

PARTLY CLOUDY: WHY THE PHYSICIAN PAYMENT SUNSHINE ACT WILL NOT RESULT IN MORE INFORMED PATIENTS

Allison M. Whelan*

“Sunshine is said to be of the best disinfectants.” – Justice Louis Brandeis¹

INTRODUCTION

Drug and device manufacturing is a highly profitable enterprise. A high demand—and often legitimate need—for drugs, devices, biologics, and other medical supplies gives manufacturers the power to produce these profits. In 2011, \$263 billion was spent on retail prescription drugs and \$85.9 billion was spent on durable and non-durable medical equipment.² Many companies’ profits exceeded one billion dollars in 2011.³

The industry’s power and influence has caused concerns about relationships between health care providers and the profit-driven industry and the potential impact such relationships may have on professional medical judgments.⁴ Vast sums of money flow from the industry to doctors.⁵ According to a study conducted by the Pew Prescription Project, the drug industry

*J.D. and M.A. Bioethics Candidate 2015, University of Minnesota.

¹ LOUIS DEMBITZ BRANDEIS, OTHER PEOPLE’S MONEY, AND HOW THE BANKERS USE IT 92 (1914).

² CTR. MEDICARE & MEDICAID SERV., *National Health Expenditures 2011 Highlights*, <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/highlights.pdf> (last accessed Feb. 21, 2013).

³ For example, Pfizer earned over \$10 billion in profits, Johnson & Johnson over 9 billion, and Merck over \$6 billion. Medtronic, a device manufacturer, profited over \$3 billion. *Fortune 500 2012*, CNNMONEY, 2012, http://money.cnn.com/magazines/fortune/fortune500/2012/full_list/.

⁴ See, e.g., Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 J. AM. MED. ASS’N 373 (2000); Donna Shaw, *Drug Companies Attacked for Inducements to Doctors*, SEATTLE TIMES, Dec. 12, 1990, <http://community.seattletimes.nwsour.com/archive/?date=19901212&slug=1109031> (discussing a 1990 Senate Hearing where witnesses testified that “the nation’s pharmaceutical industry has wooed doctors with gifts as inducements to prescribe their medicines”).

⁵ Not only are *manufacturers* rewarded, individual *physicians* have much to gain as well. On March 12, 2013, ProPublica released the names of 22 physicians who received more than \$500,000 since 2009 from pharmaceutical companies. The highest earner was Dr. John Draud, medical director of the psychiatric and addiction medicine program at Baptist Hospital in Nashville, Tennessee. Dr. Draud has received a total of \$1,009,213 from AstraZeneca, Cephalon, Eli Lilly, Forest, Merck, Novartis, and Pfizer. On average, approximately 50% of the payments went toward speaker fees, consulting, meals and travel, and educational materials. Deborah Brauser, *Psychiatrists Top List of Big Pharma Payments Again*,

spent \$29 billion on marketing in 2011, \$25 billion of which was spent on marketing directly to physicians.⁶ These concerns have been the impetus for federal regulations, state laws, and professional codes and guidance documents governing provider-industry relationships. The Physician Payment Sunshine Act (PPSA), part of the Patient Protection and Affordable Care Act, is the most recent regulatory attempt to increase transparency of physician-industry relationships and improve patient knowledge.⁷ There are many reasons, however, to seriously question the ability of the PPSA—or any disclosure law—to improve patient knowledge.

Part I provides a brief overview of current laws, regulations, and guidelines governing provider-industry relationships and the intent and goals of these regulations. Part II analyzes why the PPSA will *not* achieve its stated objectives: improving patient knowledge and promoting patients’ best interests. To ensure equitable and effective enforcement and to protect the most vulnerable patient populations, a single national standard with stricter regulations and a broader scope than the PPSA should be adopted. Part III suggests some possible solutions going forward.

I. EXISTING LAWS & REGULATIONS: FROM FEDERAL AND STATE LAWS TO VOLUNTARY PROFESSIONAL CODES AND GUIDANCES

There is an expansive body of laws and regulations governing health care providers, ranging from those covering fraud, bribery, and theft, to others prohibiting certain types of contractual relationships, investments, and marketing and recruitment practices that are frequently legal in other business areas.⁸ These rules seek to “rectify a number of serious flaws in

MEDSCAPE MED. NEWS, Mar. 14, 2013; *see also* Jeremy B. Merrill et al., *Dollars for Docs: How Industry Dollars Reach Your Doctors*, PROPUBLICA (last updated Mar. 11, 2013), <http://projects.propublica.org/docdollars/>.

⁶ Pew Prescription Project, *Persuading the Prescribers: Pharmaceutical Industry Marketing and its Influence on Physicians and Patients*, PEW CHARITABLE TRUSTS (Jan. 2, 2013), <http://www.pewhealth.org/other-resource/persuading-the-prescribers-pharmaceutical-industry-marketing-and-its-influence-on-physicians-and-patients-85899439814>.

⁷ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

⁸ HEALTH LAW: CASES, MATERIALS, AND PROBLEMS 1023 (Barry R. Furrow et al. eds., 6th ed. 2008).

the health care financing system, save the government money, and prevent conflicts of interest that taint the physician-patient relationship.”⁹ This has included attempts to ban, limit, or improve the transparency of provider-industry relationships.

The PPSA is the most recent attempt to regulate physician-industry relationships. As a federal law, it seeks to have broader regulatory implications than existing *state* laws (adopted in a minority of states)¹⁰ and voluntary regulations promulgated by professional societies and trade associations.¹¹ The PPSA acts as a regulatory floor, allowing states and other entities to impose stricter regulations.¹² Part A overviews existing state laws, Part B discusses regulations promulgated by professional associations or trade organizations, and Part C details the PPSA.

A. EXISTING STATE LAWS

States with their own “sunshine laws” and/or gift bans include California,¹³ Colorado,¹⁴ Connecticut,¹⁵ Massachusetts,¹⁶ Minnesota,¹⁷ Nevada,¹⁸ Vermont,¹⁹ Washington D.C.,²⁰ and

⁹ *Id.*

¹⁰ See generally HEALTH INDUS. DISTRIB. ASS’N, 2011 GIFT DISCLOSURE REPORT (2011) (providing overview of state marketing and gift disclosure laws), available at http://www.hida.org/App_Themes/Member/docs/Healthcare%20reform/2011%20Gift%20Disclosure%20Rpt.pdf. The PPSA preempts state laws when they require the same types of disclosures. 42 U.S.C. § 1320a-7h(d)(3)(2012) provides:

In the case of payment or other transfer of value . . . the provisions of this section shall preempt any statute or regulation of a State . . . that requires an applicable manufacturer to disclose or report, in any format, the type of information . . . regarding such payment or other transfer of value.

¹¹ ADVANCED MED. TECH. ASS’N (ADVAMED), CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS (July 2007) [hereinafter ADVAMED, CODE OF ETHICS], available at <http://advamed.org/res/112/advamed-code-of-ethics-on-interactions-with-health-care-professionals>; PHARM. RESEARCH & MFR. AM. (PHRMA), CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS (2009) [hereinafter PHRMA CODE], available at http://www.phrma.org/sites/default/files/108/phrma_marketing_code_2008.pdf.

