present, individual VA hospital queries of the PDC have incurred fees for services in the amount of \$374,814.

Year	Agency or Department	Amount	Purpose
2012	Department of Veterans Affairs	\$68,750.00	Physician Data Licensing Directory Subscription
	FAA Civil Aerospace Medical Institute	\$5,752.50	Physician Data Licensing Directory Subscription
2013	Department of Veterans Affairs	\$68,750.00	Physician Data Licensing Directory Subscription
	FAA Civil Aerospace Medical Institute	\$7,507.50	Physician Data Licensing Directory Subscription
2014	Department of Veterans Affairs	\$77,378.44	Physician Data Licensing Directory Subscription
	FAA Civil Aerospace Medical Institute	\$5124.50	Physician Data Licensing Directory Subscription
2015	Department of Veterans Affairs	\$79,700.10	Physician Data Licensing Directory Subscription
2016	Department of Veterans Affairs	\$82,091.10	Physician Data Licensing Directory Subscription
	Department of HSS/OIG	\$13,000.00	Physician Data Licensing Directory Subscription
2017	Department of Veterans Affairs	\$84,553.83	Physician Data Licensing Directory Subscription
	Department of HSS/OIG	\$18,750.00	Physician Data Licensing Directory Subscription
	FAA Civil Aerospace Medical Institute	\$17,500.00	Physician Data Licensing Directory Subscription
2018	Drug Enforcement Administration	\$99,000.00	Physician Data Licensing Directory Subscription
	Department of Veterans Affairs	\$86,400.00	Physician Data Licensing Directory Subscription
	Department of HSS/OIG	\$6,500.00	Physician Data Licensing Directory Subscription
	FAA Civil Aerospace Medical Institute	\$17,500.00	Physician Data Licensing Directory Subscription
2019	FAA Civil Aerospace Medical Institute	\$17,500.00	Physician Data Licensing Directory Subscription

- b. Please provide copies of all comments or other written materials that your organization has made to Federal task forces, committees, advisory groups, or other similar entities from 2012 to present.

Answer 5b:

The FSMB routinely and effectively represents the interests of state medical boards before Congress and health care regulatory officials. As part of its advocacy efforts, the FSMB monitors federal legislation and regulations and provides commentary or testimony on behalf of state medical boards on a wide range of issues impacting state medical boards and medical regulation.

2012

- Joint Comments on “Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests”
- FSMB Comments on “Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests”

- Federation of State Medical Boards (FSMB) Response to the Request for Information for Input into the Scientific Strategic Plan for the Proposed National Institute of Substance Use and Addiction Disorders (Notice Number: NOT-OD-12-045)

2013

- Federation of State Medical Boards (FSMB) Response to the Notice for Comments for the Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule, DME Face to Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013 (Document ID: CMS_FRDOC_0001-1076)
- FSMB Comments on National Action Plan for the Prevention of Adverse Drug Events
- Federation of State Medical Boards (FSMB) Comments on Indian Health Service Medical Staff Credentials and Privileges Files (OMB Control Number 0917-0009)

2014

- Federation of State Medical Boards (FSMB) Response to the Notice for Comments for the Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015. (CMS-1612-P)
- U.S. Senate Special Committee on Aging Roundtable Meeting on Harnessing the Power of Telehealth: Promises and Challenges
- Federation of State Medical Boards (FSMB) Comments on Federal Trade Commission (FTC) Workshop, Examining Health Care Competition
- U.S. House Energy and Commerce Committee, Subcommittee on Health Hearing on Telehealth to Digital Medicine: How 21st Century Technology Can Benefit Patients

2015

- FSMB Comments for Senate Finance Committee Chronic Care Working Group
- Federation of State Medical Boards (FSMB) Response to the Notice for Comments for the Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015.

2016

- Federation of State Medical Boards (FSMB) Comments on Medicare Program: Payment Policies under the Physician Fee Schedule
- FSMB Comments to White House Rural Council's National Convening on Rural Telehealth
- FSMB Comments to U.S. Senate Judiciary Committee, Subcommittee on Antitrust, Competition Policy and Consumer Rights, Hearing on License to Compete: Occupational Licensing and the State Action Doctrine

2017

- Comments on Federal Trade Commission (FTC) Economic Liberty Task Force Roundtable: Streamlining Licensing Across State Lines: Initiatives to Enhance Occupational License Portability
- Testimony of Dr. Humayun J. Chaudhry, Subcommittee on Oversight and Investigations, Committee on Veterans Affairs, United States House of Representatives
- Comments to United States Copyright Office regarding Secure Test Copyright Registration

2018

- Federation of State Medical Boards (FSMB) Comments on the Draft Report - Health Research and Development to Stem the Opioid Crisis: A Federal Roadmap
- Federation of State Medical Boards (FSMB) Comments on Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program (CMS-1693-P)

2019

- Federation of State Medical Boards (FSMB) Comments on Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021
 - Federation of State Medical Boards (FSMB) Comments on 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule (HHS-ONC-2019-002-0001)
 - Federation of State Medical Boards (FSMB) Comments on The Office of the National Coordinator for Health Information Technology: Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs (Draft Report)
- c. In the event any activity identified in Questions 5a and 5b pertains to information distributed to physicians and patient concerning prescription pain medications, please identify any materials developed, in whole or in part, by organizations identified in request Question 2, please provide copies of these materials.

