



Regenerative and Stem Cell Therapy Practices

Report and Recommendations of the Workgroup to Study Regenerative and Stem Cell Therapy Practices

*Adopted as policy by the Federation of State Medical Boards
April 2018*

Section One. Introduction and Charge:

The Federation of State Medical Boards (FSMB) Workgroup to Study Regenerative and Stem Cell Therapy Practices was convened in May of 2017 by FSMB Chair Gregory B. Snyder, M.D., DABR, in response to a letter (Attachment 1) from U.S. Senator Lamar Alexander (R-TN), Chairman of the U.S. Senate Health, Education, Labor, and Pensions (HELP) Committee, urging the FSMB to develop best practices for state medical and osteopathic boards (hereinafter referred to as “state medical boards”) in regulating the promotion, communication, and practices of treatments received at stem cell clinics in the United States.

In order to address Senator Alexander’s request, Dr. Snyder charged the Workgroup with:

- 1) Evaluating the prevalence, promotional practices, and incidences of patient harm related to regenerative medicine and adult stem cell therapies in the U.S.;
- 2) Evaluating current regulatory approaches that will protect the public, recognizing the potential for improved patient outcomes through health innovation and technology;
- 3) Identifying best practices for state medical and osteopathic boards in investigating complaints of patient harm, fraud, and compliance with licensure requirements; and
- 4) Issuing a report on the Workgroup’s findings from prevailing research and recommending best regulatory practices and guidelines related to physicians’ use of regenerative medicine and adult stem cell therapies in a manner consistent with safe and responsible medicine.

Stem cell and regenerative therapies offer opportunities for advancement in the practice of medicine and the possibility of an array of new treatment options for patients experiencing a variety of symptoms and conditions. Despite significant momentum in research and development, and the potential for such medical advancements, there is reasonable concern about a growing number of providers and clinics in the United States that are undermining the field. Such providers and clinics have been known to apply, prescribe or recommend therapies inappropriately, over-promise without sufficient data to support claims, and exploit patients who are often in desperate circumstances and willing to try any proposed therapy as a last resort, even if there is excessive cost or scant evidence of efficacy.

The following report aims to raise awareness about regenerative and stem cell therapy practices generally, outline their potential benefits and risks, and provide basic guidance for state medical boards and licensed physicians and physician assistants. Central to all of the recommendations provided herein is a range of imperatives, including the importance of protecting the public, respecting patient autonomy, preventing patient exploitation, obtaining informed consent, and appropriately documenting care that is recommended and provided.

The Workgroup's deliberations were aided by participants and subject matter experts who brought varying perspectives. For example, Dr. Ronald Domen has expertise in stem cell therapies, bioethics and humanities, and has served on numerous ethics committees at institutional, state, and national levels. Dr. Zubin Master of the Mayo Clinic has extensive training and education in cellular and molecular biology, bioethics and genetics, as well as research and publications on stem cell therapies. Mr. Douglas Oliver became known to the Workgroup through a recommendation by Senator Lamar Alexander of Tennessee, was a recipient of stem cell therapies himself, and has a foundation that advocates for stem cell therapies based on his own experiences and those of others like him. Dr. Bruce White has educational backgrounds in medicine, law, pharmacy and ethics and currently serves as Director of the Alden March Bioethics Institute at Albany Medical College and is Chair of Medical Ethics at the College. The Workgroup also received written comments from several external organizations. The sum of these perspectives aided the Workgroup in producing a balanced report on this emerging issue of national importance.

Section Two. Definitions:

Homologous (Allogeneic) Use: the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with a HCT/P (human cells, tissues, and cellular and tissue-based product) that performs the same basic function or functions in the recipient as in the donor, including when such cells or tissues are for autologous use.¹

According to the Food and Drug Administration's (FDA) *Regulatory Considerations for Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use / Guidance for Industry and Food and Drug Administration Staff (November 2017)*, the FDA "generally considers an HCT/P to be for homologous use when it is used to repair, reconstruct, replace, or supplement:

- Recipient cells or tissues that are identical (e.g., skin for skin) to the donor cells or tissues, and perform one or more of the same basic functions in the recipient as the cells or tissues performed in the donor; or
- Recipient cells or tissues that may not be identical to the donor's cells or tissues, but that perform one or more of the same basic functions in the recipient as the cells or tissues performed in the donor."²

¹ 21 CFR 1271.3(c)

²U.S. Food and Drug Administration (November 2017). *Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use Guidance for Industry and Food and Drug Administration Staff*.

Autologous Use: the implantation, transplantation, infusion, or transfer of human cells or tissue back into the individual from whom the cells or tissue were recovered.³

Informed and Shared Decision Making: The process by which a physician discusses, in the context of the use of regenerative and stem cell therapies, the risks and benefits of such treatment with the patient.⁴ The patient is given an opportunity to express preferences and values before collaboratively evaluating and arriving at treatment decisions.⁵

Informed Consent:⁶ Evidence documenting appropriate patient informed consent typically includes the following elements:

- Identification of the patient, the physician, and the physician’s credentials;
- Types of transmissions permitted using regenerative and stem cell therapies (e.g. prescription refills, appointment scheduling, patient education, etc.);
- Agreement from the patient with the physician’s determination about whether or not the condition being diagnosed and/or treated is appropriate for regenerative and stem cell therapy;⁷ and
- Express patient consent to forward patient-identifiable information to a third party
- An accurate description of the benefits and risks of treatment or intervention, based on scientific evidence, as well as an explanation of alternatives to treatment or an intervention, and the right to withdraw from treatment or an intervention without denial of standard of care to patients.

Minimal Manipulation: (minor processing including purification, centrifugation, washing, preservation, storage) – the Food and Drug Administration (FDA) argues that it has the authority to regulate anything beyond minimal manipulation and homologous use:

“(1) For structural tissue, processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement; and
(2) For cells or nonstructural tissues, processing that does not alter the relevant biological characteristics of cells or tissues.”⁸

Unproven Stem Cell Intervention: Stem cell therapy that lacks compelling evidence, based upon scientific studies, to validate its treatment efficacy.⁹

³ 21 CFR 1271.3(a)

⁴ Federation of State Medical Boards (2016). Model Guidelines for the Recommendation of Marijuana in Patient Care.

⁵ Barry, MJ, Edgman-Levitan, S. (2012). Shared Decision Making – The Pinnacle of Patient-Centered Care. *N Engl J Med*, 366:780-781.

⁶ With respect to informed consent for the purposes of research studies involving human subjects, researchers should be aware of the basic elements of informed consent outlined in 21 CFR Part 50.25 “Protection of Human Subjects.”

⁷ Federation of State Medical Boards (2014). Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine.

⁸ 21 CFR 1271.3(f)

⁹ Sipp D, et al. (2017). Marketing of Unproven Stem Cell-Based Interventions: A Call to Action. *Science Translational Medicine*, 9:397.

Section Three. Background, Prevalence and Marketing of Regenerative and Stem Cell Therapies:

Historically, many of the clinics providing unproven stem cell interventions fell under the definition of “stem cell tourism” because most patients seeking such interventions had to travel outside of North American jurisdictions to receive them. The landscape in the United States has evolved considerably over the last few years with hundreds of new clinics opening across the country and many more physicians willing to provide stem cell and regenerative therapies. A study identified 351 U.S. businesses with over 570 clinics engaged in direct-to-consumer (DTC) marketing of stem cell interventions.¹⁰ It has also been suggested that growth in this area of medicine, especially in terms of adult, amniotic, fat-derived and bone marrow stem cell therapies to treat a host of conditions and injuries, is accelerating, both in the U.S. and internationally, and, perhaps counterintuitively, such growth is noted to be most significant in jurisdictions with more stringent regulatory frameworks.¹¹

Stem cell clinics typically reach their patients through online DTC marketing, primarily through information provided on company websites. Data purportedly supporting unproven stem cell interventions commonly undermine information about risks and overemphasize information about benefits. Treatment options are described on such websites and are often accompanied by supporting information in the form of journal articles, patient testimonials, and accolades related either to the clinic itself or its affiliated physicians and researchers. Supporting information that accompanies marketing materials can appear to be legitimate, but can also overemphasize, exaggerate, inflate, or misrepresent information derived from legitimate (or even questionable) sources. A physician engaging in such practices of deceptive or false advertising can be in violation of a state’s *Medical Practice Act*. Information provided on clinic websites should be represented accurately and come from reputable peer-reviewed publications or respected external organizations.

Some clinics, however, that are engaged in the provision of treatment modalities that lack evidence – or an appropriate rationale for application of that modality to particular medical conditions – often use what have been described as “tokens of scientific legitimacy” to lend credence to treatments offered or the quality of a clinic and its associated professionals. Examples of such tokens of legitimacy include patient or celebrity testimonials and endorsements, clinician affiliations or memberships in academic or professional societies, registrations in clinical trials, claims of various types of certifications or awards, and others.¹² Further detail and explanations are provided in **Table 1**.

Physicians are ordinarily permitted to advertise themselves, their practice and services offered, provided that such advertisements do not contain claims that may be deceptive or are intentionally false or misleading. Further, physicians should be mindful of ways in which patient

¹⁰ Turner L, Knoepfler P. (2016). Selling Stem Cells in the USA: Assessing the Direct-to-Consumer Industry *Cell Stem Cell* 19, August 4, 154-7.

¹¹ Berger, et al. (2016) Global Distribution of Businesses Marketing Stem Cell-Based Interventions. *Cell Stem Cell* 19, August 4, 158-62.

¹² Sipp D, et al. (2017). Marketing of Unproven Stem Cell-based Interventions: A Call to Action. *Sci. Transl. Med.* 9, eaag0426.

testimonials, quality ratings, or other evaluative data is presented to prospective patients through advertisements. In advertising stem cell treatments to potential patients, physicians are responsible for ensuring that all information, especially in terms of risks, benefits and efficacy, is presented in an objective manner. Physicians must not deliberately misrepresent the expected outcomes or results of treatments offered. Physicians should be prepared to support any claims made about benefits of treatment(s) with documented evidence, for example with studies published in peer-reviewed publications.¹³

Physicians must be accurate and not intentionally misleading in providing descriptions of their training, skills, or treatments they are able to competently offer to patients. This includes descriptions of one's specialization and any specialty board certifications.¹⁴

A recent study on the prevalence and marketing practices of businesses offering stem cell treatments internationally noted the presence of the following elements in their marketing practices:

- Mention of affiliations with a professional society or network
- Claims of partnerships with academic institutions
- Statements of receipt of FDA approval, or explicit mention of exemption from FDA oversight
- Mention of official endorsement from a local or other authority, or professional accreditation
- Listing of patents granted
- Statement that clinical trials of investigational stem cell-based interventions are being conducted¹⁵

The marketing practices and information found on a business' website can be important sources of data for state medical boards as they investigate complaints made against physicians affiliated with businesses providing regenerative and stem cell treatments. Even where an appropriate informed consent process seems to be in place, deceptive or fraudulent information on clinic websites and other marketing materials could mislead patients into consenting to treatment, thereby invalidating the informed consent process.

Physicians must make accurate claims about the enrollment process of subjects, treatments, and products in clinical trials and are responsible for ensuring that any research conducted and described in marketing materials is carried out according to accepted research protocols and recognized standards. Physicians should consider consulting with Institutional Review Boards (IRBs) to clarify processes and must seek IRB approval, where necessary. The National Institutes of Health (NIH) provides helpful guidance on clinical trials and research methods.¹⁶ Physicians are also encouraged to consult the guidance contained in the *International Conference*

¹³ Federation of State Medical Boards (2016). *Position Statement on Sale of Goods by Physicians and Physician Advertising*.

¹⁴ *Ibid.*

¹⁵ Berger, et al. (2016) Global Distribution of Businesses Marketing Stem Cell-Based Interventions. *Cell Stem Cell* 19, August 4, 158-62.

¹⁶ National Institutes of Health, Office of Science Policy: <https://osp.od.nih.gov/clinical-research/clinical-trials/>

on Harmonisation's Harmonised Tripartite Guideline for Good Clinical Practice to support acceptability of clinical data by patients, state medical boards, and other regulatory authorities.¹⁷

Table 1: Co-opted Tokens of Scientific Legitimacy¹⁸

Accreditations and awards	Asserting certification of products or practices by international standards organizations or claiming training certification
Boards and advisers	Convening scientific or medical advisory boards featuring prominent business leaders and academic faculty members
Clinical study registration	Registering trials whose apparent purpose is solely to attract patients willing to pay to participate in them
Ethics review	Using the imprimatur of "ethics review" to convey a sense of legitimacy to their products or procedures
Location	Renting of laboratory or business space within a legitimate scientific or government institution
Membership	Joining established academic or professional societies to suggest legitimacy by association
Outcome registries	Publication of open-ended voluntary monitoring data sets rather than undertaking controlled clinical trials
Patenting	Suggesting that patent applications or grants indicate clinical utility rather than initiation of an application process or recognition of novelty and inventiveness
Publication	Publishing research and commentary in journals with limited anonymous peer review
Rationales	Citing preclinical and other research findings to justify clinical application without sufficient efficacy testing in humans
Self-regulation	Forming organizations to self-regulate in ways that support premature commercialization
Technical Language	Using scientific-sounding words that imply academic rigor
Testimonials and Endorsements	Providing expert opinions or celebrity comments on unsupported clinical uses or standing of the provider

Section Four. Patient Perceptions:

In seeking treatment for any condition, patients desire safety and efficacy, but may overlook risks to their own safety or a lack of evidence of efficacy in favor of access to treatment, particularly in circumstances where traditional treatment options seem limited or have been exhausted. The power of hope also is known to play a significant role in how patients attempt to gain control over their illness and its potential treatments, thereby putting them in a position of

¹⁷ International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. (2016). ICH Harmonised Tripartite Guideline for Good Clinical Practice E6(R2).

¹⁸ Sipp D, et al. (2017). Marketing of Unproven Stem Cell-based Interventions: A Call to Action. *Sci. Transl. Med.* 9, eaag0426.

increased vulnerability.¹⁹ This is especially the case when patients and their families have overcome various obstacles on the path to a treatment, including raising large sums of money to pay for it. This can lead to a psychological predisposition to anticipate and assume a positive outcome, regardless of the treatment in question or the availability of compelling evidence.

Given the vulnerable state of some patients who seek regenerative and stem cell therapies, perhaps without the requisite knowledge for making informed decisions, there is increased potential for patient exploitation. Physicians must therefore be mindful of the ways in which at-risk or susceptible patients may process information and arrive at decisions about their treatment options, expectations, and ultimately, the potential for success. A promising way of navigating such difficult circumstances, where treatment options are uncertain or complex, is through the use of shared decision making. This process, whereby the physician describes the risks and benefits of potential treatment options and the patient is given an opportunity to express preferences and values before collaboratively arriving at and evaluating treatment decisions,²⁰ may help mitigate the risk of patient exploitation and ensure that consent to any treatment option has been provided in an informed manner.