¹² States can still require reporting of categories and payments types *not* required under the PPSA. Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458, 9508–09 (Feb. 8, 2013).

¹³ CAL. HEALTH & SAFETY CODE ANN. § 119402 (2005).

¹⁴ COL. REV. STAT. ANN. § 24-34-111 (2010).

¹⁵ CONN. GEN. STAT. ANN. § 21a-70e (2010).

West Virginia.²¹ Some state laws are stricter than the PPSA (such as Minnesota’s prohibition on practitioner gifts),²² while others essentially mirror the PPSA.²³ The PPSA preempts state laws that require reporting of the same type of information concerning payments/ transfers of values from applicable manufacturers to covered recipients.²⁴ Therefore, state and local governments cannot require separate reporting for information already reported under the PPSA.²⁵

Some state laws are stricter and farther-reaching than the PPSA. The PPSA only applies to payments made to *physicians* and *teaching hospitals*, whereas some state laws cover payments to a broader provider population. Vermont’s law, one of the strictest, requires manufacturers to disclose “the value nature, purpose, and recipient information of any allowable expenditure and gift . . . to *any* health care provider.”²⁶ A “health care provider” is any “person, partnership, corporation, facility, or institution, licensed or certified by law to provide professional health care service in this state.”²⁷ Similarly, the Washington, D.C. statute requires reporting certain expenses involving *any* “person[] or entit[]y licensed to provide health care in the District.”²⁸ Other states, such as West Virginia, go beyond health care providers, requiring disclosure of

¹⁶105 MASS. CODE REGS. §§ 970.000–970.011 (2013).

¹⁷MINN. STAT. ANN. § 151.461 (1994).

¹⁸NEV. REV. STAT. § 639.570 (2007).

¹⁹VT. STAT. ANN. tit. 18, § 4632 (2012).

²⁰D.C. CODE § 48.833.01 (2012).

²¹W. VA. CODE § 16-29H-8 (2009).

²²“It is unlawful for any manufacturer or wholesale drug distributor, or any agent thereof, to offer or give any gift of value to a practitioner.” MINN. STAT. ANN. § 151.461.

²³Colorado’s statute, for example, mirrors the PPSA and makes a “knowing” failure to submit payment information subject to civil monetary penalties. COLO. REV. STAT. ANN. § 24-31-111.

²⁴42 U.S.C. § 1320a-7h(d)(3).

²⁵The only exception is if the information is collected by a Federal, state, or local governmental agency for public health surveillance, investigation, or other oversight. 42 U.S.C. § 1320a-7h(d)(3)(B)(iv).

²⁶VT. STAT. ANN. tit. 18, § 4632 (a)(1)(A) (emphasis added).

²⁷VT. STAT. ANN. tit. 18, § 9432 (2009).

²⁸D.C. CODE § 48-833.03. California and Massachusetts also have broader definitions of health care providers. For a summary of what distributors and manufacturers must do to comply with the various state laws and what providers are covered, see HEALTH INDUS. DISTRIBUTORS ASS’N, *supra* note 10.

payments to providers *and* disclosure of aggregate *advertising* costs associated with promotions and prescription drug advertising to West Virginia *residents*.²⁹

B. VOLUNTARY REGULATIONS AND GUIDELINES

The Office of the Inspector General (OIG), professional organizations, and trade associations have also issued recommendations and voluntary guidelines for provider-industry relationships.³⁰

1. OIG Program Guidance for Pharmaceutical Manufacturers³¹

The OIG issued a “Compliance Program Guidance for Pharmaceutical Manufacturers” in May 2003.³² Although the guidance is not mandatory,³³ some states require pharmaceutical companies to adopt the OIG’s recommendations.³⁴ The guidance sets forth seven fundamental elements for a compliance program³⁵:

1. Implementing written policies and procedures;
2. Designating a compliance officer and compliance committee;
3. Conducting effective training and education;
4. Developing effective lines of communication;
5. Conducting internal monitoring and auditing;
6. Enforcing standards through well-publicized disciplinary guidelines;
and
7. Responding promptly to detected problems and undertaking corrective action.

²⁹ W. VA. CODE § 16-29h-8(c) (requiring development of a rule for reporting requirements of national aggregate expenses associated with advertising and direct-to-consumer prescription drug promotion “through radio, television, magazines, newspapers, direct mail and telephone communications”).

³⁰ The regulations discussed in this section are far from exhaustive and merely intend to illustrate the current thinking of various professional and industry-related groups.

³¹ 68 Fed. Reg. 23731 (May 5, 2003).

³² *Id.* at 23731. Although the guidance applies to pharmaceutical companies, the OIG states that the compliance program guidelines may apply to medical device manufacturers. *Id.* at 23742 n.5.

³³ *Id.*

³⁴ California requires every pharmaceutical company to adopt a “Comprehensive Compliance Program” in accordance with the OIG recommendations. CAL. HEALTH & SAFETY CODE ANN. § 119402.

³⁵ 68 Fed. Reg. 23731, 23731 (May 5, 2003).

The OIG emphasizes certain factors when assessing physician-industry relationships, such as the parties' intent and whether the relationship may "diminish, or appear to diminish, the objectivity of professional judgment" which could impact patient safety and/or quality of care.³⁶ The guidance has similarities to anti-kickback and self-referral laws, such as requiring certain agreements be in writing and emphasizing "fair market value."³⁷

The OIG's guidance has influenced state laws and other industry guidelines. For example, in 2009, AdvaMed adopted the OIG's seven elements of an effective compliance program in its *Code of Ethics on Interactions with Health Care Professionals*.³⁸

2. Pharmaceutical Research & Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals³⁹

The PhRMA *Code on Interactions with Healthcare Professionals* took effect in January 2009.⁴⁰ Its intent is to ensure that interactions between pharmaceutical companies and health care providers are legal and ethical and are *perceived* to be ethical by patients and the public.⁴¹ The Code emphasizes that its objective is to benefit *patients* and is based on the principle that patient care "should be based . . . solely on each patient's medical needs and the healthcare professional's knowledge and experience."⁴²

The Code provides guidelines regarding when payments/transfers of value are or are not appropriate. It covers a range of circumstances, including meal provision, financial support or

³⁶ *Id.* at 23737.

³⁷ *Id.* at 23738. The anti-kickback law, for example, allows vendors to pay group purchasing organizations if there is a "written contract . . . which specifies the amount to be paid . . ." 42 U.S.C. § 1320a-7b(b)(3)(C). The Stark Law allows payments made by a lessee to a lessor as long as the lease is in writing and "consistent with fair market value." 42 U.S.C. § 1395nn(e)(1)(A).

³⁸ ADVAMED, CODE OF ETHICS, *supra* note 11, at 3. Because of its similarities to the OIG Federal notice, the AdvaMed's *Code of Ethics* will not be discussed in a separate section.

³⁹ PHRMA CODE, *supra* note 11.

⁴⁰ *Id.* at 3.

⁴¹ *Id.* at 2.