Answer 5c:

Not Applicable

- d. Please provide a list of all instances from 2012 to present in which a board member, executive, staff or affiliated volunteer has served on any Federal taskforce, committee, advisory group, or other entity.

Answer 5d:

Year	Name	Title	Description of Involvement
2012-2013	Lisa Robin	Chief Advocacy Officer	Member of the FDA Opioid Patient Prescriber Pain Treatment Agreement Working Group
2014	Humayun J. Chaudhry, DO	CEO and President	Committee Member for National Institutes of Health, Interagency Pain Research Coordinating Committee which was developing a National Pain Strategy
2018-present	J. Daniel Gifford, MD	FSMB Past Chair	FSMB representative to the National Academy of Medicine Action Collaborative to Counter Opioid Epidemic

Question 6:

Please identify any person employed by your organization who communicated with an entity identified in Question 2 regarding the content of materials distributed to patients and physicians pertaining to opioid use and/or prescribing practices from 2012 to the present. Please include their name, position, dates of employment, and job description. Please provide this information in hard copy, PDF, and in a Microsoft Excel Workbook.

Answer 6:

The following FSMB employees served in some capacity in the discussion about, or development of, FSMB model pain policies and educational programming as well as federal and state responses to address opioid abuse.

Last Name	First Name	Job Title	Job Description	Dates of Employment
Alfred	Kelly	FSMB Senior Director, Education Services	Under the supervision of the Chief Advocacy Officer, the Director of Education Services manages all functions of the Education Department. This includes the development and delivery of educational services, programs and products, accreditation for CME, providing educational assistance to state medical boards, and collaborating with external entities in the interest of state medical boards.	3/2/98-present
Chaudhry, DO, MACP	Humayun	FSMB President and Chief Executive Officer	Under the general direction of the Board of Directors, the President/CEO for the Federation of State Medical Boards (FSMB) is responsible for the overall leadership and corporate direction of the organization's activities. The President/CEO serves as the primary spokesperson and represents the FSMB to the leadership of other organizations as the premier organization concerned with medical licensure and discipline. The President/CEO has the ultimate responsibility for carrying out the mission of the FSMB and achieving all of its goals in a manner that is in keeping with the core values of the organization. Key partnerships include those with the National Board of Medical Examiners, the Education Commission for Foreign Medical Graduates, the American Medical Association, the Association of American Medical	10/19/09-present

			Colleges, and the American Osteopathic Association.	
Edwards	Rose	CME Program Manager, Education Services	Supports the Education Services department and facilitates all appropriate documentation necessary for CME accreditation of FSMB education programming.	10/31/2016-Present
Hickman	Shiri	Director, State Policy and Legal Services	The Director of State Policy and Legal Services is a position within the Federation of State Medical Boards (FSMB) Washington, D.C. Advocacy Office that reports directly to the Chief Advocacy Officer. The position contributes to the overall success of the FSMB's Washington, D.C. Advocacy Office in working with state boards to achieve advocacy and policy goals.	1/2/2013-2/4/2019
Jagoda	Jonathan	Director, Federal Government Relations	The Director of Federal Government Relations is a position within the Federation of State Medical Boards (FSMB) Washington, D.C. Advocacy Office that reports directly to the Chief Advocacy Officer. The position contributes to the overall success of the FSMB's Washington, D.C. Advocacy Office in achieving advocacy and policy goals.	7/28/10 – 2/22/2018
Robin	Lisa	FSMB Chief Advocacy Officer	The Chief Advocacy Officer (CAO) directs the FSMB's Washington, DC advocacy office and directly oversees and manages a wide range of services on behalf of and promoting state medical and osteopathic boards and the FSMB. These include: state and federal legislative services, advocacy and outreach activities, public policy, education, and public affairs and other projects as assigned by the President/CEO. The CAO oversees the FSMB federal and state public policy strategy, which entails formulating and implementing the FSMB's legislative and regulatory agenda on behalf of FSMB member boards and the FSMB.	8/24/94 – present

Conclusion

The FSMB has worked with federal regulators and state medical boards to develop thoughtful policies on the regulation of the prescription, monitoring, and use of opioids that allow patients to access these medications when needed, but that minimize overprescription, misuse, and diversion of these substances. The FSMB is committed to continued collaboration with interested stakeholders and will continue to assist state medical boards in their efforts to regulate the practice of medicine in a manner designed to ensure proper treatment and patient safety.

Please do not hesitate to contact the FSMB's Washington, DC office for additional information, if needed. The FSMB also welcomes the opportunity to personally discuss these questions further with members and staff of the Committee.

Respectfully,



Humayun J. Chaudhry, DO, MACP

President and CEO

Enclosures

1. FSMB Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain (2013)
2. FSMB Guidelines for the Chronic Use of Opioid Analgesics (2017)
3. FSMB Form 990s (2012-2017)
4. FSMB Foundation Form 990s (2012-2017)
5. FSMB Conflict of Interest Policy (2010-2019)
6. FSMB Conflict of Interest Policy (2019-current)
7. FSMB Board of Directors Code of Ethics
8. FSMB Policy on Identification, Resolution and Disclosure of Conflicts of Interest for CME Programs
9. ACCME Policy on Identification, Resolution and Disclosure of Conflicts of Interest
10. Disclosed interests of participants of FSMB educational programs on pain management
11. FSMB Submitted Commentary and Testimony (As listed in Response to Question 5b)