The process of obtaining informed consent and engaging in shared decision making with patients involves conveying information about the reasonable effectiveness of a proposed treatment, as well as its risks and benefits. This can be particularly difficult with respect to regenerative and stem cell therapies, as this is an area of medicine that currently lacks substantive data on efficacy. Generation of relevant data and evidence has not occurred to a sufficient enough degree and this is often blamed on the difficulty involved in organizing large-scale, randomized controlled trials as part of the approval process for novel therapies. However, the FDA has recently argued that a statistically significant 100% improvement in an outcome measure ($\alpha = 0.05$, $\beta = 0.1$) may be detected with a randomized trial involving as few as 42 participants.²¹

The lack of a formal mechanism for reporting outcomes of unproven stem cell interventions, both positive and negative, adds to the difficulty involved in generating data on the effectiveness of such interventions, as does the fact that there is neither a requirement, nor a mechanism, for reporting adverse events related to interventions administered outside of clinical trials and investigations. In the current environment, this increases the importance of appropriate documentation of treatment(s) and ongoing care in patients' medical records. A centralized cell therapy registry for reporting treatment and outcomes may improve the current information available about the effectiveness of such therapies and interventions. It may also dissuade unscrupulous practitioners from engaging in the provision of unproven interventions without an adequate or appropriate basis in theory or peer-acknowledged practice, a pre-requisite for the provision of any intervention, whether proven or not.²²

¹⁹ Petersen, et al. (2014). Therapeutic Journeys: The hopeful travails of stem cell tourists, *Sociology of Health & Illness*, 36(5):670-85, pp. 1–16.

²⁰ Barry, MJ, Edgman-Levitan, S. (2012). Shared Decision Making – The Pinnacle of Patient-Centered Care. *N Engl J Med*, 366:780-781.

²¹ Marks PW, et al. (2017). Clarifying Stem-Cell Therapy's Benefits and Risks, *NEJM* 376;11, 1007-9.

²² White, BD, Gelinas, LC, (2016). "Balancing the Surgeon's Responsibility to Individuals and Society," published in S.C. Stain et al. (eds.), *The SAGES Manual Ethics of Surgical Innovation*, Switzerland: Springer International Publishing, 191-211.

Section Five. Regulatory Landscape:

The current state of affairs for regulatory oversight on regenerative and stem cell therapies (including human cells and tissues), at both the federal and state level, is evolving and will continue to change in the coming years. In November 2017, the FDA released two guidance documents to explain the Agency’s current thinking on stem cell policy. However, this thinking, as well as the agency’s jurisdiction and authority, may evolve in the future.

Until recently, the regulatory landscape for stem cell and regenerative therapies has been at times restrictive, allowing patients to access stem cell interventions only under the *Expanded Access to Investigational Drugs for Treatment Use* program. Treatments are eligible under this program if they are undergoing testing in a clinical trial and are subject to approval by the FDA. Three-quarters of the states in the nation have passed “Right to Try” legislation, however, which allows terminally ill patients to receive experimental therapies that have passed phase 1 trials without seeking FDA approval.²³ The U.S. Congress is also considering similarly proposed legislation and in August of 2017, the U.S. Senate passed *S. 204, Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017*.

The *21st Century Cures Act* (Public Law 114–255), signed into law in December of 2016, represents legislative efforts at the federal level to expand and accelerate patient access to treatment, in addition to promoting innovation in medical products and treatments. With respect to regenerative medicine, the Act amends Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) by requiring expedited review for regenerative medicine therapies, including human cells and tissues, intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, where there is preliminary clinical evidence indicating that the drug has the potential to address unmet medical needs. There are also ongoing efforts at the federal level to ensure even greater access to treatments that are not subject to FDA approval prior to administration to patients.

Regulation in the regenerative and stem cell therapy arena is continuing to evolve. Human cells, tissues, and cellular or tissue-based products (HCT/Ps) are currently regulated under Sections 351 and 361 of the Public Health Service Act.²⁴ However, a HCT/P can be regulated solely under Section 361 of the PHS Act if it is:

1. Minimally manipulated,
2. Intended for homologous use only,
3. Not combined with another article, and
4. Either:
 - a. Does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or

²³Lancet Commission: Stem Cells and Regenerative Medicine. Published Online October 4, 2017

[http://dx.doi.org/10.1016/S0140-6736\(17\)31366-1](http://dx.doi.org/10.1016/S0140-6736(17)31366-1)

²⁴ The Public Health Service Act of 1944 outlines a policy framework for federal and state cooperation in health services and provides for the licensing of biological products.

- b. Has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and is for autologous use, use in a first or second-degree blood relative, or reproductive use.²⁵

The difference between an HCT/P that is regulated under both sections of the Public Health Service Act, as opposed to solely under Section 361, is significant for providers of stem cell treatments since the requirements for pre-market authorization of a product are much more stringent under Section 351 and require conducting clinical investigations under an investigational new drug (IND) application and obtaining a biologics license through the FDA, whereas requirements under Section 361 focus only on the prevention of communicable diseases.²⁶ This represents a lower regulatory threshold for HCT/Ps; their use and transplantation can be considered to fall under the practice of medicine and would, therefore, be regulated by state medical boards.

In regulating this evolving area of medical practice, state medical boards will need to strive to achieve an appropriate balance between respecting the autonomy of patients as they seek viable and reasonable treatment options, and adequately safeguarding them against the risks presented by novel, but often unproven and potentially dangerous, interventions. Results from a 2017 survey of its member boards conducted by the FSMB indicate that a third (n = 17) of the 51 responding boards have investigated complaints against physicians related to regenerative medicine or stem cell therapy, and that eight of those boards have taken disciplinary action against physicians for issues relating to regenerative medicine or stem cell therapy.

In ensuring that physicians offer regenerative and stem cell therapies in a manner that is consistent with safe and responsible practices, state medical boards should ensure that any treatment offered to patients is informed by an appropriate history and physical examination; such informed consent is obtained after an explanation has been provided describing risks, benefits, alternative treatment options, expected convalescence, and expected treatment outcomes; that relevant information about the clinical encounter and ongoing care plans has been documented in the patient's medical record; that the physician is appropriately trained in, and knowledgeable about the proposed treatment; and that the patient has not been coerced in any way into receiving treatment(s) or exploited through the charging of excessive fees.

In order to implement best practices for regenerative and stem cell therapies, physicians must understand the relevant clinical issues and should obtain sufficient targeted continuing education and training.²⁷

The recommendations in the final section of this report provide further detail on various requirements that apply to the provision of regenerative and stem cell therapies that state medical boards may wish to consider.

²⁵ 21 CFR 1271.10(a)

²⁶ United States Food and Drug Administration: Regulatory Considerations for Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use

²⁷ Federation of State Medical Boards (2017). *Guidelines for the Chronic Use of Opioid Analgesics*.

Section Six. Recommendations:

The recommendations that follow address the regulation of the provision of stem cell and regenerative therapies, as well as their promotion and communication to patients, and documentation of treatments provided. The recommendations do not address which uses are appropriate or not for specific conditions or symptoms, as this area of medicine continues to be dynamic and subject to change. Rather, they focus on sensible and necessary principles of patient safety, autonomy, and non-exploitation.

The FSMB recommends that:

1. Where evidence is unavailable for a particular treatment in the form of clinical trials or case studies, physicians must only proceed with an appropriate rationale for the proposed treatment, and justification of its use, in relation to the patient's symptoms or condition. Novel, experimental, and unproven interventions should only be proposed when traditional or accepted proven treatment modalities have been exhausted. In such instances, there must still be a basis in theory or peer-acknowledged practice.²⁸
2. State medical boards raise awareness among licensees of applicable federal and state legislation and guidelines regarding regenerative and stem cell therapies, including "right to try" legislation existing or pending at the state and federal levels. State medical boards should also keep their licensees and the public apprised of new developments and regulations in the field of regenerative and stem cell therapies. This may include educational resources, guidance documents, and appropriate industry and stakeholder information on a state medical board's website. State medical boards should further provide information as to reporting procedures of adverse actions related to stem cell interventions.
3. State medical boards should examine their policies and rules addressing informed consent and consider expanding these to include a shared decision making framework that includes the following general elements at a minimum:
 - An explanation, discussion, and comparison of treatment options with the patient
 - An assessment of the patient's values and preferences
 - Arrival at a decision in partnership with the patient
 - An evaluation of the patient's decision in partnership with the patient
4. State medical boards should review professional marketing materials and claims, including any office/clinic and/or doctor websites, and information publicly available about an office/clinic or licensee on online blogs or social media, as information sources in the investigation of complaints made against physicians.
5. State medical boards should pro-actively monitor warning letters sent to licensees that are made publicly available on the FDA website in order to ascertain information, and consider opening an investigation, about licensees who may be engaged in other unscrupulous or

²⁸ White, BD, Gelinas, LC, (2016). "Balancing the Surgeon's Responsibility to Individuals and Society," published in S.C. Stain et al. (eds.), *The SAGES Manual Ethics of Surgical Innovation*, Switzerland: Springer International Publishing, 191-211.

unprofessional practices related to the provision of regenerative and stem cell therapy. State medical boards should investigate such practices, when appropriate, in conjunction with applicable state laws, policies, and procedures.²⁹

6. Physicians must only offer treatments to patients for which they have a bona fide physician-patient relationship. Physicians must have received adequate and appropriate training, and be able to perform any proposed intervention safely and competently.³⁰

7. Physicians should employ a “shared decision making” process when discussing treatment options with patients. Physicians must avoid any claims that may be deceptive or are intentionally or knowingly false or misleading, especially in terms of making promises about uncertain or unrealistic outcomes.

8. Physicians should not use gag orders (rulings that a case must not be discussed publicly) or disclaimers as a way to circumvent liability.

9. Physicians should be prepared to support any claims made about benefits of treatments or devices with documented evidence, for example with studies published in peer-reviewed publications.

10. Physicians should refrain from charging excessive fees for treatments provided. Further, physicians should not recommend, provide, or charge for unnecessary medical services, nor should they make intentional misrepresentations to increase the level of payment they receive.³¹

11. Physicians should consult and educate patients about stem cell interventions and alert them to important resources available to the community. A list of selected resources is provided in **Appendix A**.

²⁹ The FDA’s warning letters are available at the following address:

<https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm>

³⁰ Federation of State Medical Boards (2014). *Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine*.

³¹ American Medical Association, *Code of Medical Ethics*, Opinion 11.3.1.

WORKGROUP TO STUDY REGENERATIVE AND STEM CELL THERAPY PRACTICES

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APPENDIX A: SAMPLE LIST OF EDUCATIONAL RESOURCES ON REGENERATIVE AND STEM CELL THERAPY PRACTICES

[The Australian Stem Cell Handbook 2015](#)

[Stem Cell Basics \(National Institutes of Health\)](#)

[Stem Cell Patient booklet \(Albany Medical College\)](#)

[A closer look at Stem Cells \(International Society for Stem Cell Research\)](#)

[Patient Handbook on Stem Cell Therapies \(International Society for Stem Cell Research\)](#)

[Stem Cell Tourism \(California Institute for Regenerative Medicine\)](#)

[The Power of Stem Cells \(California Institute for Regenerative Medicine\)](#)

[SCOPE: Learn About Stem Cells in Your Native Language \(The Niche\)](#)

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United States Senate

WASHINGTON, DC 20510

April 21, 2017

Gregory B. Snyder, MD, DABR
Chair-Elect
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1300 Connecticut Ave NW, Suite 500
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Dear Dr. Snyder:

Doctors, researchers, and patients have identified regenerative medicine and adult stem cell therapies as potential treatments to heal damaged, diseased, or deteriorated tissues and organs. In recent years, some of that promise has been realized. There are new therapies to treat burn and skin wounds, diabetic ulcers, and damaged knee cartilage, and clinical trials are underway for currently untreatable diseases.^[1] Doug Oliver, a constituent of mine who was diagnosed with malattia leventinese, a rare form of macular degeneration, participated in a clinical trial that used his own adult bone marrow stem cells to restore his eyesight.^[2] His remarkable progress is a testament to the potential of these treatments, and one of the reasons it was so important to pass the 21st Century Cures Act to provide clarity for regenerative medicine regulated by the Food and Drug Administration.

Unfortunately, recent reports indicate that some patients have been harmed by unproven or investigational treatments received at stem cell clinics. In one evaluation, published in *The New England Journal of Medicine*, three patients developed severe bilateral vision loss as a result of an injection of adult adipose tissue-derived stem cells.^[3] Other reports find stem clinics advertising their therapies as having the potential to treat diseases like Parkinson's or multiple sclerosis, including in circumstances where little, if any, evidence of their efficacy exists.^[4] Therefore, I urge your organization to develop best practices for state medical and osteopathic regulatory boards to follow regarding promotion, communication, and practices at stem cell clinics. I also seek information on the following questions:

1. How do state medical boards investigate complaints against stem cell clinics?
2. How are the existing false claims best practices enforced or used by state medical boards?
3. Are there standards or best practices regarding the use and communication of novel technology, such as adult stem cells?

^[1] <https://report.nih.gov/NIHfactsheets/ViewFactSheet.aspx?csid=62>

^[2] <http://www.tennessean.com/story/opinion/contributors/2016/06/19/restored-sight-shows-potential-stem-cell-therapy/86042514/>

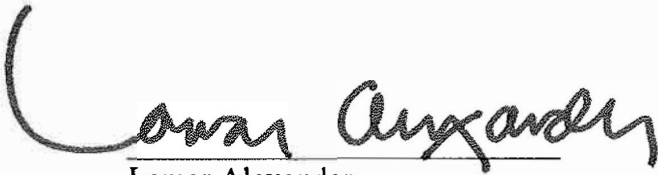
^[3] <http://www.nejm.org/doi/full/10.1056/NEJMoa1609583>

^[4] <https://www.nytimes.com/2016/07/28/upshot/stem-cell-therapies-are-still-mostly-theory-yet-clinics-are-flourishing.html>

3. Are there standards or best practices regarding the use and communication of novel technology, such as adult stem cells?
4. Are there standards for education necessary before implementing novel technology, such as adult stem cell procedures?

Thank you.

Sincerely,

A handwritten signature in black ink that reads "Lamar Alexander". The signature is written in a cursive style with a large, sweeping initial "L".