⁴² *Id.*

sponsorship of Continuing Medical Education (CME), consulting arrangements, and non-educational and practice-related items, among others.⁴³ For example, the Code prohibits non-educational and practice-related gifts such as pens or pads of paper, but allows company-sponsored meals, drug samples, and educational materials valued less than \$100.⁴⁴

Similar to the OIG guidance, PhRMA’s Code is not mandatory but has been quite influential. For example, a California law references the Code, stating that “every pharmaceutical company shall include in its Comprehensive Compliance Program policies for compliance with the [PhRMA Code].”⁴⁵ Furthermore, some of the largest pharmaceutical companies have agreed to annually certify that they have policies and procedures in place to ensure compliance. Signatory companies include, among others, AstraZeneca, Eli Lilly & Co., GlaxoSmithKline, Johnson & Johnson, Pfizer, and Purdue Pharma.⁴⁶

3. Association of American Medical Colleges (AAMC)

In 2008, the AAMC endorsed policies similar to the PhRMA Code, illustrating recent attempts to restrict pharmaceutical companies’ access to academic medical centers (AMCs).⁴⁷ Some of AAMC’s recommendations include: prohibiting acceptance of gifts; creating policies for central management of free samples to ensure they are provided to appropriate patients (i.e., the needy); limiting pharmaceutical representative access to only nonpatient and nonpublic areas; ensuring that any payments are at fair market value; requiring complete disclosure and transparency of faculty/staff involvement in industry-sponsored studies; prohibiting any quid pro

⁴³ *Id.* at 4–12.

⁴⁴ *Id.*

⁴⁵ CAL. HEALTH & SAFETY CODE ANN. § 119402(b).

⁴⁶ PhRMA, *PhRMA Code on Interactions with Healthcare Professionals—Signatory Companies* (Feb. 2013), available at

http://phrma.org/sites/default/files/108/signatory_companies_phrma_code_020813.pdf.

⁴⁷ ASS’N AM. MED. COLL., *INDUSTRY FUNDING OF MEDICAL EDUCATION: REPORT OF AN AAMC TASK FORCE* (2008), available at

<https://members.aamc.org/eweb/upload/Industry%20Funding%20of%20Medical%20Education.pdf>.

quo relationships; and requiring disclosure of all potential conflicts of interest by individuals involved in the process of purchasing drugs, devices, and equipment.⁴⁸

C. PHYSICIAN PAYMENT SUNSHINE ACT⁴⁹

The PPSA was co-authored by Senator Chuck Grassley of Iowa and former Senator Herb Kohl of Wisconsin. Grassley initiated the legislation after an investigation revealed many questionable financial relationships between drug companies and physicians.⁵⁰

According to Senator Grassley:

Disclosure brings about accountability, and accountability will strengthen the credibility of medical research, the marketing of ideas and, ultimately, the practice of medicine. The lack of transparency regarding payments made by the pharmaceutical and medical device community to physicians has created a culture that this law should begin to change substantially. The reform represented by the [PPSA] *is in patients' best interests*. . . . The goal is straightforward, and CMS needs to make certain the reporting and disclosure are complete and clear.⁵¹

On February 8, 2013, the Centers for Medicare and Medicaid Services (CMS) published final regulations implementing the PPSA.⁵² The PPSA “require[s] applicable manufacturers of drugs, devices, biological, or medical supplies covered by Medicare, Medicaid, or the Children’s Health Insurance Program (CHIP) to report annually to the Secretary certain payments or transfers of values provided to physicians or teaching hospitals (‘covered recipients’).”⁵³ It also requires applicable manufacturers and group purchasing organizations (GPOs) to annually report

⁴⁸ *Id.* at 14–23.

⁴⁹ 42 U.S.C. § 1320a-7h.

⁵⁰ A 16-month investigation of Medtronic revealed questionable ties between Medtronic and physician consultants who tested and reviewed Medtronic products. For example, over a 15 year period, Medtronic made over \$210 million in payments to physicians who authored studies about their product. These financial ties were not disclosed. Memorandum to Reporters & Editors, Physician Payments Sunshine Act Regulations Released (Feb. 1, 2013), *available at* http://www.grassley.senate.gov/news/Article.cfm?customel_dataPageID_1502=44416.

⁵¹ *Id.* (emphasis added).

⁵² Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458 (Feb. 8, 2013).

⁵³ *Id.* at 9458.

physician ownership or investment interests.⁵⁴ The Secretary of the Department of Health and Human Services is required to publish this information on a free and public website.⁵⁵

The legislative intent of the PPSA is to increase transparency by requiring disclosure of relationships between “applicable manufacturers”⁵⁶ and physicians and to discourage inappropriate relationships that could influence a physician’s judgment.⁵⁷ Transparency is meant to allow patients to identify potential physician conflicts of interest and influences on their physician’s medical judgments. It does not *prohibit* the relationships—it only requires that they be disclosed. CMS avoided complete prohibition because of the importance of “collaboration among physicians . . . and industry manufacturers in contributing to the design and delivery of life-saving drugs and devices.”⁵⁸ PPSA supporters also hope it will discourage the formation of inappropriate and/or unethical physician-industry financial relationships; discourage inappropriate influences on professional medical judgment that could harm patients and/or increase health care costs (i.e., through unnecessary prescriptions); and promote physician-

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ An applicable manufacturer is defined as:

[A]n entity that is operating in in the United States and that falls within one of the following categories:

(1) An entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply

. . . .

(2) An entity under common ownership with an entity in paragraph (1) . . . which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

Id. at 9521.

⁵⁷ Although the PPSA also requires disclosure of applicable manufacturer payments/transfers to teaching hospitals, the focus of this article is on physicians.

⁵⁸ Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458, 9459 (Feb. 8, 2013); *see also* 155 CONG. REC. S733, S788 (daily ed. Jan. 22, 2009) (statement of Sen. Kohl) (“Many of these relationships are beneficial and appropriate. That is why we don’t outlaw these relationships. What we do is make them be reported.”).

patient trust.⁵⁹ However, there is skepticism about the *true* purpose of the PPSA—some commentators believe it is simply a means of identifying prohibited kickbacks and other improper financial relationships that can result in prosecution and legal liability.⁶⁰

A common (but increasingly questioned) belief is that transparency and conflict of interest disclosures can reduce or eliminate the potential negative consequences of physician-industry relationships.⁶¹ The PPSA reflects this belief by attempting to use mandatory disclosure as a means to promote self-regulation. The PPSA takes a relatively *passive* regulatory approach, hoping to achieve its goals by preventing inappropriate relationships as well as informing patients about potential influences on their doctors’ medical decisions. The yet-unanswered question, however, is whether the PPSA will actually achieve its goals. The structure of the PPSA and evidence from other areas of law suggest that it will not. Part II takes up this issue.