Lamar Alexander
U.S. Senator



Prescription Drug Monitoring Programs (PDMPs)

Report and Recommendations of the Workgroup on PDMPs

*Adopted as policy by the Federation of State Medical Boards
April 2018*

INTRODUCTION

In April 2017, the Federation of State Medical Boards (FSMB) Chair, Gregory B. Snyder, MD, DABR, appointed a Workgroup on Prescription Drug Monitoring Programs (PDMP) in accordance with FSMB Resolution 17-1: Mandatory Use of Prescription Drug Monitoring Programs, which was adopted by the FSMB's House of Delegates and which directed the FSMB to establish a task force to study PDMP use in the United States and its territories. The Workgroup was charged with evaluating the impact of mandatory PDMP query on patient outcomes and the prescribing of controlled substances; evaluating challenges to increasing PDMP utilization, including, but not limited to: a) authority to access; b) currency of data; c) Electronic Medical Record (EMR) integration; and d) interoperability; and developing recommendations to state medical and osteopathic boards (hereafter referred to as "state medical boards") regarding physician utilization of PDMPs, including a recommendation regarding mandatory query.

This document provides recommendations for state medical boards and other state agencies to maximize the effective use of PDMPs.

In developing the recommendations that follow, the Workgroup conducted a review of PDMP statutes, rules, and state medical board policies currently enacted across the United States, research reports and peer-reviewed articles in the medical literature and policy statements regarding the use of PDMP.

Section 1. Background

Overdose deaths from prescription opioids in the United States quintupled between 1999-2016, totaling more than 200,000 deaths during that time. In 2016, more than 46 people died every day from overdoses involving prescription opioids.¹² This escalating public health epidemic has led to a wave of implementations and upgrades to states' prescription drug monitoring programs over the past decade in an effort to curb substance use disorder.

State regulatory, administrative, and law enforcement agencies have long seen the need to establish systems to track and monitor the prescribing and dispensing of certain controlled substances, a recognition that dates to 1918.³ California has the oldest continuous program, created in 1939. Early PDMPs were paper-based and collected data on Schedule II prescribing and dispensing only. Collected data was typically reported into such systems within 30 days of the time from dispensing.

In 1990, a new era of electronic PDMPs broke ground when Oklahoma became the first state to require electronic transmission of such data, which helped reduce operational costs and increase accuracy and timely submissions. By 1992, 10 states had operational PDMPs and many other states were considering establishing their own. In 1995, Nevada became the first state to expand the type of drugs reported to the PDMP, expanding from Schedule II only to Schedules II-IV. At the same time, Nevada also became the first state to provide unsolicited reports back to prescribers. By 2000, 15 states had established PDMPs. Between 2000-2012, 34 additional states established such a program, bringing the total number to states with PDMPs to 49. In 2014, the District of Columbia established a PDMP, bringing the total of operational PDMPs to 49 states, plus D.C. and Guam. Puerto Rico has also enacted legislation creating a PDMP but it is not yet operational.

As of September 2017, Missouri remains the only state without a statewide, operational PDMP. To work around this obstacle, St. Louis County established its own PDMP in March 2016 and, since then, this PDMP has gone live (as of April 2017) and more than 50 counties in the state and several individual cities have joined as participants, representing more than 70 percent of Missouri's population and 91 percent of its prescribers.⁴ Separately, in July 2017, the Missouri governor issued an executive order to create a statewide PDMP that allows the Missouri Department of Health and Senior Services to analyze and identify inappropriate prescribing, dispensing, and obtaining of controlled substances, and to address these actions by making

¹ Centers for Disease Control, Opioid Data Analysis. <https://www.cdc.gov/drugoverdose/data/analysis.html>

² Centers for Disease Control, Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2016. <http://wonder.cdc.gov>

³ Blumenschein, Karen, et. al. "Review of Prescription Drug Monitoring Programs in the United States." Institute for Pharmaceutical Outcomes and Policy, University of Kentucky, June 2010. <http://chfs.ky.gov/NR/rdonlyres/85989824-1030-4AA6-91E1-7F9E3EF68827/0/KASPEREvaluationPDMPStatusFinalReport6242010.pdf>.

⁴ St. Louis County Prescription Drug Monitoring Program, "PDMP Program Update." <http://www.stlouisco.com/Portals/8/docs/document%20library/PDMP/UPDATE-%20St.%20Louis%20County%20PDMP.pdf>

referrals to appropriate government officials, including law enforcement and professional licensing boards.⁵

While the common goal of PDMPs is to provide prescribers and other health care professionals with accurate information about the prescriptions that patients have obtained, a state's decision to apply comprehensive mandates varies widely. The differences between states relate to the types of drugs monitored and the types of prescribers who are mandated to query, as well as to the circumstances which necessitate querying the PDMP, among other differences.⁶⁷ For instance, some PDMPs monitor Schedules II-IV controlled substances, while others monitor Schedules II-V or certain non-controlled substances.⁸ Thirty-six states and the District of Columbia mandate PDMP query under certain circumstances. Of those, 27 states require querying the PDMP during the initial prescribing of a designated substance, while nine states require querying the PDMP before each prescription of a designated substance. Twelve states mandate querying the PDMP when prescribing for the treatment of pain and 14 states require it when prescribing for drug addiction. Among those states requiring a prescriber to query the PDMP prior to the initial prescription of a designated substance, some only require it if it is a Schedule II or III opioid, while others require it only if the initial opioid prescription surpasses a seven-day supply.⁹

This report aims to provide guidance to state medical boards about effective PDMP use, one of many strategies being recommended to address the growing prescription opioid epidemic.

Section 2. Definitions

Mandatory Registration – A state's requirement that prescribers of controlled substances must register with the state's PDMP.

Prescription Drug Monitoring Program – A patient safety tool designed to facilitate the collection, analysis, and reporting of information about the prescribing and dispensing of controlled substances.¹⁰

⁵ Missouri Executive Order. No. 17-18, 2018. <https://www.sos.mo.gov/library/reference/orders/2017/eo18>

⁶ Blumenschein, Karen, et. al. "Review of Prescription Drug Monitoring Programs in the United States." Institute for Pharmaceutical Outcomes and Policy, University of Kentucky, June 2010. <http://chfs.ky.gov/NR/rdonlyres/85989824-1030-4AA6-91E1-7F9E3EF68827/0/KASPEREvaluationPDMPStatusFinalReport6242010.pdf>.

⁷ Wen, Hefei, et al. "States with Prescription Drug Monitoring Mandates Saw A Reduction in Opioids Prescribed to Medicaid Enrollees." Health Affairs, vol. 36, no. 4, Apr. 2017, pp. 733–741., www.ncbi.nlm.nih.gov/pubmed/28373340.

⁸ "Substances Monitored by PMP." National Alliance for Model State Drug Laws, May 2016, www.namsdl.org/library/8D7261F8-E47D-B6A5-DD0CAFA98FEA4846.

⁹ "Mandated Use of State Prescription Drug Monitoring Programs: Highlights of Key State Requirements." National Alliance for Model State Drug Laws, June 2017. <http://www.namsdl.org/library/6735895A-CA6C-1D6B-B8064211764D65D0/>

¹⁰ Federation of State Medical Boards (FSMB). Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain. Washington, DC: The Federation, 2013.

Universal Use – A state’s requirement that prescribers must query the patient’s PDMP history before initially prescribing opioid pain relievers and benzodiazepines, and at certain intervals thereafter.¹¹

Unsolicited Reports – Proactive communications from the PDMP to prescribers, dispensers, law enforcement, and/or regulators to provide information about patient prescriptions and/or the prescribing activity of a health care professional based upon PDMP data.¹²

3. Mandatory Registration

Studies show that between 2010-2012, states with operational PDMPs saw an average registration rate of 35 percent among licensed prescribers who prescribed at least one controlled substance during that period.¹³ In 2014, a national survey found that 53 percent of primary care physicians used their state’s PDMP at least once, but many were not using the PDMP on a routine basis.¹⁴ Although there have been extensive educational campaigns to recruit prescribers to participate in their state’s PDMP, results have not always been successful.¹⁵ At the same time, however, PDMP registration has increased significantly, increasing from approximately 471,000 to more than 1.3 million from 2014 to 2016. During the same time period, queries by physicians and other health care professionals increased from approximately 61 million to more than 136 million.¹⁶

States are seeing success in increasing prescriber PDMP registration rates through other methods, such as mandatory registration. Massachusetts took a staggered, low resource-intensive approach by linking PDMP enrollment to the renewal of state controlled substance registration, where renewals are required every three years for practitioners. The process established by Massachusetts allowed for a continuous workflow for PDMP staff, rather than a surge in applications immediately after the enactment of mandatory PDMP registration legislation. As a result, the state first saw a gradual increase in registration, followed by a more dramatic increase, between 2011-2016. In 2011 and 2012, only 1 percent and 2 percent of prescribers were registered with the PDMP, respectively. By the end of 2014, however, nearly 66 percent of prescribers were enrolled. By September 2015, that percentage increased to 83 percent, and by January 2016, more than 90 percent had enrolled.¹⁷

¹¹ CDC Prevention Status Report, <https://www.cdc.gov/psr/NationalSummary/NSPDO.aspx>

¹² The PEW Charitable Trusts, *Prescription Drug Monitoring Programs: Evidence-Based Practices to Optimize Prescriber Use*, December 2016. www.pewtrusts.org/en/research-and-analysis/reports/2016/12/prescription-drug-monitoring-programs.

¹³ Wen, Hefei, et al. “States with Prescription Drug Monitoring Mandates Saw A Reduction in Opioids Prescribed to Medicaid Enrollees.” *Health Affairs*, vol. 36, no. 4, Apr. 2017, pp. 733–741., www.ncbi.nlm.nih.gov/pubmed/28373340.

¹⁴ Ibid.

¹⁵ Ibid.

¹⁶ Survey of state PDMP administrators. American Medical Association.

¹⁷ The PEW Charitable Trusts, *Prescription Drug Monitoring Programs: Evidence-Based Practices to Optimize Prescriber Use*, December 2016. www.pewtrusts.org/en/research-and-analysis/reports/2016/12/prescription-drug-monitoring-programs.

4. Universal Use

Research shows that between 2011-2014, 85 percent of states that implemented some form of a PDMP universal use mandate were based upon legislation that was of limited scope and strength. Due to the weakness of the mandates in these cases, it is unlikely that they will prove effective in improving opioid prescribing practices.¹⁸ Efforts to strengthen universal use mandates are supported by President Donald Trump’s Commission on Combating Drug Addiction and the Opioid Crisis, which recommends that federal agencies mandate PDMP querying.¹⁹

States that have established an effective PDMP, in part or in whole, employ certain evidence-based practices. These practices include delegated authority, unsolicited reports, data timeliness, streamlined enrollment, educational initiatives, integration and data sharing, enhanced user interfaces, and proper funding, with delegated authority, data timeliness, and integration and data sharing being critical elements.²⁰

Delegated Authority

Prescription Drug Monitoring Programs can serve as valuable tools to help inform prescribers’ decision making and identify potential substance use disorder, but a significant barrier to increasing prescriber use of them is the time typically needed to query the system.²¹ To decrease the time spent by prescribers reviewing patient records, many states authorize registered users to delegate non-prescriber employees the ability to access the system using sub-accounts. States vary, however, in whether a delegate has to be a licensed individual or not, as well as in the number of prescriber delegates permissible. Currently, 47 states and the District of Columbia authorize prescribers to delegate such authority, with 36 states actively doing so.²² Some states only permit two delegates per prescriber, while others impose no limits.²³

In Kentucky, the state’s PDMP, known as the Kentucky All Schedule Prescription Electronic Reporting Program (KASPER), does not restrict the number of subaccounts to licensed staff. Prescribers also have no limit on the number of designated delegates, who are also permitted to serve as a delegate for multiple prescribers. For prescribers sharing multiple delegates, delegates are able to select the prescriber from a dropdown list to accurately record for which prescriber a

¹⁸ Wen, Hefei, et al. “States with Prescription Drug Monitoring Mandates Saw A Reduction in Opioids Prescribed to Medicaid Enrollees.” *Health Affairs*, vol. 36, no. 4, Apr. 2017, pp. 733–741., www.ncbi.nlm.nih.gov/pubmed/28373340.

¹⁹ The President’s Commission on Combating Drug Addiction and the Opioid Crisis, “Final Report,” 15 November 2017. https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf

²⁰ The PEW Charitable Trusts, *Prescription Drug Monitoring Programs: Evidence-Based Practices to Optimize Prescriber Use*, December 2016. www.pewtrusts.org/en/research-and-analysis/reports/2016/12/prescription-drug-monitoring-programs.

²¹ Rutkow, L. et al. “Many primary care physicians are aware of prescription drug monitoring programs, but many find the data difficult to access.” *Health Affairs*, vol. 34, no. 3, March 2015, pp. 484-492., <http://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.1085>

²² Brandeis University PDMP Training and Technical Assistance Center. “PDMPs Authorized and Engaged in Sending Solicited and Unsolicited Reports to Health Care Providers and Patients.” http://www.pdmpassist.org/pdf/Health_Care_Entity_Table_20170824.pdf

²³ The PEW Charitable Trusts, *Prescription Drug Monitoring Programs: Evidence-Based Practices to Optimize Prescriber Use*, December 2016. www.pewtrusts.org/en/research-and-analysis/reports/2016/12/prescription-drug-monitoring-programs.

report is being queried. The prescriber is responsible for deactivating accounts of delegates who leave the practice or otherwise warrant discontinuance of PDMP access. Delegates are permitted to conduct queries and provide reports for prescriber review, but are prohibited from conducting the clinical review of data that the state's mandate requires. As a result of allowing such delegated authority, during the fourth quarter of 2015 delegates requested nearly 64 percent of in-state prescriber reports, despite accounting for 42 percent of combined delegate and prescriber master accounts by the end of that year.²⁴

Unsolicited Reports

PDMPs provide prescription history reports to authorized users upon request (these are also known as "solicited" reports), but when these reports are not requested useful information can go unseen or unused by prescribers. In an effort to increase utilization, many PDMPs proactively send "unsolicited" (and, therefore, unrequested) reports to specific prescribers, dispensers, state licensing boards, and law enforcement agencies that contain data suggestive, or indicative, of multiple provider episodes or inappropriate prescribing and dispensing.²⁵

In 2005, Maine began sending prescribers quarterly threshold notification reports via U.S. mail, but in 2013 moved to monthly emailed alerts. Originally, these alerts were sent to registered PDMP users only when one of three criteria was met by a patient: 1) exceeds a certain number of prescribers and pharmacies in a three-month period; 2) exceeds a specified average daily dose of acetaminophen coming from prescriptions of opioid-acetaminophen combination drugs; or 3) is prescribed buprenorphine and another opioid in a 30-day period. In 2015, however, the state's legislature added two new criteria to initiate alerts: 1) multiple overlapping prescriptions for medications containing opioids; and 2) prescriptions for more than 300 morphine milligram equivalents daily for more than 45 consecutive days within a 90 day period. Alert recipients must log into their PDMP account to review the patient's prescription history, which includes the other providers who prescribed to the patient, the pharmacies that dispensed to the patient, drugs and quantities and other details of prescriptions dispensed for the past three months. Additionally, the state recently enabled prescribers to request reports based on their own set thresholds. It is believed that unsolicited reports may have affected prescriber behavior from 2010 to 2014 when the state saw a steady decline in the rate of multiple provider episodes.²⁶

Additionally, in Indiana, a prescriber who believes a patient's PDMP data suggests questionable activity has the option to send email alerts to other prescribers and dispensers of the patient. These "user-led unsolicited report" email alerts do not contain a patient's name or any conclusions, but rather contains a hyperlink to a patient's prescription history report that registered users can review after logging into the PDMP, thus ensuring Health Insurance Portability and Accountability Act (HIPAA) compliance. These alerts serve to notify prescribers and dispensers that a patient may be using unnecessary prescription drugs, may be receiving controlled substances from multiple providers, or may be involved in controlled substance

²⁴ Ibid.

²⁵ Brandeis University PDMP Training and Technical Assistance Center, "Guidance on PDMP Best Practices: Options for Unsolicited Reporting," May 2016.
http://www.pdmpassist.org/pdf/COE_documents/Add_to_TTAC/Update%20to%20Brandeis%20COE%20Guidance%20on%20Unsolicited%20Reporting%20final.pdf

²⁶ Ibid.

diversion. Indiana first launched its user-led unsolicited reports in March 2012. After the first three months of the program, 140 practitioners had sent 2,284 alerts on 214 unique patients, at virtually no cost to the program.²⁷

Data timeliness

A prescriber's ability to effectively use PDMP data to assess a patient's prescription history can only be as complete as the data that is transmitted into the system by a dispenser. If a PDMP report does not contain information about the most recently dispensed controlled substances, a prescriber may lack valuable data to determine the best course of treatment. Because of this, it is imperative to minimize the pharmacy reporting interval. States are increasingly moving away from weekly reporting towards daily PDMP data reporting. In 2015, 24 states required daily data submissions. As of July 2017, 40 states and the District of Columbia required data to be reported within 24 hours or one business day. Oklahoma is the only state currently requiring real-time reporting,²⁸ but the transition from daily reporting to real-time required two years and involved intensive effort and overtime for the PDMP, as well as redesign for pharmacy data systems and workflow procedures.²⁹

Streamlined Enrollment

In order to access PDMP data, prescribers must typically establish online accounts with a state's PDMP system. This process requires the prescriber to submit, and the PDMP to verify, identifying information, such as name, date of birth, state controlled substance prescribing or medical practice license number, DEA registration number, driver's license number, place of employment, medical specialty, and contact information. Once the prescriber's state controlled substance prescribing or medical practice license number and a DEA registration number is verified, the prescriber may create an account and begin to query patients' controlled substance prescription history. Unfortunately for many prescribers, the process can be time consuming to complete registration applications as some states require paper applications and notarization.³⁰ To expedite PDMP registration, and to transition away from paper applications, some states began migrating to an online registration system, in addition to automatic prescriber enrollment, during initial medical licensure and licensure renewal.

In 2012, the Tennessee Legislature enacted legislation mandating that prescribers use the state's PDMP and dispensers register. The comprehensive mandate required DEA-registered prescribers and dispensers to register with the PDMP within the first eight months after the law's enactment. New licensees are required to register with the PDMP within 30 days. The universal use mandate went into effect four months after prescribers and dispensers were required to register. In an

²⁷ Indiana Scheduled Prescription Electronic Collection & Tracking (INSPECT). "Presentation on User-Led Unsolicited Reporting (ULUR)." 2012.

http://www.pdmpassist.org/pdf/PPTs/National2012/2_Allain_StatePanelInnovationsIndiana.pdf

²⁸ National Alliance for Model State Drug Laws, "Frequency of Prescription Drug Monitoring Program Data," 30 June 2017. <http://www.namsdl.org/library/03B95893-0EE2-3766-EABAD212B5C8E8D3/>

²⁹ The PEW Charitable Trusts, *Prescription Drug Monitoring Programs: Evidence-Based Practices to Optimize Prescriber Use*, December 2016. www.pewtrusts.org/en/research-and-analysis/reports/2016/12/prescription-drug-monitoring-programs.

³⁰ The Network for Excellence in Health Innovation, "Issue Brief – Physicians and PDMPs: Improving the Use of Prescription Drug Monitoring Programs," November 2015.

https://www.nehi.net/writable/publication_files/file/pdmp_issue_brief_11.18.pdf

effort to handle the influx of registrations, Tennessee adopted an online registration system. This system automatically attempts to validate a prescriber's information using electronic databases for the state's professional health care licenses, driver's licenses, and DEA prescriber registration. For prescribers who do not have health care licenses or DEA numbers, such as medical residents in hospitals in some states, PDMP registration is still processed manually. As a result of the streamlined online registration system for licensed prescribers and dispensers, the number of registered prescribers has increased 127 percent between 2011 (a year before the mandate went into effect) and 2014. Additionally, average queries per month have increased 203 percent during that same time period.³¹

Educational Initiatives

Many state medical boards require physicians to complete continuing medical education (CME) in specific content areas, such as pain management and controlled substance prescribing practices. Thirty-two of the 50 states, and the District of Columbia, mandate at least one content-specific CME course. Of those 32 states, 29 states require CME focused on either pain management or controlled substance prescribing practices, or in some circumstances both. In 26 out of those 29 states, the CME requirements are for both allopathic and osteopathic physicians. In two states, Oklahoma and Nevada, only osteopathic physicians are required to complete CME on pain management/controlled substance prescribing practices, while in Vermont only allopathic physicians are required to complete such CME. Additionally, 12 of the 29 states require CME on pain management/controlled substance prescribing practices for all physicians, while the other 17 states only require a subset of physicians to complete such requirements, such as controlled substance providers or certain providers who work in pain clinics.³²

In order to assist prescribers in completing CME requirements, as well as educate prescribers who are not required to complete content-specific CME, the federal government promotes certain educational initiatives. The U.S. Department of Health and Human Services (HHS) Substance Abuse and Mental Health Services Administration (SAMHSA) and the Health Resources and Services Administration (HRSA) jointly developed the "Substance Use Trainings" webpage as an online educational resource that provides one-time and ongoing training activities dedicated to pain management and controlled substance prescribing practices. HHS's Office of Disease Prevention and Health Promotion also developed an online education resource, *Pathways to Safer Opioid Use*, while the U.S. Food and Drug Administration's (FDA) Risk Evaluation and Mitigation Strategy (REMS) for extended release/long-acting opioids requires CME to be offered by opioid manufacturers.³³ As part of REMS, the FDA released the *FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics*, which contains core educational messages for the development of continuing

³¹ The PEW Charitable Trusts, *Prescription Drug Monitoring Programs: Evidence-Based Practices to Optimize Prescriber Use*, December 2016. www.pewtrusts.org/en/research-and-analysis/reports/2016/12/prescription-drug-monitoring-programs.

³² Xu, Jing, PhD, MA; Gribble, Anna, MSW, MPH, et al. "State Continuing Education Requirements for Physicians and Dentists, Including Requirements Related to Pain Management and Controlled Substance Prescribing," *Journal of Medical Regulation*, Vol. 103, Number 3, 2017.

³³ *Ibid.*

education activities focused on safe prescribing.³⁴ The Centers for Disease Control (CDC) also provides educational materials, such as *Applying CDC's Guideline for Prescribing Opioids: An Online Training Series for Providers* and *What Healthcare Providers Need to Know About PDMPs*.^{35,36}

While a majority of states require physicians to complete certain content-specific CME, FSMB policy states that, “the FSMB believes mandatory continuing medical education is a matter reserved for the individual state jurisdictions.”³⁷

Integration and Data Sharing

The value of PDMP data is based in part on whether such data is readily available and accessible. Although PDMPs collect controlled substance prescription information in a central repository, the adoption and utilization of a PDMP by prescribers is slowed when such data is not integrated into health information technology (HIT) systems, specifically electronic health records (EHR).

There have been several efforts and initiatives to spur the pace at which PDMP data is integrated, such as SAMHSA's PDMP Electronic Health Records Integration and Interoperability Expansion (PEHRIIE) program, which funded projects in nine states from 2012-2016. The goal of this program was to increase prescriber utilization by integrating PDMP data into HITs. The program also sought to increase the comprehensiveness of PDMP data by increasing interstate PDMP data sharing.³⁸

Programs such as PEHRIIE demonstrate the effectiveness of integrating PDMP data into HITs. During the fourth quarter of 2014, the state of Washington became interoperable with OneHealthPort, a statewide HIE, enabling integration with the Emergency Department Information Exchange (EDIE), a hub connecting hospital emergency departments. In 2015, the first full calendar year after integration, the PDMP provided 2,222,446 solicited reports to prescribers, compared to 2014, when 26,546 solicited reports were provided to prescribers.³⁹ Significant increases in solicited reports were also experienced in Kansas after PDMP data was integrated with the Via Christi Health Network, the largest healthcare provider in Kansas, in late 2013. After integration, solicited reports provided to Via Christi prescribers increased from 31,156 reports in 2013 to 223,000 reports in 2015. Compared to other prescribers in Kansas, the number of solicited reports increased significantly less, from 23,171 in 2013 to 65,242 in 2015.

³⁴ United States Food and Drug Administration, *Introduction for the FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics*, May 2017.

³⁵ Centers for Disease Control, *Applying CDC's Guideline for Prescribing Opioids: An Online Training Series for Provider*. <https://www.cdc.gov/drugoverdose/training/overview/index.html>

³⁶ Centers for Disease Control, *What Healthcare Providers Need to Know About PDMPs*. <https://www.cdc.gov/drugoverdose/pdmp/providers.html>

³⁷ Federation of State Medical Boards (FSMB), *FSMB Policy 100.2, Mandating Continuing Medical Education*, Washington, DC: The Federation, 1980.

³⁸ Centers for Disease Control (CDC). “Integrating & Expanding Prescription Drug Monitoring Program Data: Lessons from Nine States,” February 2017. https://www.cdc.gov/drugoverdose/pdf/pehriie_report-a.pdf

³⁹ Ibid.

Several states also announced efforts to integrate prescription drug information into EHRs and other HITs. In August 2017, Indiana announced that it would integrate PDMP data into EHRs at hospitals and physician practices across the state at no cost to the facility or individual practitioner. The phased-in integration is scheduled to be completed by 2020.⁴⁰ Michigan also announced in June 2017 that state and federal funds will be invested over a two year period to integrate the state's PDMP, Michigan Automated Prescription System, into EHRs and pharmacy dispensation systems.⁴¹ Additionally, Arizona, Kansas, Massachusetts, Ohio, Pennsylvania, and Virginia are supporting integration into EHRs, HITs, and pharmacy dispensing systems at no cost.

These recent state trends to integrate PDMP data are in line with recommendations being conveyed at the federal level, including the President's Commission on Combating Drug Addiction and the Opioid Crisis, which recommended in November 2017 that "PDMP data integration with electronic health records, overdose episodes, and substance use disorder-related decision support tools for providers is necessary to increase effectiveness."⁴²

The ability for prescribers to view prescription drug history information across state lines can assist in identifying a potential substance use disorder. To facilitate interstate PDMP data sharing and integration, states have opted to connect to a data sharing hub. Forty-five states and the District of Columbia are currently engaged in some form of interstate data sharing, while three other states are in the process of implementing data sharing.⁴³ Not all states, however, allow universal data sharing among states. Some states allow prescribers in any state to access PDMP data, while other states allow prescribers from specific states within a region. These are usually in-state policy decisions that often change to expand toward a goal of universal access.

The President's Commission on Combating Drug Addiction and the Opioid Crisis also recommended supporting federal legislation mandating states that receive grant funds to comply with PDMP requirements, including data sharing, and establishing and maintaining a data-sharing hub.⁴⁴

In an effort to reduce barriers to data sharing across state lines, there have been various data sharing hubs launched to facilitate data sharing in compliance with each state's data access regulations. At the request of several PDMPs, the National Association of Boards of Pharmacy (NABP) created Prescription Monitoring Program (PMP) InterConnect in 2011. PMP InterConnect provides for encrypted data to be transmitted across state lines. To date, 45 states have executed a memorandum of understanding (MOU) with NABP to participate and 42 of

⁴⁰ Sweeney, Evan, "Indiana announces plans to integrate PDMP data into EHRs across the state," FierceHealthcare, 25 August 2017. <https://www.fiercehealthcare.com/ehr/indiana-announces-plans-to-integrate-pdmp-data-into-ehrs-across-state>

⁴¹ Office of Governor Rick Snyder, "Patient Protections Strengthened as State Fully Integrates MAPS into Health Systems," 19 June 2017. http://www.michigan.gov/snyder/0,4668,7-277-73341_73343-424218--,00.html

⁴² The President's Commission on Combating Drug Addiction and the Opioid Crisis, *Final Report*, 15 November 2017. https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf

⁴³ Brandeis University PDMP Training and Technical Assistance Center, "Interstate Data Sharing," 20 September 2017. http://www.pdmpassist.org/pdf/Interstate_Data_Sharing_20170920.pdf

⁴⁴ The President's Commission on Combating Drug Addiction and the Opioid Crisis, "Final Report," 15 November 2017. https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf

those states are now live. Each month, PMP InterConnect processes more than 15 million requests.⁴⁵

Separately, RxCheck is another data sharing hub that was created with support from the U.S. Bureau of Justice Assistance (BJA) and using the Prescription Monitoring Information Exchange (PMIX) National Architecture specifications. As of July 2017, there are four states that are engaged in interstate data sharing with RxCheck, while two states are currently implementing interstate data sharing and eight states have plans to connect to RxCheck.

Enhanced User Interfaces

While having access to PDMP data is integral for prescribers, it is equally important that prescribers are able to quickly analyze and use that data. As the amount of controlled substance prescription information available to prescribers has increased in recent years, prescribers have sought ways to quickly analyze the most important information for clinical decision making. To address this, states began exploring ways to better interpret the data. Some of these methods included adding an enhanced user interface to the PDMP system that includes, but is not limited to, a total morphine milligram equivalent (MME) calculation for each opioid prescription, a daily MME dose level, and flags or alerts if a patient's MME surpasses a certain threshold.⁴⁶

In 2016, the California PDMP, Controlled Substance Utilization Review and Evaluation System (CURES) underwent a redesign to help prescribers improve their clinical decision-making when evaluating whether to prescribe a controlled substance. The new updated program contains a dashboard that provides users patient alerts, including a list of patients who are prescribed more than 100 MME per day; have obtained prescriptions from six or more prescribers or pharmacies during the past 12 months; are prescribed more than 40 milligrams of methadone daily; have been prescribed opioids for more than 90 consecutive days; or are concurrently prescribed benzodiazepines and opioids.⁴⁷

Enhanced user interfaces are a recent development and, as such, there is a paucity of evidence on its effectiveness in identifying a potential substance use disorder or coordinating care in the case of a multiple provider event.