II. MANDATORY DISCLOSURE LAWS ARE INEFFECTIVE TOOLS TO PROMOTE PATIENT KNOWLEDGE

Concerns about conflicts of interest in medical care and research are not new, and so-called “sunshine laws” have frequently been viewed as tools to combat potential negative consequences of conflicts of interest. This belief is largely premised on the idea that disclosure

⁵⁹ See Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458, 9458–59; see also *Prescription Drug Abuse: How are Medicare and Medicaid Adapting to the Challenge?: Hearing Before the Subcomm. On Health Care of the Sen. Finance Comm.* (Mar. 22, 2012) (statement of Sen. Chuck Grassley, Member, Sen. Comm. Finance) (commenting that “over prescription . . . strains the financial viability of the Medicaid and Medicare system and threatens the health and well-being of the American people”).

⁶⁰ Sheva J. Sanders, Address at the Minn. State Bar Ass’n Health Law & Food, Drug, & Device Law Sect. Co-Sponsored CLE: Shedding Light on the Sunshine Act (Mar. 14, 2013) [hereinafter Sanders, *Shedding Light on the Sunshine Act*].

⁶¹ See, e.g., *Aligning Incentives: The Case for Delivery System Reform, Testimony Before the S. Comm. on Fin.*, (2008) (statement of Eric G. Campbell, Associate Professor of Med., Inst. Health Pol’y Mass. Gen. Hosp. & Harv. Med. Sch.) (arguing that greater disclosure of industry relationships “is advisable”), available at <http://www.finance.senate.gov/imo/>; News Release, Mass. Gen. Hosp., Although Less Prevalent, Physician-Industry Relationships Remain Common (Nov. 8, 2010), available at <http://cdn1.hubspot.com/hub/162029/2012WBI-Composite.pdf> (stating that the prevalence of physician-industry relationships supports the need for greater public disclosure).

may decrease physician acceptance of gifts, decrease use of industry-controlled presentations, and decrease relationships that may compromise physician impartiality and medical judgment.⁶²

However, on closer inspection, Senator Grassley⁶³ and other PPSA supporters may have inappropriately high hopes for the law. To achieve Senator Grassley's and CMS's alleged goals—to improve patient knowledge and to ensure professional, unbiased medical treatment in patients' best interests—the PPSA must be strengthened and its scope widened. The goals are laudable, but as long as these relationships are allowed and merely required to be disclosed on a website, most patients will continue to lack this information and physicians' decisions will continue to be influenced, however subtly, by their financial ties to the industry.⁶⁴

A. PATIENT ACCESS AND ACTUAL USE

When considering whether patients will use the information, a threshold question is whether they can *access* the information easily and efficiently, if at all. Not all Americans have access to or use in-home internet, the easiest method of obtaining the reported information from the website that will be created by CMS. According to the United States Census Bureau, in 2010 54.3% of Americans fifteen and older connected to the internet at home, with the elderly having the lowest rate at 29.8%.⁶⁵ This is particularly relevant because the elderly population has the highest rate of multiple-prescription drug use—one study found that more than 76% of

⁶² INST. MED., CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE 67 (Bernard Lo & Marilyn J. Field eds., 2009).

⁶³ See *supra* text accompanying note 50.

⁶⁴ This is *not* to imply that doctors are *intentionally* biased or knowingly sacrifice patient safety for profits. They may still have the best intentions. However, gifts may *subconsciously* influence behavior—accepting a gift can create feelings of indebtedness and obligation to prescribe/use a company's product. Amanda L. Connors, *Big Bad Pharma: An Ethical Analysis of Physician-Directed and Consumer Directed Marketing Tactics*, 73 ALB. L. REV. 243, 265 (2009); see also Alexandros Stamatoglou, Comment, *The Physician Payment Sunshine Act: An Important First Step in Mitigating Financial Conflicts of Interest in Medical and Clinical Practice*, 45 J. MARSHALL L. REV. 963, 971–72 (2012).

⁶⁵ U.S. CENSUS BUREAU, *Computer and Internet Use in the United States: 2010—Table 4: Reported Computer and Internet Access, by Selected Individual Characteristics: 2010*, U.S. DEP'T COMMERCE (last revised July 11, 2012), <http://www.census.gov/hhes/computer/publications/2010.html>.

Americans aged sixty and over used two or more prescription drugs in the past thirty days.⁶⁶ Minorities, those with lower incomes, and those with less education are also less likely to have in-home internet connections.⁶⁷ However, those with lower rates of in-home internet use did *not*, in most cases, have higher rates of internet use *outside* the home, such as at work, school, or a public library.⁶⁸ Thus it is reasonable to hypothesize that many cannot access this public Web site or will not due to the time and burden it would require to find a computer to obtain access.

Furthermore, those most likely and able to access the information—Whites of higher income and education—are among the *least* vulnerable patient populations. This is a general issue with any mandatory disclosure requirement—they tend to “help[] most those who need help least and help[] least those who need help most.”⁶⁹ Large health disparities *already* exist between the wealthy and the poor, and by placing the responsibility on patients to seek out and understand the information, mandatory disclosure laws may only exacerbate disparities.

For those able to access the data, many will not do so. This is a concern many have raised about the PPSA’s ability to achieve its stated goals.⁷⁰ A more likely outcome, and a concern expressed by the industry, is that the data will not be used by *patients*, but primarily by

⁶⁶ Qiuping Gu et al., *Prescription Drug Use Continues to Increase: U.S. Prescription Drug Data for 2007–2008*, NCHS DATA BRIEF NO. 42 (Sept. 2010), available at <http://www.cdc.gov/nchs/data/databriefs/db42.pdf>.

⁶⁷ U.S. CENSUS BUREAU, *supra* note 65.

⁶⁸ For example, 69.7% of Whites connected to the internet at home and 9.1% connected at a public library. In comparison, 35.4% of Hispanics connected at home and 9.0% connected at a public library. *Id.*

⁶⁹ Omri Ben-Shahar & Carl E. Schneider, *The Failure of Mandated Disclosures*, 159 U. PA. L. REV. 647, 740 (2011).

⁷⁰ See, e.g., Kathleen M. Boozang, *Physician Payment Sunshine Act Proposed Regulations Out*, HEALTH REFORM WATCH (Jan. 3, 2012), <http://www.healthreformwatch.com/2012/01/03/physician-payment-sunshine-act-proposed-regulations-out/>; Carl Elliot, *Who’s Afraid of Sunshine Laws?*, CHRON. HIGHER EDUC. (July 3, 2012), <http://chronicle.com/blogs/brainstorm/whos-afraid-of-sunshine-laws/48641>; Alison Hwong & Lisa Lehmann, *Putting the Patient at the Center of the Physician Payment Sunshine Act*, HEALTH AFFAIRS BLOG (July 13, 2012), <http://healthaffairs.org/blog/2012/06/13/putting-the-patient-at-the-center-of-the-physician-payment-sunshine-act/>; James Swann, *Is the Sunshine Act Too Much of a Burden for the Health Care Industry?*, BLOOMBERG BNA HEALTH CARE BLOG (Feb. 5, 2013) (citing Kirk Nahra, an attorney with Wiley Rein in Washington, D.C., who “said there is a real chance the payment transparency information will never be used by patients”).

prosecutors and the government as a “roadmap” to violations of the Anti-Kickback law, False Claims Act, and Stark Law.⁷¹ Lawyers at Morrison & Forester posit that the data could also be used to support liability against individual executives under the “Responsible Corporate Officer Doctrine,” which permits prosecution of individuals in positions to prevent the violation(s), even if they were not personally involved in the violation or did not know it was occurring.⁷²