Data Security/Patient Protections

As the use of PDMP increases nationwide and controlled substances prescription history is increasingly used by prescribers, patients are increasingly concerned about the security of their data and the possibility of law-enforcement scrutiny. Prescribers are also increasingly concerned

⁴⁵ National Association of Boards of Pharmacy, "Connecting State Prescription Monitoring Programs Nationwide," November 2017. <https://nabp.pharmacy/wp-content/uploads/2017/11/NABP-InterConnect-Flyer-November-2017.pdf>

⁴⁶ The PEW Charitable Trusts, *Prescription Drug Monitoring Programs: Evidence-Based Practices to Optimize Prescriber Use*, December 2016. www.pewtrusts.org/en/research-and-analysis/reports/2016/12/prescription-drug-monitoring-programs.

⁴⁷ California Department of Justice, "CURES 2.0: Prescription Drug Monitoring Program" (presentation September 2015). https://www.sfhpa.org/files/providers/Best_Practices/CURES_2.0_PPT.pdf

that medical consultations are no longer a private affair and that staff access pose the potential for unscrupulous use and data leaking.⁴⁸

Substance use disorder is a multifaceted problem and often requires collaboration among various agencies and stakeholders. PDMPs are primarily used as a public health tool, but law enforcement agencies see PDMPs as a potential law enforcement tool. An increase in law enforcement scrutiny of PDMP data may significantly affect a prescriber's clinical decision making and cause a prescriber to under prescribe.⁴⁹

A balanced approach between patient safety and data protection has been encouraged by various stakeholders. Both the American Medical Association (AMA) and the American Society of Addiction Medicine (ASAM) believe that PDMP data should be considered protected health information, and should not be released outside of the health care system unless there is authorization for release from the individual patient. The AMA also supports access to PDMP data via a warrant, as well as when the public safety demands in certain situations.⁵⁰⁵¹

The United States District Court for the District of Oregon, Portland Division affirmed the limits of law enforcement access in February 2014 in *Oregon Prescription Drug Monitoring Program v. United States Drug Enforcement Administration*. The Court found that federal drug investigators cannot access patients' prescription information without proving probable cause and obtaining a warrant. The Court also found that administrative subpoenas are insufficient to demand information relevant to investigations into potential drug violations, such as a doctor who improperly prescribes drugs.⁵² In June 2017, the United States Court of Appeals for the Ninth Circuit reversed the ruling as it found that requiring a court order to enforce the subpoena on the DEA interfered with Congress' intent to strengthen law enforcement tools against the traffic of illicit drugs. It recognized, however, that medical records require strong legal safeguards.⁵³

In Georgia, in addition to authorizing prescribers and dispensers, and their designated delegates, the Georgia Drugs and Narcotics Agency is authorized to provide requested prescription information collected to a patient, or the patient's attorney; local or state law enforcement or prosecutorial officials pursuant to the issuance of a search warrant from an appropriate court or

⁴⁸ Islam, M Mofizul and McRae, Ian S, "An inevitable wave of prescription drug monitoring programs in the context of prescription opioids: pros, cons and tensions," BMC Pharmacology & Toxicology, 6 August 2014. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4138942/>

⁴⁹ Ibid.

⁵⁰ American Society of Addiction Medicine, "Public Policy Statement on Measures to Counteract Prescription Drug Diversion, Misuse and Addiction," 25 January 2012. <https://www.asam.org/advocacy/find-a-policy-statement/view-policy-statement/public-policy-statements/2012/01/26/measures-to-counteract-prescription-drug-diversion-misuse-and-addiction>

⁵¹ American Medical Association, "Prescription Drug Monitoring Program Confidentiality H-95.946, 2015. <https://policysearch.ama-assn.org/policyfinder/detail/prescription%20drug%20monitoring%20program?uri=%2FAMADoc%2FHOD.xml-0-5325.xml>

⁵² *Oregon Prescription Drug Monitoring Program v. US Drug Enforcement Administration*, 998 F.Supp.2d 957 (2014) <https://www.leagle.com/decision/infdco20140212990>.

⁵³ *Oregon Prescription Drug Monitoring Program v. US Drug Enforcement Administration*, 860 F.3d 1228 (2017) <https://www.leagle.com/decision/infco20170626117>

official in the county in which the office of such law enforcement or prosecutorial officials are located or to federal law enforcement or prosecutorial officials pursuant to the issuance of a search warrant or a grand jury subpoena; to the Georgia Drugs and Narcotics Agency, the Georgia Composite Medical Board or any other state regulatory board governing prescribers or dispensers in this state, or the Department of Community Health for purposes of the state Medicaid program upon the issuance of a subpoena by such agency, board, or department pursuant to their existing subpoena power or to the federal Centers for Medicare and Medicaid Services upon the issuance of a subpoena by the federal government pursuant to its existing subpoena powers.⁵⁴

Proper Funding

To continually maintain and update a state's PDMP system often comes with a certain level of financial need. It is often difficult, however, for states to properly fund such operations and projects. In order to meet these demands, states use a wide variety of funding mechanisms, whether in whole or in part, including state appropriations, registration and licensing fees, and federal grants.

One source of funding for states has been legislative appropriations and state government funding. In October 2015, Ohio Governor John Kasich announced that the state would invest up to \$1.5 million a year to integrate the Ohio Automated Rx Reporting System (OARRS) directly into electronic medical records and pharmacy dispensing systems across the state, allowing instant access for prescribers and pharmacists.⁵⁵

In addition to licenses to practice medicine, several states require a controlled substance prescribing license that is separate from DEA registration. The registration fees from these state prescribing licenses frequently go to support the PDMP, whether in full or in part. This funding mechanism assesses a fee on a subset of providers while the more current thinking is that all licensed providers should have access to their patients' PDMP data.⁵⁶

Instead of allocating funds from a specific controlled substance prescribing license, some states allocate a certain percentage from all professional licensing fees to go towards the state's PDMP. Although this avenue provides consistent funding, it is limited in dollar amount and increasing the allocated percentage may affect other operations of the Board.^{57,58}

States often leverage federal grants to fund and maintain PDMP projects, as well. Since 2003, the U.S. Department of Justice's Bureau of Justice Assistance has administered the Harold Rogers PDMP Grant Program to reduce opioid misuse and the number of overdose fatalities by supporting the implementation, enhancement, and proactive use of state PDMPs. For Fiscal Year

⁵⁴ Ga. Code § 16-13-30

⁵⁵ Ohio Automated Rx Reporting System, <https://wholesale.ohiopmp.gov/Portal/Integration.aspx>

⁵⁶ PDMP TTAC, "Funding Options for Prescription Drug Monitoring Programs," 3 July 2013.

http://www.pdmpassist.org/pdf/PDMP_Funding_Options_TAG.pdf

⁵⁷ Brandeis University PDMP Training and Technical Assistance Center, "Funding Options for Prescription Drug Monitoring Programs," 3 July 2013. http://www.pdmpassist.org/pdf/PDMP_Funding_Options_TAG.pdf

⁵⁸ National Alliance for Model State Drug Laws, "Funding Provisions of PDMPs," May 2016.

<http://www.namsdl.org/library/57555C8D-B77F-0F68-987334839CA29924/>

2017, two-year grants were awarded to 10 states and Puerto Rico totaling \$3,966,932.⁵⁹ The CDC also provides funding opportunities to support states' efforts to enhance and maximize PDMPs, including the Data Driven Prevention Initiative (DDPI) and Prevention for States (PFS) Funding Opportunity Announcements.⁶⁰⁶¹ Additionally, SAMHSA also provides a variety of funding opportunities for states to enhance their PDMPs.⁶²

5. Recommendations

1. Mandatory Registration –

States should require PDMP registration for prescribers of controlled substances. This registration should take place at the time of the prescriber's initial medical licensure application or next renewal. In an effort to expedite the process, state PDMPs should facilitate online registration to meet the expected increase in applications.

2. Universal Use of PDMPs–

States should require universal use of PDMPs if the state's PDMP contains certain characteristics. Ideally, all the characteristics listed below would be present within a state's PDMP system but some are more critical than others to the functionality of the PDMP.

a. Group 1: Critical Characteristics Needed for an Effective PDMP

i. Delegation –

Each prescriber should be permitted to delegate authority to access the PDMP to any member of their health care team by creating subaccounts without limitations. Delegates should be able to be shared by multiple providers, such as a physician group or emergency department or similar setting. The prescriber must have the authority to deactivate a delegate's subaccount for any reason, including, but not limited to, leaving the practice or no longer serving in that capacity.

In order to ensure delegate accountability, prescribers must be allowed to audit their delegates' activity and use of the PDMP.

ii. Data timeliness/accuracy –

State PDMPs should require daily reporting of controlled substance prescription. Although it may be ideal to have real-time reporting, there is a paucity of data at this time to support it.⁶³

⁵⁹ U.S. Department of Justice, Bureau of Justice Assistance, Harold Rogers PDMP Grant Program, <https://www.bja.gov/funding/Category-5-awards.pdf>

⁶⁰ Centers for Disease Control, *Data Driven Prevention Initiative*. <https://www.cdc.gov/drugoverdose/foa/ddpi.html>

⁶¹ Centers for Disease Control, *Prevention for States*.

https://www.cdc.gov/drugoverdose/states/state_prevention.html

⁶² Substance Abuse and Mental Health Services Administration. Grants Related to Prescription Drug Misuse and Abuse. <https://www.samhsa.gov/prescription-drug-misuse-abuse/grants>

⁶³ The PEW Charitable Trusts, *Prescription Drug Monitoring Programs: Evidence-Based Practices to Optimize Prescriber Use*, December 2016. www.pewtrusts.org/en/research-and-analysis/reports/2016/12/prescription-drug-monitoring-programs.

In order to ensure data accuracy, prescribers should be able to review their prescribing history and provide corrections to it, if necessary.

iii. Integration and Data Sharing –

In order to minimize any workflow disruption, states should integrate their PDMP system with electronic health records and pharmacy systems. Ideally, this integration will provide near-instant and seamless access to critical prescription history information to both prescribers and pharmacists.

States should engage in interstate PDMP data sharing.

b. Group 2: Other Characteristics Needed for an Effective PDMP

i. Unsolicited reports –

In an effort to notify prescribers of a patient’s prescribing information, as well as the prescriber’s own prescribing history, PDMP systems should provide unsolicited reports. Examples of information in such reports may include multiple provider episodes, combinations of commonly misused drugs, or exceeding a designated threshold for an average daily dose of an opioid in morphine milligram equivalents.

To protect patients, prescribers should generate user-led unsolicited reports to send to other prescribers treating the same patient. These user-led unsolicited reports are sent at the discretion of the prescriber and serve as a judgment that the patient may be receiving a potentially harmful controlled substance or has experienced a situation, such as an overdose, that may increase the patient’s future risk of overdose or abuse.

When possible, these reports should be sent electronically and should not contain identifying patient information, but rather alert and direct the prescriber to query the PDMP to view the information.

ii. Educational initiatives –

A state medical board may choose to encourage or require prescribers to complete content-specific continuing medical education related to prescribing practices including, but not limited to, PDMP utilization.

iii. Enhanced user interface –

PDMP system tools to increase usability for prescribers should be considered. These components, as part of a PDMP’s interface, may include, but are not limited to, a summary of morphine milligram equivalent (MME) for each opioid prescription and a daily MME dose level, as well as any other “red” flags or alerts for a specific patient.

iv. Data Security/Patient Privacy –

States should grant PDMP data access to local, state, and federal law enforcement only when there is an issuance of warrant/judicial finding of probable cause.

States should grant PDMP data access to state medical boards when a licensee is under investigation by the board for inappropriate prescribing.

In order to protect the privacy of patient information and to ensure proper patient treatment, Medicare, Medicaid, state health insurance programs and/or health care payment benefit providers and insurers should not have access to a patient's PDMP record unless a subpoena has been issued in accordance with existing subpoena powers.

v. Proper funding –

To meet the demands of updating and maintaining a PDMP, states should implement a sustainable funding mechanism, whether through state funding or federal grant programs.

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Physician Wellness and Burnout

Report and Recommendations of the Workgroup on Physician Wellness and Burnout

*Adopted as policy by the Federation of State Medical Boards
April 2018*

Executive Summary:

The Federation of State Medical Boards (FSMB) Workgroup on Physician Wellness and Burnout was convened in April of 2016 by FSMB Chair Arthur S. Hengerer, M.D. to identify resources and strategies to address physician burnout.

While the Workgroup examined the issue of physician burnout from a broad perspective, reviewing as many facets of this complex issue as possible, including existing research, resources, and strategies for addressing it, the recommendations for state medical and osteopathic boards (hereinafter referred to collectively as “state medical boards”) found in this report focus first and foremost on the licensing process. The Workgroup also saw fit to include commentary and recommendations on several other aspects of physician wellness and burnout, though some of these areas may not be under the direct purview of the FSMB or its member boards. The FSMB recognizes the importance of collaboration for effectively supporting physicians and protecting patients in the face of circumstances that lead to burnout, which is ultimately a patient safety issue. A shared accountability model that includes responsibilities to be carried out by providers from all the health professions, including physicians and physician assistants, and with organizations from across the health care community is therefore recommended as the most promising course of action to address this important issue.

Recommendations for state medical boards related to the licensing process include considering whether it is necessary to include probing questions about a physician applicant’s mental health, addiction, or substance use on applications for medical licensure or their renewal, and whether the information these questions are designed to elicit, ostensibly in the interests of patient safety, may be better obtained through means less likely to discourage treatment-seeking among physician applicants.

Where member boards strongly feel that questions addressing the mental health of physician applicants must be included on medical licensing applications, several recommendations are included in this report for the appropriate phrasing of such questions, including focusing only on current impairment, which may be more meaningful in the context of a physician’s ability to provide safe care to patients in the immediate future.

State medical boards are also encouraged to approach physician wellness and burnout from a non-punitive perspective, avoiding public disclosure of any information about a physician’s diagnosis during licensing processes and offering “safe haven” non-reporting

options (mentioned later in this report) to physicians who are under treatment and in good standing with a recognized physician health program (PHP) or other appropriate care provider.

It is also recommended that boards take advantage of all opportunities available to them to discuss physician wellness, communicate regularly with licensees about relevant board policies and available resources, and make meaningful contributions to the ongoing national dialogue about burnout in order to advance a positive cultural change that reduces the stigma among and about physicians seeking treatment for mental, behavioral, physical or other medical needs of their own.

The Workgroup's recommendations to external organizations and stakeholders focus on increasing the awareness and availability of information and resources for addressing physician burnout and improving wellness. The value of noting and listing the availability of accessible, private, confidential counselling resources is a particular point of emphasis in this report, as is dedicating efforts to ensuring that any new regulation, technology, or initiative is implemented with due consideration to any potential for negative impact on physician wellness.

This report, which follows two years of careful study, evaluation and discussion by Workgroup members, FSMB staff, and various stakeholders, is intended to support initial steps by the medical regulatory community to begin to address the issues associated with promotion of physician wellness and mitigation of burnout, to the extent that is possible. The information and recommendations contained herein are based on principles of fairness and transparency, and grounded in the primacy of patient safety. They emphasize a responsibility among state medical boards to work to ensure physician wellness as a component of their statutory right and duty to protect patients.

Background and Charge:

In 2014, the Ethics and Professionalism Committee of the Federation of State Medical Boards (FSMB) engaged in several discussions about the risks to patient safety that may result from disruptive physician behavior. As these discussions proceeded, it became apparent from a review of the literature and discussions with state medical boards that a link exists between many instances of disruptive behavior and symptoms of professional burnout experienced by so-called "disruptive physicians." The Committee, chaired by Dr. Janelle A. Rhyne, M.D., MACP, determined that further research into physician health, self-care, and burnout should be conducted to identify resources that may be of value for state medical boards and physicians alike, and to outline possible roles for the FSMB and its partners to better promote patient safety and quality health care.

Given the complexity of the issue and the many factors contributing to physician burnout, in 2016, Dr. Arthur S. Hengerer, MD, (while serving as Chair of the FSMB), established the FSMB Workgroup on Physician Wellness and Burnout to study the issue further. The Workgroup was specifically charged with identifying resources and strategies to address

physician burnout. To accomplish its charge, the Workgroup reported that it would engage in a multi-part work program that would likely involve: 1) educating state medical boards and physicians through the creation of a compendium of research and resources on identifying, managing and preventing physician burnout; 2) raising awareness about the prevalence of burnout among physicians and other health care professionals, helping reduce the stigma sometimes associated with physicians seeking help for burnout symptoms; 3) evaluating current research on the impact of physician burnout on patient care; and 4) convening stakeholder organizations and experts to discuss physician wellness and to recommend best practices for promoting physician wellness and helping physicians identify, manage and prevent burnout throughout their career continuum (i.e. from medical school through residency training and throughout their years of licensed, unsupervised practice.)

The purpose of this report is to summarize the steps taken by the Workgroup in fulfillment of their charge, to share information gathered as part of this process, and to provide a series of recommendations for state medical boards and others to consider for addressing burnout and its symptoms. It should be noted that the Workgroup's charge does not include tasks related to defining the phenomenon of burnout or performing further analysis into the concept itself, as it was felt there is a significant amount of valuable research that has already been done in these areas and is ongoing. Much of this research, including some that is inchoate, was reviewed by the Workgroup in fulfillment of the third component of its charge. This body of research is referenced herein and informs many of the recommendations contained in this report. While burnout is a phenomenon that may impact physicians at all stages of their career, it should be noted that the recommendations specific to state medical boards in this report focus primarily on the licensing process. The Workgroup feels it is also important, however, to share information in this report related to issues beyond the licensing process. Such additional information and guidance is provided for the benefit of relevant partner organizations and stakeholders responsible for undergraduate, graduate and continuing medical education; medical school, residency training and health facility accreditation; governance, information technology, health insurance, and other activities and functions that support the provision of health care to the nation's citizens.

In developing the content and recommendations of this report, the Workgroup understands and endorses the importance of the "quadruple aim," which added a call for improvements in the quality of work lives of physicians and other health care providers¹ to the existing three aims of improving the health of populations, enhancing the patient experience of care, and reducing the per capita cost of health care.² As argued by proponents of the fourth aim, improved population health cannot be achieved without ensuring the health and well-being of health care providers.

¹ Bodenheimer T, Sinsky C (2014), From Triple to Quadruple Aim: Care of the Patient Requires Care of the Provider. *Ann Fam Med*, 12 (6): 573-576.

² Berwick DM, Nolan TW, Whittington J. (2008). The Triple Aim: care, health, and cost. *Health Aff* (Millwood), 27(3):759-69.

Several definitions have been applied to the phenomenon of physician burnout and, for the purposes of this report, it is considered a psychological response that may be experienced by doctors exposed to chronic situational stressors in the health care practice environment. This is characterized by overwhelming exhaustion, feelings of cynicism and detachment from work, and a sense of ineffectiveness and lack of accomplishment.³ While burnout's manifestations and consequences vary widely, they could result in significant harm to patients.

It has been widely reported for more than a decade that nearly 100,000 preventable medical errors occur in the United States each year.⁴ More recent findings suggest that between 210,000 and 400,000 deaths each year are associated with preventable harm.⁵ Many of these errors may be attributed to physician burnout and its drivers, such as excessive caseloads, negative workplace culture, poor work-life balance, or perceived lack of autonomy in one's work.⁶ Burnout affects a significant proportion of the U.S. physician workforce. A 2012 study conducted by Shanafelt and colleagues showed that 45.5% of surveyed physicians demonstrated at least one symptom of burnout.⁷ When this study was repeated three years later with a different sample, the authors demonstrated that burnout and work-life dissatisfaction had increased by 9% over the three year period.⁸ In addition to obvious risks to patient safety, an alarming and extreme result of physician burnout has been the disproportionate (relative to the general population) levels of suicide in recent years by physicians, medical residents and even medical students.^{9,10} One is hard-pressed to find a phenomenon that negatively affects a broader array of stakeholders in health care than burnout. It impacts providers from all health professions. State medical boards' duty to protect the public, in this regard, also includes a responsibility to ensure the wellness of its licensees.

³ Maslach, C., Jackson, S.E. (1981). The Measurement of Experienced Burnout. *Journal of Occupational Behavior*, 2(2):99-113. See also, Maslach C, Jackson SE, Leiter MP. (1996). *Maslach Burnout Inventory Manual*. 3rded. and Maslach C, et al. (2001). Job Burnout. *Annu Rev Psychol*, 52:397-422.

⁴ Kohn LT, Corrigan J, Donaldson MS. (2000). *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academies Press (US).

⁵ James JT. (2013). A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care. *Journal of Patient Safety*, 9(3):122-128.

⁶ Shanafelt TD, Noseworthy JH. (2016). Executive leadership and physician well-being: Nine organizational strategies to promote engagement and reduce burnout. *Mayo Clin Proc*, 92:129-146.

⁷ Shanafelt TD, et al. (2012). Burnout and satisfaction with work-life balance among US physicians relative to the general US population. *Archives of Internal Medicine*, 172(18):1377-1385.

⁸ Shanafelt TD, Hasan O, Dyrbye L, et al. (2015). Changes in burnout and satisfaction with work-life balance in physicians and the general US working population between 2011 and 2014. *Mayo Clin Proc*, 90:1600-1613.

⁹ Rubin R. (2014). Recent Suicides Highlight Need to Address Depression in Medical Students and Residents. *JAMA*, 312(17):1725-1727.

¹⁰ Gold KJ, Sen A, Schwenk TL. (2013). Details on suicide among US physicians: data from the National Violent Death Reporting System. *Gen Hosp Psych*, 35:45-49.

Features and Consequences of Burnout:

Physicians experiencing burnout, according to the medical literature, exhibit a wide array of signs, symptoms and related conditions, including fatigue, loss of empathy, detachment, depression, and suicidal ideation. The three principal components of burnout are widely described in the medical literature as emotional exhaustion, depersonalization, and diminished feelings of personal accomplishment.¹¹ Many of these symptoms are also said to be linked to low levels of career satisfaction.

Career satisfaction may be diminished by even a single influencing factor. Unreasonable increases in workload, for example, may quickly lead to dissatisfaction with one's career. Loss of job satisfaction has been noted as both a primary contributor to burnout as well as a contributor to its further progression.¹² Burnout has specifically been found to be the single greatest predictor of surgeons' satisfaction with career and choice of specialty.¹³ It may also be a significant contributor to increased rates of suicidal ideation among both physicians¹⁴ and medical students.¹⁵

Physicians experiencing manifestations of burnout are also reported to be more prone to engage in unprofessional behavior,¹⁶ commit surgical or diagnostic medical errors,^{17,18,19} and lose the trust²⁰ of their patients, while also decreasing their satisfaction.²¹ At a time when there is compelling evidence of a shortage of qualified practicing physicians in many parts of the United States, losing additional physicians to early or unnecessary retirement would have a detrimental impact on patient access to care across the country. As the American Medical Association's Policy on Physician Health and Wellness states,

¹¹ Maslach C, Schaufeli WB, Leiter MP. (2001). Job burnout. *Annual Review of Psychology*, 52:397-422.

¹² Mirvis DM, Graney MJ, Kilpatrick AO. (1999). Burnout among leaders of the Department of Veterans Affairs medical centers: contributing factors as determined by a longitudinal study. *J Health Hum Serv Adm*, 21:390-412, and Mirvis DM, Graney MJ, Kilpatrick AO. (1999). Trends in burnout and related measures of organizational stress among leaders of Department of Veterans Affairs medical centers. *J Healthc Manag*, 44(5):353-365. (Via Chopra SS. (2004). *JAMA*, 291(5):633).

¹³ Shanafelt TD, et al. (2009). Burnout and Career Satisfaction among American Surgeons. *Annals of Surgery*, 250(3):463-471.

¹⁴ Shanafelt TD, Balch CM, Dyrbye LN, et al. (2011). Suicidal ideation among American surgeons. *Arch Surg*, 146:54-62.

¹⁵ Schwenk TL, Davis L, Wimsatt LA. (2010). Depression, stigma, and suicidal ideation in medical students. *JAMA*, 304(11): 1181-1190.

¹⁶ Dyrbye LN, Massie FS, Jr., Eacker A, et al. (2010). Relationship between burnout and professional conduct and attitudes among US medical students. *JAMA*, 304: 1173-1180.

¹⁷ Privitera MR, et al. (2015). Physician Burnout and Occupational Stress: An inconvenient truth with unintended consequences. *Journal of Hospital Administration*, 4(1).

¹⁸ Shanafelt TD, Balch CM, Bechamps G, et al. (2010). Burnout and medical errors among American surgeons. *Ann Surg*, 251:995-1000.

¹⁹ West CP, Huschka MM, Novotny PJ, et al. (2006). Association of perceived medical errors with resident distress and empathy: a prospective longitudinal study. *JAMA*, 296(9):1071-1078.

²⁰ Haas JS, Cook EF, Puopolo AL, Burstin HR, Cleary PD, Brennan TA. (2000). Is the professional satisfaction of general internists associated with patient satisfaction? *J Gen Intern Med*, 15(2):122-128.

²¹ Anagnostopolous F, Liolios E, Persefonis G, Slater J, Kefetsios K, Niakas D. (2012). Physician burnout and patient satisfaction with consultation in primary health care settings: evidence of relationships from a one-with-many design. *J Clin Psychol Med Settings*. 19(4):401-410.

"When health or wellness is compromised, so may be the safety and effectiveness of the medical care provided."²²

Factors Contributing to Burnout:

While a large proportion of physicians are said to experience burnout and its correlates, they do not always experience it in the same way or for the same reasons. Physicians may be predisposed to burnout because of personality traits that led them to pursue a medical career in the first place, such as perfectionism, self-denial, and compulsiveness. These are traits that are said to be common among practicing physicians. Predisposition to burnout may be stronger in instances where personal factors such as denial of personal vulnerability, tendencies to delay gratification, or excess feelings of guilt are layered onto these aforementioned personality traits. While burnout is a distinct phenomenon from mental illness and substance use disorders, the latter two issues can play a compounding role in a physician's struggle with burnout, making the identification and effective treatment of its symptoms or causes even more difficult.²³

It is a common misconception that physicians are more susceptible to suffering from burnout at later stages in their career, presumably from fatigue and aging. In fact, research has demonstrated that physicians in the middle of their careers are at the highest risk for burnout.²⁴ Education and training also appear to be critical peak times for physicians, physicians-in-training or medical students to suffer from burnout.^{25,26}

The environment in which physicians work, including their choice of specialty, also plays a significant role in contributing to burnout. Shanafelt and colleagues have shown substantial differences in burnout rates by specialty, although changes in the highest and lowest rates were noted between 2011²⁷ and 2014.²⁸ The control, or lack thereof, that physicians have over their work environment plays a significant role in predisposition to burnout. This may explain why emergency medicine is frequently found at or near the top of the list of medical and surgical specialties with the highest proportion of physicians experiencing burnout. Emergency physicians often work in environments that are high-demand and low-control.²⁹ While finding meaning in one's work has long been claimed

²² *Code of Medical Ethics*, (2016). American Medical Association, Opinion 9.3.1.

²³ Oreskovich M, Kaups K, Balch C, et al. (2011). The prevalence of alcohol use disorders among American surgeons. *Arch Surg*, 147:168-174.

²⁴ Dyrbye LN, et al. (2013). Physician satisfaction and burnout at different career stages. *Mayo Clinic Proceedings*, 88(12):1358-1367.

²⁵ Dyrbye LN, Shanafelt TD. (2016). A narrative review on burnout experienced by medical students and residents. *Med Educ*, 50:132-149.

²⁶ Dyrbye LN, et al. (2014). Burnout among U.S. medical students, residents, and early career physicians relative to the general U.S. population. *Academic Medicine*, 89(3):443-451.

²⁷ Shanafelt TD, et al. (2012). Burnout and satisfaction with work-life balance among US physicians relative to the general US population. *Archives of Internal Medicine*, 172(18):1377-1385.

²⁸ Shanafelt TD, Hasan O, Dyrbye L, et al. (2015). Changes in burnout and satisfaction with work-life balance in physicians and the general US working population between 2011 and 2014. *Mayo Clin Proc*, 90:1600-1613.

²⁹ <https://www.medpagetoday.com/emergencymedicine/emergencymedicine/54916>

to be the antidote to burnout,³⁰ it may be difficult to find such meaning absent an adequate degree of control over one's work environment.