Accessibility issues highlight another problem of disclosure laws: they place great—and perhaps excessive—responsibility on patients,⁷³ and essentially require patients to police their doctors’ behavior and determine the impact of industry relationships on their doctors’ medical judgments. And although patient autonomy has become a *sine qua non* element of American health care, placing responsibility on patients to actively seek out the disclosed information essentially requires patients to *presume* their doctors are in unethical financial relationships that will cloud their professional judgment and decisions with potentially harmful results. This goes against every ethos in medicine, particularly *primum non nocere*—“first, do harm,” a principle which requires a doctor to act in the patient’s best interest.⁷⁴

⁷¹ Daniel M. Bernick & Michael W. Federer, *CMS Issues Final Physician Payment Sunshine Act Rule*, HEALTH CARE GROUP (2013), available at <http://www.thehealthcaregroup.com/temp/CMSFinalRuleSunshineAct.pdf>; see also Adam S. Hoffinger et al., *Physician Payment Sunshine Act: Challenge for Companies, Tool for Enforcers*, MORRISON FOERSTER CLIENT ALERT 2, Oct. 19, 2012, available at <http://www.mofo.com/files/Uploads/Images/121019-Physician-Payment-Sunshine-Act.pdf> (“[B]ecause disclosures are certified . . . [they] could serve as the basis for false statement violations, or violations of the False Claims Act.”); *CMS Publishes the Final Physician Payment Sunshine Rule*, HALL RENDER BLOG (Feb. 20, 2013), <http://blogs.hallrender.com/cms-publishes-the-final-physician-payment-sunshine-rule> (“CMS and HHS acknowledge that they may use these records and public data to prosecute investigations under the False Claims Act, Anti-Kickback Law and the Stark Law.”);

⁷² Hoffinger et al., *supra* note 71.

⁷³ Providing more information assumes patients can assess and understand the information and their options. When there are many options and the information is difficult to understand, more information and greater responsibility may not always benefit the patient. K. Ladin & D.W. Hanto, *Informed Consent and Living Kidney Donation: More (Information) Is Not Always Better*, 11 AM. J. TRANSPLANTATION 2547, 2547 (2011); see also Connors, *supra* note 64, at 280 (commenting that an internet registry would “erroneously misplace the burden on the patient when it should remain with the physician”).

⁷⁴ Raanan Gillon, “*Primum Non Nocere*” and the Principle of Non-Maleficence, 291 BRIT. MED. J. 130, 130 (1985).

B. ACTUAL ACCESS & INFORMATION OVERLOAD

The PPSA requires the Secretary to publish the disclosed data on a public Web site and the data “must be downloadable, easily searchable, and aggregated.”⁷⁵ The site must be “user-friendly and provide accurate and understandable information to the public.”⁷⁶ The “Official Website for National Physician Transparency Program: OPEN PAYMENTS” is currently under development and CMS will release the first round of public data by September 30, 2014.⁷⁷

As suggested above, it is questionable whether those with access to the site will actually use it to inform their health care decisions.⁷⁸ Any impact of the PPSA will likely have to come from changes in *industry* and *physician* behavior rather than *patient* enlightenment.⁷⁹ Mandatory disclosure laws are pervasive in many contexts,⁸⁰ and “the more-information-is-better mantra” is popular because it serves two highly-regarded American values: autonomy and free-market principles.⁸¹ Mandatory disclosures serve the autonomy principle by reflecting the ideas that people are entitled to freedom in decision-making and that individuals know what is in their own best interests.⁸² Disclosure also promotes free-market principles—it counteracts the “caveat emptor” doctrine but is a “soft” intervention that leaves most things the same, such as prices, quality, and market entry.⁸³ It assumes that information promotes rational consumer decisions.⁸⁴

⁷⁵ Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458, 9459 (Feb. 8, 2013)

⁷⁶ *Id.* at 9503. What it means to be “user-friendly,” however, is subjective and open to interpretation.

⁷⁷ *National Physician Payment Transparency Program: OPEN PAYMENTS*, CTR. MEDICARE & MEDICAID SERV. (last modified Mar. 7, 2013), <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html>.

⁷⁸ This point was noted by Sheva Sanders in her CLE discussion on the PPSA. *See Sanders, supra* note 60.

⁷⁹ Boozang, *supra* note 70.

⁸⁰ *See generally* Ben-Shahar & Schneider, *supra* note 69, at 650 (listing many other areas in which mandated disclosures have been used, such as consumer loans, real estate, education, consumer goods/services, and many others).

⁸¹ *Id.* at 681.

⁸² *Id.*

⁸³ *Id.*

Furthermore, legislators and policy makers often assume disclosure is a relatively cheap and “easy” solution—simply provide more information and the problem will take care of itself.

According to Omar Ben-Shahar and Carl E. Schneider: “[W]hen law makers are pressed to act, mandated disclosure is appealing. Its critics are few. The law maker can be seen to have acted. . . . Disclosure’s political utility does much to explain its use and over-use.”⁸⁵

Despite the ubiquitous nature of mandatory disclosure laws and the belief that “knowledge is power,” more information is *not* always beneficial.⁸⁶ To draw an analogy from another area of health care law, there is evidence that when obtaining informed consent, “more is not always better.”⁸⁷ The degree of disclosures required by the PPSA and the complicated methodologies for computing some of the data may overwhelm and confuse patients, making them unable to distinguish what information is and is not relevant for their particular situations. This concern was raised by Senator Norm Coleman of Minnesota, when he questioned how “the public would actually use this data when shopping around for health care? . . . How would folks actually make use of what we’re trying to gather here of this greater transparency?”⁸⁸

When too much information is disclosed, it may become “too copious and complex” for patients to effectively interpret.⁸⁹ Not only will there be a lot of information and data for patients to sort through and understand, this information is not the only, nor necessarily the most

⁸⁴Federal Trade Commission: Proprietary Vocational and Home Study Schools, 43 Fed. Reg. 60796, 60805 (Dec. 28, 1978).

⁸⁵ Ben-Shahar & Schneider, *supra* note 69, at 684.

⁸⁶ DAVID HODGSON & SETH WHITELAW, PHYSICIAN PAYMENT SUNSHINE ACT: PHYSICIANS AND LIFE SCIENCES COMPANIES COMING TO TERMS WITH TRANSPARENCY? 1 (2012) (quoting Dr. Genevieve Fairbrother, chief of medical and dental staff at Northside Hospital in Atlanta). Despite her belief that “knowledge is power”, Dr. Fairbrother recognizes the potential for information to mislead: “incomplete knowledge of what this kind of data is really saying will lead to misrepresentations.” *Id.*

⁸⁷ Yael Schenker & Alan Meisel, *Informed Consent in Clinical Care: Practical Considerations in the Effort to Achieve Ethical Goals*, 305 J. AM. MED. ASS’N 1130, 1130 (2011).