The movement towards maximal standardization of processes, often labeled a phenomenon of "deprofessionalization," is also claimed to be a contributor to burnout among physicians. There is worry among some professionals, in medicine and other health care fields, that an expectation for rigid adherence to guidelines will replace what were formerly considered the more elegant, artistic and satisfying aspects of medical practice.³¹ These movements need not be perceived as threats to physician autonomy or to the exercise of professional judgment. Rather, embracing evidence-based medicine, focusing on the value of care that is provided, and celebrating increasingly positive outcomes can contribute to great improvements in patient and population health. Professional judgment will continue to play an important role in realizing these improvements.

Frustrations have also been voiced in relation to the move in health care delivery away from paper-based records to electronic health records (EHRs). Many physicians have expressed dissatisfaction with the intrusiveness and complexity of EHR use and the limits this sometimes places on the ways in which they are able and capable of effectively documenting treatment decisions and provision of care.³² These frustrations exist in addition to those related to the often complex, redundant, or non-intuitive methods of data entry and other elements of medical record keeping associated with EHRs,^{33,34,35} as well as the fact that most systems are not yet fully interoperable. However, complaints made about particular aspects of an evolving or disruptive technology should not be interpreted as calls to abandon the important gains in patient safety, professional communication, and even efficiency that have been brought about by the introduction and implementation of EHR systems. Rather, they should be interpreted as important user feedback that may contribute to ongoing improvement of such technology.

The constantly changing and evolving nature of medicine, as well as the challenges faced by the American health care system itself, also appear to be affecting the way many physicians feel within their professional roles. A recent study reported that 65% of physicians who were surveyed predicted an ongoing deterioration in the quality of health care that they deliver, which in turn has been attributed, in part, to the erosion of

³⁰ Sotile W. (2002). *The Resilient Physician*.

³¹ Aasland OG. (2015). Healthy Doctors – Sick Medicine. *Professions and Professionalism*, 5(1).

³² Friedberg MW, et al. (2013). Factors Affecting Physician Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy. RAND Corporation, https://www.rand.org/pubs/research_reports/RR439.html.

³³ Arndt BG, et al. (2017). Tethered to the EHR: Primary Care Physician Workload Assessment Using EHR Event Log Data and Time-Motion Observations. *Ann Fam Med*, 15(5):419-426.

³⁴ Levinson J, Price BH, Saini V. (2017). Death By A Thousand Clicks: Leading Boston Doctors Decry Electronic Medical Records. *Common Health*, <http://www.wbur.org/commonhealth/2017/05/12/boston-electronic-medical-records>.

³⁵ Sinsky C, et al. (2016) Allocation of Physician Time in Ambulatory Practice: A Time and Motion Study in 4 Specialties. *Ann Intern Med*. 165:753-760.

physician autonomy.³⁶ When evolving requirements are layered onto new expectations with regard to technology, quality reporting, increased clinical volume, and numerous other initiatives required by payers, employers, and even state medical boards, it may not be surprising that physicians are experiencing burnout at alarming rates. While many of the initiatives that place additional burdens on physicians are grounded in strong rationales related to patient safety and quality care, the burnout resulting from their combined effect may actually inhibit the success of the initiatives themselves.³⁷ This should certainly bring pause to those charged with implementing initiatives and requirements to carefully evaluate their effectiveness, unintended consequences, and potential burden, but also to communicate their goals and perceived value. The reaction of the profession to the ongoing changes that are occurring may also indicate particular attitudes within the culture of medicine that would benefit from further discussion, as would support to integrate positive change into practice.

Burnout is not always related to stressors arising in a physician's work environment or to a physician's character traits. Family issues, personal and professional relationships, financial pressures, insufficient work-life balance, or other external stressors may also contribute to burnout. Efforts aimed at the identification, treatment, or prevention of burnout must, therefore, approach the issue from a broad enough perspective to take all of these factors into account.

Challenges and Barriers to Addressing Burnout:

While there has been a promising rise in the number of peer-reviewed research publications addressing the topic of physician burnout, in the academic medical literature, popular media and so-called gray literature (e.g., white papers, position statements, organizational reports), there seems to be a perceived lack of resources available to identify and address the issue. This perception may be misguided, however, since several academic institutions, health systems, medical specialty societies, independent physicians, physician health programs, and state medical boards make many useful, high-quality resources available (See Appendix A.). While more resources would be beneficial to physicians, and ultimately their patients, their development should be complemented with efforts aimed at highlighting best practices. Research is also needed to identify how sources of burnout might differ for male and female physicians in order that resources may be appropriately tailored. A more coordinated effort to raise awareness not only about the issue of physician burnout but also about resources for ameliorating related circumstances may also serve to reduce stigma and facilitate identification and treatment. It may also help improve systems issues that impact burnout by improving communication, team building, and collaboration within and among health care

³⁶ Emanuel EJ, Pearson SD. (2012). Physician autonomy and health care reform. *Journal of the American Medical Association*, 307(4), 367-368.

³⁷ Dyrbye LN, Shanafelt TD. (2011). Physician Burnout: A Potential Threat to Successful Health Care Reform. *JAMA* 305(19):2009-2010.

professions. Broader awareness may also better equip physicians in their capacity as leaders to improve circumstances for those with whom they work.³⁸

Many physicians are reluctant to seek help for burnout or any of its many underlying causes for fear that they will be perceived as weak or unfit to practice medicine by their colleagues or employers, or because they assume that seeking such care may have a detrimental effect on their ability to renew or retain their state medical license, arguably the most important credential a physician receives during their professional career.^{39,40,41,42,43} This stigma may be felt as early as medical school,⁴⁴ a particularly dangerous cultural feature in a population where symptoms of anxiety and depression have been found to be more prevalent than in the general population.⁴⁵ In a study by Dyrbye and colleagues, it was found that only a third of the medical students experiencing features of burnout sought help and that stigma was seen as a barrier for those who chose not to seek help.⁴⁶ The same reluctance is seen with respect to help-seeking for other types of stigmatized suffering such as depression, substance use disorders, or suicidal ideation.⁴⁷ Without adequate modeling of appropriate self-care behaviors among faculty mentors, progress at stigma reduction will likely be slow. Further, while there are laudable examples of programs at academic medical centers across the country which responsibly offer accessible, complementary, private, and confidential counselling to medical students,⁴⁸ these programs are by no means widely available.

Privacy and confidentiality of a physician's health and treatment history is important to allow those in need of help to come forward without fear of punishment, disciplinary

³⁸ Shanafelt TD, et al. (2015). Impact of Organizational Leadership on Physician Burnout and Satisfaction, *Mayo Clinic Proceedings*, 90(4):432-440.

³⁹ Chew-Graham CA, et al. (2003). 'I wouldn't want it on my CV or their records': medical students' experiences of help-seeking for mental health problems. *Medical Education*, 37(10):873-880.

⁴⁰ Federation of State Medical Boards. (2011). Policy on Physician Impairment.

⁴¹ Guille C, et al. (2010). Utilization and Barriers to Mental Health Services Among Depressed Medical Interns: A Prospective Multisite Study, *Journal of Graduate Medical Education*, 2(2):210-214.

⁴² Gold K, et al. (2016). "I would never want to have a mental health diagnosis on my record": A survey of female physicians on mental health diagnosis, treatment, and reporting. *General Hospital Psychiatry*, 43:51-57.

⁴³ Dyrbye LN, et al. (2017). Medical Licensure Questions and Physician Reluctance to Seek Care for Mental Health Conditions. *Mayo Clin Proc*, 92(10):1486-1493.

⁴⁴ Schwenk TL, et al. (2010). Depression, Stigma, and Suicidal Ideation in Medical Students. *JAMA*, 304(11):1181-1190.

⁴⁵ Rotenstein LS, Ramos MA, Torre M, et al. (2016). Prevalence of depression, depressive symptoms, and suicidal ideation among medical students, a systematic review and meta-analysis. *JAMA*, 316(21):2214-2236.

⁴⁶ Dyrbye LN, et al. (2015). The Impact of Stigma and Personal Experiences on the Help-Seeking Behaviors of Medical Students with Burnout. *Academic Medicine*, 90(7):961-969.

⁴⁷ Dyrbye LN, et al. (2017). Medical Licensure Questions and Physician Reluctance to Seek Care for Mental Health Conditions. *Mayo Clin Proc*, 92(10):1486-1493.

⁴⁸ Examples include the HEAR Program at UC San Diego (available to everyone at the UCSD Health System, not only medical students), the Henderson Student Counseling Center at Nova Southeastern University, the Wellness Resources offered at Oregon Health and Science University, and the Medical Student Counseling and Wellness Center at the Herbert Wertheim College of Medicine, Florida International University.

action, embarrassment or professional isolation. The use of confidential services whenever possible in lieu of regulatory awareness is preferred in order to mitigate fear of negative impacts on licensure, employment, or collegial relationships. When confidential services are not utilized, it is less likely licensees will receive early intervention and appropriate treatment, thereby foregoing opportunities for early detection of potentially impairing illness or recovery.

Funding for important programs and initiatives such as those identified above is often difficult to obtain. However, there is a growing body of research that identifies the cost savings for hospitals and employers associated with providing them, particularly when costs associated with medical errors and lower quality of care attributed to burnout are mitigated, as are high turnover rates, absenteeism, and loss of productivity.⁴⁹

Another challenge to identifying and addressing burnout is the fact that the associated stigma may reduce the degree to which the phenomenon itself is discussed. This impacts not only a physician's own willingness to discuss or seek help for burnout, but also the willingness of fellow physicians to address or report instances of impairment among their colleagues, especially that which unduly risks the safety of patients. While the duty to report impairment or incompetence and the duty to encourage help-seeking may seem to conflict, in that a fear of being reported could cause a physician to conceal problems and avoid help, the duty to report is actually based on principles of patient safety and ethics. The duty to report also aims to assist physicians in seeking the help they need in order to continue practicing safely.

In addition to the cultural stigma associated with admitting experiences of burnout, recent research has shed light on the potential impact of licensure and license renewal processes of state medical boards that may discourage treatment-seeking among physicians.^{50,51} State medical boards may inadvertently discriminate unfairly against physicians suffering from mental illness or substance use disorders, or against those who choose to take a leave of absence from practice to prevent or recover from burnout. The very presence of application questions for medical licensure or licensure renewal may stigmatize those suffering from mental and behavioral illnesses for which physicians might otherwise seek care. In fact, questions about substance abuse and mental illness on state medical licensure renewal applications have nearly doubled between 1996 and 2006.⁵² While information about a physician's health status (both mental and physical) may be essential to a state medical board's solemn duty to protect the public, the FSMB has previously noted that a history of mental illness or substance use does not reliably predict future risk

⁴⁹ Shanafelt T, Goh G, Sinsky C. (2017). The Business Case for Investing in Physician Well-Being. *JAMA Intern Med.* 177(12):1826-1832.

⁵⁰ Gold K, et al. (2016). "I would never want to have a mental health diagnosis on my record": A survey of female physicians on mental health diagnosis, treatment, and reporting. *General Hospital Psychiatry*, 43:51-57.

⁵¹ Dyrbye LN, et al. (2017). Medical Licensure Questions and Physician Reluctance to Seek Care for Mental Health Conditions. *Mayo Clin Proc.* 92(10):1486-1493.

⁵² Polfliet SJ. (2008). A National Analysis of Medical Licensure Applications. *J Am Acad Psychiatry Law*, 36(3): 372.

to the public.⁵³ It is also very important to recognize that court interpretations of the Americans with Disabilities Act (ADA) have suggested that state medical boards should focus on current functional impairment rather than a history of diagnoses or treatment of such illness.⁵⁴

In carrying out their duty to protect the public and ensure that only individuals who are fully qualified to practice medicine are granted licenses, state medical boards usually, and for good reasons, insist that they must have sufficient information with which to make medical licensure decisions. During the licensure granting process, state boards also work diligently to ensure that candidates for licensure (or renewal) provide a thorough assessment of their fitness to practice, balanced by protecting their rights as contained in ADA legislation. Fear among prospective and current licensees about potential limitations placed on their ability to practice medicine independently, however, or of their previous diagnoses or treatments somehow being made public despite HIPAA and other federal privacy and confidentiality laws, may cause some physicians to misrepresent personal information that is requested or not respond accurately at all to licensing application questions.⁵⁵ In such instances, paradoxically, the efforts of state medical boards to get comprehensive information may not yield the accurate information they seek about a physician's practice risks to patients. They may also discourage treatment-seeking among physicians, thereby increasing the degree of risk to patients presented by physicians experiencing conditions that remain undiagnosed or untreated.

Recommendations:

The majority of the recommendations that follow are designed for state medical boards to consider and pertain mainly to the inclusion and phrasing of questions on state medical licensing applications. Appropriately addressing the issue of physician burnout provides a unique opportunity for state medical boards to declare, directly or indirectly, that it is not only normal but anticipated and acceptable for a physician to feel overwhelmed from time to time and to seek help when appropriate. This is also an important opportunity for state medical boards to highlight and promote the benefits of physician health, both mental and physical, to help reduce stigma, to clarify related regulatory and reporting issues, promote patient safety and assure the delivery of quality health care. Physicians should feel safe about reporting burnout and be able to take appropriate measures to address it without fear of having their licensure status placed in jeopardy.

Safeguarding physician wellness and mitigating damage caused by burnout cannot be accomplished through isolated actions and initiatives by individual organizations alone. Coordinated efforts and ongoing collaboration will be essential not only for addressing

⁵³ Federation of State Medical Boards. (2006). Federation of State Medical Boards: Americans With Disabilities Act of 1990. License Application Questions: A Handbook for Medical Boards.

⁵⁴ Polfliet SJ. (2008). A National Analysis of Medical Licensure Applications. *J Am Acad Psychiatry Law*, 36(3):373.

⁵⁵ Gold K, et al. (2016). "I would never want to have a mental health diagnosis on my record": A survey of female physicians on mental health diagnosis, treatment, and reporting. *General Hospital Psychiatry*, 43:51–57.

the many systemic issues that contribute to burnout but also for ensuring that appropriate tools, resources, and programs are continuously in place and readily available to help physicians avoid and address burnout. As such, the FSMB also offers suggestions and recommendations to its partner organizations, many of which have been instrumental in furthering the FSMB's current understanding of burnout, its related features, and the role of the regulatory community in addressing and safeguarding physician health.

Ultimately, the Workgroup and the FSMB believe that a shared accountability model that includes several related responsibilities among regulatory, educational, systemic, organizational, and administrative stakeholders provides a promising way forward. The specific recommendations outlined below begin to address what such responsibilities should entail.

The FSMB recognizes its responsibility to help address physician burnout, not only through following its own recommendations and promoting the resources provided in this report, but also by continuing its collaborative efforts with partner organizations from across the wider health care community.