⁸⁸ *Surgeons for Sale: Conflicts and Consultant Payment in the Medical Device Industry: Hearing Before the S. Special Comm. on Aging*, 110th Cong. 75 (2008) (statement of Sen. Norm Coleman, Member, Special Comm. on Aging).

⁸⁹ Ben-Shahar & Schneider, *supra* note 69, at 687.

important, information to patients when making health care decisions.⁹⁰ Because it is unclear what information patients need and want when making decisions, lawmakers assume that consumers want to know “virtually everything,” resulting in a proliferation of disclosure laws.⁹¹ However, adding yet *another* piece of information for patients to consider may not be beneficial and could even be counterproductive.⁹²

C. INTERPRETATION DIFFICULTIES AND MISCONSTRUED DATA

Interpreting the data will likely be difficult, even for those *with* industry knowledge and experience. Some commenters on the final regulations, for example, noted that the reporting requirements are so complicated that it would be impossible, even for the reporting entity, “to know whether the data submitted was accurate.”⁹³ Both physicians and “applicable manufacturers” are concerned the data will be misconstrued—simply posting a dollar amount next to a physician’s name does not tell the whole story and will often be misleading and suggest that *all* physician-industry relationships are unethical or at least suspect.⁹⁴ The American Medical Association (AMA) argues that the information will be misleading because the PPSA will be carried out by the CMS Center for Program Integrity (CPI), which is, “in plain language, its anti-fraud unit.”⁹⁵ The AMA contends that this makes CMS the “ethical police” of the

⁹⁰ Other factors could include the provider’s experience, quality, costs and benefits of treatment, insurance coverage considerations, and convenience/access. *See, e.g., id.* at 685.

⁹¹ *Id.*

⁹² *See id.* at 721; *see also* Judith H. Hibbard et al., *Informing Consumer Decisions in Health Care: Implications from Decision-Making Research*, 75 MILBANK Q. 395, 398 (1997) (“[W]hen individuals had more information, their ability to use it ‘consistently’ declined.”).

⁹³ Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458, 9498 (Feb. 8, 2013)

⁹⁴ *See, e.g.,* Letters from Phil Gingrey et al., U.S. Rep., to Marilyn Tavenner, Acting Adm’r Ctr. Medicare & Medicaid Serv. (May 18, 2012), *available at* <http://policymed.typepad.com/files/doc-caucus-letter-to-cms-5-21-12.pdf> (“[C]ompliance with the regulation would provide a distorted view of provider compensation resulting from this type of work.”).

⁹⁵ Am. Med. Ass’n, Opinion, *Transparency or Suspicion?: A Wrong Turn for Reports on Financial Ties in Medicine*, AM. MED. NEWS, Nov. 12, 2012, <http://www.amednews.com/article/20121112/opinion/311129961/4/>.

medical profession, “creat[ing] the impression that any physician who appears on the list, no matter how limited financially or legitimate the nature of the interaction, is somehow engaged in behavior that could be seen as ethically or legally suspect.”⁹⁶ Doctor James L. Madara, AMA Executive Vice President, reiterated these concerns in a letter to Marylyn B. Tavenner, Acting Administrator of CMS, stating that “[t]here is a danger in conflating these issues since it could lead to a public perception that most, if not all, transparency reports are prima facie evidence of unethical or illegal behavior” (i.e., violations of federal and state fraud and abuse laws).⁹⁷

The potential for interpretation difficulties is further exacerbated by the different” forms” and “natures” of payments that must be reported, some of which represent more legitimate payments than others (e.g. payments covering bona fide research expenses versus gifts with no benefit to patients or no educational purpose).⁹⁸ This problem is even acknowledged by CMS: “We recognize that *disclosure is not sufficient* to differentiate beneficial, legitimate financial relationships from those that create a conflict of interest or are otherwise improper.”⁹⁹

For example, many required disclosures under “research” payments include money that a physician does not *personally* keep, but instead spends on the actual cost of *performing* the research, such as laboratory expenses and provision of drugs, devices, biological, and other

⁹⁶ *Id.*; see also Bob Spoerl, *Sunshine Act May Not Be So Bright: Why Hospitals, Physicians Are Concerned*, BECKER’S HOSP. REV., June 4, 2012, <http://www.beckershospitalreview.com/legal-regulatory-issues/sunshine-act-may-not-be-so-bright-why-hospitals-physicians-are-concerned.html>.

⁹⁷ Letter from James L. Madara, Exec. Vice President of the Am. Med. Ass’n, to Marilyn B. Tavenner, Acting Adm’r Ctr. Medicare & Medicaid Serv. (Oct. 10, 2012), *available at* <http://www.ama-assn.org/resources/doc/washington/aging-roundtable-sunshine-letter-10oct2012.pdf>.

⁹⁸ Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458, 9479 (Feb. 8, 2013) (listing the forms and natures of payments required to be reported).

⁹⁹ *Id.* at 9519 (emphasis added).

medical supplies necessary during the course of research.¹⁰⁰ This concern was expressed by Doug Peddicord, Executive Director of the Association of Clinical Research Organizations:

Quite unlike payments or other transfers of value that might support activities that benefit (and potentially influence) physicians and teaching hospitals without requiring an actual exchange of value between the payor and the payee, payments made to support or purchase clinical research activities from physicians and teachings hospitals are, simply, fair-market payments for goods (e.g., laboratory tests) and services (e.g. physical examinations).¹⁰¹

In partial recognition of the issues involving research payments, the final regulations provide that research payments will be reported and listed separately from other payments (e.g., meals, gifts, etc.).¹⁰² However, there is no indication that the separate listing will differentiate between the money spent on *performing* the research versus the amount that was a personal payment to the physician. Under the final regulations, the physicians name will still be provided next to the *total* dollar amount paid by the manufacturer. Therefore, if a manufacturer pays a physician \$50,000 to conduct research but the physician is personally compensated only \$5,000 for performing the research, the website will only list the \$50,000, much more than the physician *personally* earned. Given the complexity of research-related payments and the numerous activities research money funds, many patients may not understand what is being reported and what implications (if any) it has for their health care.

D. USING DISCLOSURES & MAKING DECISIONS

Disclosure laws place the burden on patients to obtain and understand the data. The PPSA does not require physicians to disclose potential conflicts of interest on a patient-by-patient basis. Thus, the PPSA's ability to achieve its goals of transparency and improved patient

¹⁰⁰ *Id.* at 9484.

¹⁰¹ Doug Peddicord, Statement for the Record—Special Committee on Aging United States Senate, Roundtable on Implementation of the Physician Payments Sunshine Act, Sept. 12, 2012, *available at* <http://aging.senate.gov/events/hr251dp.pdf>.

¹⁰² Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458, 9484 (Feb. 8, 2013)

knowledge about potential financial conflicts of interest are largely, if not wholly, dependent on *patients* taking the time to access, interpret, and understand the reports. Independent of any other issues with the PPSA's implementation and enforcement, this fact alone may prevent its success.

Even if patients (1) access the data and (2) adequately understand it, a serious question is what patients can and should *do* with this information, if anything. The data are just that—data, numbers on a page which patients must determine how to interpret. To make the most effective use of such a database, a patient will need a basic level of knowledge about which companies make which drugs, why a company is paying a doctor, how long the doctor has been receiving payments, and whether the payment has any impact on the particular patient's care. Do payments necessarily mean a doctor will make biased and/or potentially-inappropriate decisions? Does the doctor's financial relationship with the industry have any impact at all? Should a patient get a different doctor if her current doctor has a financial relationship with a pharmaceutical company (and if so, can she even find a doctor *without* an industry relationship)? What should a patient do if her physician prescribes her a drug she knows is made by a company her physician has a financial relationship with? Should she get a second opinion? Refuse to take the drug?

The data cannot tell patients whether there will be any effect on their care. For many patients, finding a different doctor or obtaining a second opinion simply is not a viable option. For some, insurance may limit which providers they can see; others may lack easy access to another physician; and others may need urgent care and thus not have time to seek another provider.¹⁰³ Even with the information, patients may lack other options, and thus the information will have no effect on their decisions—regardless of which choices they prefer.

E. COVERED RECIPIENT CATEGORY TOO NARROW TO BE EFFECTIVE

¹⁰³ In emergencies, patients do not have time to access such data or be concerned about conflicts of interest. Even if not an emergency, an ill patient simply may not be concerned or even thinking about whether a physician has financial ties to the industry.

The PPSA only applies to “covered recipients,” defined as physicians and teaching hospitals.¹⁰⁴ However, physicians and teaching hospitals are not the only individuals/entities potentially influenced by applicable manufacturers. For example, certain “mid-level” practitioners often have authority to prescribe drugs or devices.¹⁰⁵ Nurse practitioners (NPs) have independent prescribing authority in a number of states,¹⁰⁶ suggesting that the PPSA could result in an increasing industry focus on NPs because there is no disclosure process required¹⁰⁷ (except as required by state laws and other constraints of federal fraud and abuse laws). In other states, NPs and physician assistants (PAs) are authorized to prescribe drugs when authority is delegated or directed by a supervising or collaborating physicians.¹⁰⁸

CMS acknowledged that the “other provider” exclusion prevents the PPSA from being “able to fully capture financial relationships between industry and prescribers, especially non-physician prescribers such as nurse practitioners.”¹⁰⁹ The regulations are unclear on this point, but it is possible that *some* mid-level provider-industry relationship could be reportable if

¹⁰⁴ See Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458, 9521 (Feb. 8, 2013) (defining “covered recipients”).

¹⁰⁵ 21 C.F.R. § 1300.01 (2012) (defining a mid-level practitioner as “an individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted . . . to dispense a controlled substance in the course of profession practice. Examples . . . include . . . nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specializes, and physician assistants who are authorized to dispense controlled substances by the State in which they practice.”).

¹⁰⁶ See, e.g., COLO. REV. STAT. ANN. § 12-38-111.6 (West 2013); HAW. REV. STAT. ANN. § 457-2.7 (2010); MD. CODE ANN., HEALTH OCC. § 8-508 (West 2010); N.Y. EDUC. LAW § 6902(3)(b) (McKinney 2013); WASH. REV. CODE ANN. § 18.79.250 (West 2012).

¹⁰⁷ CMS explicitly declined to expand the Act to include “other provider types.” Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458, 9521 (Feb. 8, 2013).

¹⁰⁸ See, e.g., CAL. BUS. & PROF. CODE § 3502.1 (West 2013); MINN. STAT. ANN. § 157A.18 (2009); 63 PA. STAT. ANN. § 422.13 (West 2008). See generally Susanne J. Phillips, *Twenty-Fourth Legislative Update: APRN Consensus Model Implementation and Planning*, 37 NURSE PRACTITIONER 22, 24 (2012).

¹⁰⁹ Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458, 9467 (Feb. 8, 2013).

interpreted as “passing through” to a physician as an indirect payment.¹¹⁰ This is more likely in states where physicians must personally delegate or supervise prescribing authority, which is fairly common for PA prescription privileges. However, there is no indication when payments to mid-level providers will, if ever, be considered to “pass through” to a physician and whether payment to a practitioner supervised by a physician is enough, by itself, to require disclosure even if the mid-level practitioner personally retains the payment.¹¹¹

Excluding providers such as NPs is particularly problematic given their increasing prevalence and importance to the health care system.¹¹² There were more than 150,000 NPs in 2008,¹¹³ not far from the estimated 209,000 practicing primary care physicians in 2010.¹¹⁴ Approximately 97% of all NPs prescribe medications and in the aggregate they write millions of prescriptions each year.¹¹⁵ It would be naïve to think the industry will not increasingly turn its focus to such providers if physicians, as a result of the PPSA, try to avoid relationships with the industry (for fear of the “scarlet letter” of being listed on the database). Dr. Daniel Carlet, psychiatrist and associate professor at Tufts Medical School (and former speaker for Wyeth

¹¹⁰ *Id.*

¹¹¹ For example, CMS will not require disclosure of payments to non-covered recipients that are not passed on to covered recipients, such as payment for a non-covered recipient’s travel. *Id.* at 9484.

¹¹² In the coming decade, the gap between demand for primary care physicians and their supply is expected to increase, meaning NPs will become even more important as primary care providers. See Michael J. Dill & Edward S. Salsberg, *The Complexities of Physician Supply and Demand: Projections Through 2025*, AAMC CTR. WORKFORCE STUD. 26–27 (2008) (estimating a shortage of 46,000 primary care physicians by 2025), available at

<https://members.aamc.org/eweb/upload/The%20Complexities%20of%20Physician%20Supply.pdf>

¹¹³ U.S. DEP’T HEALTH & HUMAN SERV. HEALTH RESOURCES & SERV. ADMIN., THE REGISTERED NURSE POPULATION: INITIAL FINDINGS FROM THE 2008 NATIONAL SAMPLE SURVEY OF REGISTERED NURSE 18 (Mar. 2010), available at <http://bhpr.hrsa.gov/healthworkforce/rnsurveys/rnsurveyinitial2008.pdf>.

¹¹⁴ U.S. DEP’T HEALTH & HUMAN SERV., PRIMARY CARE WORKFORCE FACTS AND STATS NO. 1 (Oct. 2011), available at <http://www.ahrq.gov/research/findings/factsheets/primary/pcwork1/pcwork1.pdf>

¹¹⁵ Elissa C. Ladd et al., “Under the Radar”: Nurse Practitioner Prescribers and Pharmaceutical Industry Promotions, 16 AM. J. MANAGED CARE e358, e358 (2010).