For State Medical Boards:

1. The FSMB recommends that state medical boards review their medical licensure (and renewal) applications and **evaluate whether it is necessary to include probing questions about a physician applicant's mental health, addiction, or substance use**, and whether the information these questions are designed to elicit in the interests of patient safety may be obtained through means that are less likely to discourage treatment-seeking among physician applicants. For example, some boards subscribe to notification services such as the National Practitioner Data Bank's "Continuous Query" service or other data services that provide information about arrests or convictions, including for driving under the influence, within their states which can serve as a proxy finding for physician impairment. The FSMB also recommends in its *Essentials of a State Medical and Osteopathic Practice Act* that boards require applicants to satisfactorily pass a criminal background check as a condition of licensure.⁵⁶
2. Where state medical boards strongly feel that questions addressing the mental health of physician applicants must be included on medical licensing applications, they should **carefully review their applications to ensure that appropriate differentiation is made between the illness with which a physician has been diagnosed and the impairments that may result**. Application questions must focus only on current impairment and not on illness, diagnosis, or previous treatment in order to be compliant with the Americans with Disabilities Act (ADA).

⁵⁶ Federation of State Medical Boards. (2015). *Essentials of a State Medical and Osteopathic Practice Act*.

3. The ADA requires licensure application questions to focus on the presence or absence of current impairments that are meaningful in the context of the physician’s practice, competence, and ability to provide safe medical treatment to patients. **Applications must not seek information about impairment that may have occurred in the distant past and state medical boards should limit the time window for such historical questions to two years or less, though a focus on the presence or absence of current impairment is preferred.**

Questions that address the mental health of the applicant should be posed in the same manner as questions about physical health, as there is no distinction between impairment that might result from physical and mental illness that would be meaningful in the context of the provision of safe treatment to patients.

Where boards wish to retain questions about the health of applicants on licensing applications, **the FSMB recommends that they use the language: *Are you currently suffering from any condition for which you are not being appropriately treated that impairs your judgment or that would otherwise adversely affect your ability to practice medicine in a competent, ethical and professional manner? (Yes/No)***^{57,58}

4. **The FSMB recommends that state medical boards consider offering the option of “safe haven non-reporting” to applicants for licensure who are receiving appropriate treatment for mental health or addiction.** While it is up to boards to determine what constitutes appropriate treatment, the FSMB recommends that physicians who are monitored by, and in good standing with, the recommendations of a state or territorial Physician Health Program (PHP) be permitted to apply for medical licensure or license renewal without having to disclose their diagnosis or treatment to the board. The option of safe haven non-reporting should only be offered when treatment received is commensurate with the illness being treated and has a reasonable chance of avoiding any resultant impairment.
5. **State medical boards should work with their state legislatures to ensure that the personal health information of licensees related to an illness or diagnosis is not publicly disclosed as part of a board’s processes.** Information disclosed must relate only to impairment of professional abilities, medical malpractice, and professional misconduct.⁵⁹

⁵⁷ American Psychiatric Association. (2015). Position statement on inquiries about diagnosis and treatment of mental disorders in connection with professional credentialing and licensing.

⁵⁸ The American Psychiatric Association (APA) passed an Action Paper in November 2017, resolving to query state medical boards and notify them about their compliance with APA policy and the ADA.

⁵⁹ Center C, Davis M, Detre T, et al. (2003). Confronting depression and suicide in physicians: a consensus statement. *JAMA*, 289(23):3161–3166.

6. **State medical boards should emphasize the importance of physician health, self-care, and treatment-seeking for all health conditions by including a statement to this effect on medical licensing applications, state board websites, and other official board communications.** Where appropriate, options for treatment and other resources should be made available, such as information about a state Physician Health Program (PHP), services offered through a county, state, or national medical society, and any other relevant programs. These means of communicating the importance of physician health and self-care are aimed at helping physicians with relevant information and resources but could also help raise awareness among patients of the importance of physician wellness and the threat of burnout to their doctors and their own care.
7. **State medical boards should clarify through communications, in print and online, that an investigation is not the same as a disciplinary undertaking.** Achieving an understanding of this distinction among licensees may help begin to dispel the stigma associated with reporting burnout and remove a barrier to physicians seeking help in times of need.
8. **State medical boards are encouraged to maintain or establish relationships with a PHP in their state and to support the use of data from these programs in a board’s decision-making.**
9. **State medical boards should examine the policies and procedures currently in place for working with physicians who have been identified as impaired in a context that is meaningful for the provision of safe care to patients to ensure that these are fair, reasonable, and fit for the purpose of protecting patients. All such processes should be clearly explained and publicly available.**
10. **State medical boards should be aware of potential burdens placed on licensees by new or redundant regulatory requirements.** They should seek ways of facilitating compliance with existing requirements to support licensees and ensure that they are able to spend time with patients and in those areas of medicine which they find most meaningful. “Reducing the cumulative burden of rules and regulations may improve professional satisfaction and enhance physicians' ability to focus on patient care.”⁶⁰

Upon implementing some or all of the above changes to state medical board policy or processes that are meant to reduce the stigma associated with mental health issues and encourage treatment-seeking, the board should communicate these, and their rationale, to current and prospective licensees, as well as patients and the public. State medical boards should also raise the issue of physician burnout more often, emphasizing the importance

⁶⁰ Friedberg MW, et al. (2013). Factors Affecting Physician Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy. RAND Corporation, https://www.rand.org/pubs/research_reports/RR439.html.

of physician wellness, help-seeking, and the availability of accessible, confidential, and private counselling programs for physicians and all health professionals.

For External Stakeholders and Partner Organizations:

Professional Medical Organizations and Societies:

11. Professional medical societies at local, state, and national levels have a key role to play in encouraging physicians to seek treatment, both preventive and curative, for the physical and mental health issues they face, as well as for features of burnout. The FSMB recognizes the many exemplary programs and initiatives of professional medical societies and encourages their continued advocacy for physician wellness and the availability of support and treatment services.
12. The FSMB recommends a sustained focus in the medical profession on the importance of self-care with an aim to reduce the stigma attached with seeking treatment for health issues, particularly ones related to mental health.
13. The FSMB recommends that attempts be made to expand the availability of accessible, private, and confidential counseling for physicians through medical societies, such as those provided by organizations like the Lane County Medical Society (Oregon), which has a program with several features identified as best practices for physician wellness by the Workgroup. Counseling via telehealth could also enhance access and provide greater assurance of privacy to those seeking care.
14. Given the prevalence of burnout, all physicians need to be educated about the resources currently available regarding burnout, including those referenced in Appendix A, for self-awareness, and for identification and referral of peer professionals who may have burnout. Medical societies are encouraged to partner with other organizations identified in this report to improve awareness of resources and their dissemination.
15. The FSMB recommends that professional medical societies and organizations representing physicians, such as the American Medical Association, the American Osteopathic Association, and the Council of Medical Specialty Societies work with state medical boards to raise awareness among the public of the importance of physician wellness not only because of its inherent value to physicians themselves but also as a significant contributor to patient safety.

Centers for Medicaid and Medicare Services:

16. The FSMB recommends careful analysis of any new requirements placed on physicians to determine their potential impact on physician wellness. Any new

requirements that could serve as a driver of burnout in physicians must be supported by evidence and accompanied by a strong rationale that is based in improving patient care to justify any new burdens imposed on physicians.

State Government, Health Departments, and Legislatures:

17. As state government, health departments, and legislatures make decisions that can impact physicians, the FSMB recommends that they weigh the potential value of proposed new regulations against potential risks to the health of physicians and other clinicians.

Vendors of Electronic Health Records (EHR) systems and standard setting organizations:

18. As a promising advancement in the provision and documentation of care, but also a key driver of frustration with medical practice, EHRs need to be improved in a way that takes the user experience into greater consideration than it does currently. This experience may be improved through facilitating greater ease of data entry into the system, as well as ease of access to data from the system. Vendors are encouraged to include end-user physicians on their builder teams to optimize input about operability and interoperability.
19. Efforts to reduce redundant or duplicative entry should be required by standard setting organizations, such as the Office of the National Coordinator for Health IT (ONC), and reflected in the EHR systems ultimately designed by vendors.
20. EHR vendors are encouraged to focus future improvements on facilitating and improving the provision of patient care. The primary purposes of an EHR relate to documentation of care received by a patient, retrieval of patient care related information and data, and patient communication.

Medical Schools and Residency Programs:

21. The FSMB encourages the Accreditation Council for Graduate Medical Education, the Association of American Medical Colleges, the American Association of Colleges of Osteopathic Medicine, the American Medical Association, the American Osteopathic Association and the institutions they represent, to continue their laudable efforts at improving the culture of medicine and facilitating open conversations about illness and wellness in order to promote positive change.
22. The FSMB recommends continued efforts to encourage medical students and residents to value self-care and understand the positive impacts that physician wellness can have on patient care.

23. The FSMB recommends that medical schools, residency programs, and their accrediting bodies consider ways of amplifying the medical student and resident voice on systemically induced pressures and support trainees by providing means for raising issues related to medical student and resident health and well-being anonymously.

Hospitals/Employers:

24. The FSMB recommends that hospitals revise, where necessary and appropriate, their questions asked as part of their credentialing process according to the recommendations made above for the medical licensing community to ensure that these are not discouraging physicians or other health professionals from seeking needed treatment.
25. The FSMB recommends that hospitals and health systems assess physician health at regular intervals using a validated instrument and act upon the results. Employers should keep results of these assessments internal to the organization or health system in order to promote workplace change, while avoiding threatening or punitive cultures.
26. Hospitals, as well as the American Hospital Association and related organizations, are encouraged to officially adopt the “Quadruple Aim” to demonstrate the importance they place in the health and wellness of the physicians and all other health professionals they employ and recognize the impact of provider health on safe patient care.
27. Hospitals should ensure that their policies and procedures are adopted with consideration given to the impact they have on the health of the hospital workforce. Decisions impacting hospital the health of hospital and health system employees should be made with adequate input from individuals representing the impacted sectors of that workforce.
28. While acknowledging the need for hospitals to acknowledge all staff in their programmatic development, employers are encouraged to make resources and programs available to physicians, including time and physical space for making connections with colleagues and pursuing personal goals that add meaning to physicians’ work lives. Resources and programs should not always be developed and implemented in a “one size fits all” manner, but should incorporate consideration of the different stressors placed on male and female physicians, within and outside of the workplace, and be tailored appropriately. Resources related to EHR implementation and use should also be made available by employers, including training to optimize use and support for order-entry such as scribes or other technological solutions aimed at restoring time available to physicians.

29. Hospitals should ensure that mandatory reports related to physician competence and discipline are made available to state medical boards and other relevant authorities.

Insurers:

30. The FSMB recommends that insurance carriers revise, where necessary and appropriate, their questions on applications for professional liability insurance according to the recommendations made above for the medical licensing community to ensure that these are not discouraging physicians or other health professionals from seeking needed treatment.
31. In evaluating the quality of care provided by physicians, insurers should look beyond cost-saving measures and use metrics related to physician health and incentivize practice patterns that contribute to physician wellness.

Accrediting Organizations:

32. In its ongoing development of standards for the accreditation of undergraduate medical education programs, graduate medical education training programs, hospitals and healthcare facilities, the FSMB encourages those organizations charged with the accreditation of institutions and educational programs to include standards related to required resources and policies aimed at protecting medical student, medical resident and attending physician health.

Physicians:

33. Physician wellness is a complex issue, made up of system-wide and individual components. However, physicians have a responsibility to attend to their own health, well-being, and abilities in order to provide care of the highest standard.⁶¹ This involves a responsibility to continually self-assess for indicators of burnout, discuss and support the identification of health issues with peers, and seek help or treatment when necessary. Physicians are encouraged to make use of services of state Physician Health Programs, which, where available, can be accessed confidentially in instances where patient harm has not occurred.
34. Physicians are encouraged to inform themselves about their ethical duty, oftentimes codified in state statutes, to report issues related to incompetence and unsafe care delivered by their peers. They are also encouraged to engage in open

⁶¹ General Assembly of World Medical Association at Geneva Switzerland. (1948). *Declaration of Geneva*, as amended by the WMA General Assembly, October 2017.

dialogue with peers about the importance of self-care, treatment-seeking, and the threats to themselves and their patients presented by burnout.

35. Physicians are also encouraged to seek an appropriate balance between time spent on practice and related work and activities external to work, particularly ones with restorative potential.

Conclusion

The duty of state medical boards to protect the public includes a responsibility to ensure physician wellness and to work to minimize the impact of policies and procedures that impact negatively on the wellness of licensees, both prospective and current. The rationale for this duty is based on the link between physician burnout and its attendant risks to patient safety, the fact that some regulatory processes employed by state medical boards can have negative impacts on the health and wellness of physicians themselves, and the potential for regulatory change to support physician wellness and help prevent further instances of burnout.

The information and recommendations in this Report of the FSMB's Workgroup on Physician Wellness and Burnout are meant to support initial steps in the medical regulatory community and to contribute to ongoing conversation about patient safety and physician health.

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APPENDIX A: SAMPLE RESOURCE LIST

The following list is offered as a sample of resources available to support and facilitate the understanding, diagnosis, treatment, and prevention of symptoms of burnout or to maintain and improve physician wellness. The FSMB has not conducted an in-depth evaluation of individual resources, and inclusion herein does not indicate, nor is it to be interpreted as, an endorsement or guarantee of quality. Further, while some resources listed below are available free of charge, others are only accessible through purchase.

Federation of State Medical Boards, [Policy on Physician Impairment](#), 2011.

Federation of State Medical Boards: Americans With Disabilities Act of 1990. License Application Questions: A Handbook for Medical Boards. Dallas, TX: Federation of State Medical Boards of the United States, Inc., 2006.

The standard tool used to evaluate rates of burnout is the [Maslach Burnout Inventory](#), developed in the 1980s by [Christina Maslach, PhD](#), a psychologist at the University of California Berkeley.

The [HappyMD.com](#) – in particular, the burnout prevention matrix, 117 ways to prevent burnout

Accreditation Council for Graduate Medical Education – [Physician Wellbeing Resources](#)

American Academy of Family Physicians - [Physician Burnout Resources](#) Page:

American College of Emergency Physicians (ACEP) – ACEP [Wellness Resource](#) page

American College of Physicians – [Resources on Physician Well-Being and Professional Satisfaction](#)

American Medical Association [Steps Forward](#) website:

American Osteopathic Association – [AOA Physician Wellness Strategy](#)

Association of American Medical Colleges – [Wellbeing in Academic Medicine](#)

[Federation of State Physician Health Programs](#)

[Mayo Physician Well-being Program](#):

[National Academy of Medicine Action Collaborative on Clinician Well-Being and Resilience](#)

[Remembering the Heart of Medicine](#)

[Stress Management and Resiliency Training](#) (SMART) program

[SuperSmartHealth](#)

The [Studer Group](#)

[The Well-Being Index](#) (Mayo Clinic)