Pharmaceuticals) predicts that “if any marketing avenue is not regulated, companies will find a way to exploit it . . . I expect we’ll see a lot more nurse practitioners giving hired-gun talks.”¹¹⁶

Massachusetts Senator Mark Montigny echoes this sentiment:

“As such [non-physician] prescribers are becoming more prevalent and becoming more key to primary care, they are becoming more of a target for the pharmaceutical and device manufacturers. Thus, reporting and disclosure of payments to these [sic] providers is now more needed than ever.”¹¹⁷

The industry already has significant relationships with mid-level providers—96% of NPs in one study reported regular contact with pharmaceutical representatives.¹¹⁸ In another study, 75% of NPs reported accepting free gifts (such as office supplies and equipment).¹¹⁹

Some state disclosure laws recognize industry’s potential influence on mid-level practitioners and include these providers in their disclosure laws and gift bans. Vermont’s disclosure law, for example, applies to “any health care provider,”¹²⁰ with health care provider defined, in part, as “a person who is authorized by law to prescribe or to recommend prescribed products,”¹²¹ which would apply to nurse practitioners (“advanced practice registered nurses”) who are authorized to prescribe medication.¹²² Reporting requirements and gift bans beyond

¹¹⁶ Arlene Weintraub, *New Health Law Will Require Industry to Disclose Payments to Physicians*, KAISER HEALTH NEWS, Apr. 26, 2010, <http://www.kaiserhealthnews.org/stories/2010/april/26/physician-payment-disclosures.aspx>; see also Hiyaguha Cohen, *Pharmaceutical Bribes Exposed*, NAT’L HEALTH BLOG (Mar. 24, 2012), <http://www.jonbarron.org/article/pharmaceutical-bribes-exposed> (noting the PPSA’s “giant built-in loophole Pharmaceutical and medical device companies can simply decide to shift their spending to areas that don’t require disclosure.”).

¹¹⁷ Letter from Mark Montigny, Mass. Sen., to Office of the Comm’r, Mass. Dep’t Health (Oct. 17, 2012)

¹¹⁸ Ladd et al., *supra* note 115, at e35.

¹¹⁹ Nancy Crigger et al., *Nurse Practitioners’ Perceptions and Participation in Pharmaceutical Marketing*, 65 J. ADVANCED NURSING 525, 530 (2009).

¹²⁰ VT. STAT. ANN. tit.18, § 4632(a)(1)(A) (West 2012).

¹²¹ VT. STAT. ANN. tit. 18, § 4631a(a)(7)(A) (West 2012).

¹²² VT. STAT. ANN. tit.26, § 1572(4) (West 2012). Massachusetts’s law would also cover NPs. MASS. GEN. LAWS ANN. ch. 112, § 80E (West 2013); 105 MASS. CODE REGS. §§ 970.004 (defining “covered recipient”); 105 MASS. CODE REGS. § 970.009 (2013) (explaining reporting requirements).

those required by the PPSA are not preempted and therefore states can continue to enforce “other provider” reporting/disclosure requirements and gift bans.¹²³

III. PROPOSAL: EXPANDING THE PPSA TO ACHIEVE ITS GOALS

Increased transparency and access to information about potential conflicts of interest in health care are, *prima facie*, valuable. The success and impact of mandatory disclosure laws, however, are complicated, with evidence from health care and other areas of law suggesting that disclosure laws are *not* as effective as commonly believed and championed by legislators. There are a number of ways to potentially improve the PPSA, allowing it to (hopefully) reduce or eliminate conflicts of interest and/or ensure better provision of information to patients.

A. ONE COMPREHENSIVE & UNIFORM LAW

The current state of disclosure laws is disjointed and complicated, varying from state-to-state and also by individual manufacturer (depending on whether they have signed on to comply with AdvaMed or PhRMA guidelines). States may still require disclosures not included in the PPSA, such as different natures or forms of payment or payments to different types of providers. This system is inefficient and potentially costly, requiring manufacturers to spend time and resources deciding whether to abide by the strictest applicable rule or have different policies depending on the state. This is a logistical nightmare for manufactures and is, in some ways, unfair to patients—why should some patients have greater protection from conflicts of interest

¹²³ Senator Montigny recognized that the state’s gift ban law and reporting requirements for non-physician prescribers were still enforceable under the PPSA. See Letter from Mark Montigny, *supra* note 117 (testifying against proposed amendments to 105 C.M.R. 970.000, Pharmaceutical and Medical Device Manufacturer Conduct, and supporting continued enforcement of disclosures of payments/transfers of values to non-physician prescribers); see also Stuart S. Kurlander et al., *CMS Announces Final Regulations Interpreting the Physician Payment Sunshine Act*, LATHAM & WATKINS CLIENT ALERT NO. 1469, Feb. 18, 2013, at 6, available at <http://www.lw.com/thoughtLeadership/final-rule-interpreting-the-physician-payment-sunshine-act> (noting applicable manufacturers need to be aware that certain states have additional disclosure requirements that will not be preempted by the PPSA).

simply based on where they live? There should be *one* uniform law governing all states and manufacturers, and the law should go beyond merely requiring disclosure on a public web site.

The previous analysis suggested why disclosure laws are often ineffective in improving patient information and knowledge. Therefore, to truly achieve the PPSA’s goal of protecting patients’ best interests and ensuring providers make unbiased, professionally-sound decisions, payments—particularly in the form of gifts (whether the gifts are small such as pens or pads of paper, or large, such as entertainment, travel, etc.)—should be banned, modeled off of state gift bans.¹²⁴ Vermont, for example, has one of the most comprehensive set of laws governing provider-industry relationships, including a gift ban making it unlawful for manufacturers “to offer or give *any* gift to a health care provider”¹²⁵ AdvaMed and PhRMA’s codes have similar prohibitions, stating that companies should not provide promotional gifts or entertainment and recreational items, such as event tickets or leisure trips.¹²⁶

A ban on gifts, no matter how small, is a necessary and important aspect of any law attempting to limit industry influence on providers.¹²⁷ A total gift ban is supported by research showing the influence gifts have on physician prescribing practices, even when the gift is *small*

¹²⁴ Vermont, Minnesota, and Massachusetts have gift bans and other states are considering it. *New Physician Gift and Disclosure Reporting Rules that Drug and Medical Device Manufacturers Should Know*, FUERST ITTLEMAN DAVID & JOSEPH PL BLOG (July 26, 2010, 8:45am), <http://www.fuerstlaw.com/wp/index.php/26/new-physician-gift-and-disclosure-reporting-rules-that-drug-and-medical-device-manufacturers-should-know/>.

¹²⁵ VT. STAT. ANN. tit. 18, § 4631a(b)(1) (2012).

¹²⁶ ADVAMED, CODE OF ETHICS, *supra* note 11, at 8 (“A company may not give Health Care Professionals any type of non-educational branded promotional items, even if the item is of minimal value and related to the Health Care Professional’s work or for the benefit of patients.”); PHRMA CODE, *supra* note 11, at 5. The OIG has specifically noted that compliance with the PhRMA Code “will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements.” 68 Fed. Reg. 23731, 23737–38 (May 5, 2003).

¹²⁷ I would not, however, include payments for bona fide research as “gifts,” which would help reduce the potential negative impact of a research-payment ban on innovative and important research.

or of *nominal* value, such as a pen or pads of paper.¹²⁸ There is also evidence that gift bans *can* be effective—research on medical students found that gift restriction policies during medical school were associated with reduced prescribing of two out of three newly introduced drugs.¹²⁹

A gift ban and greater prohibitions on physician-industry relationships are the best methods for truly protecting the most vulnerable patients who lack access or ability to understand disclosed data. However, if such a uniform, nation-wide ban is not politically feasible (and given the power of the pharmaceutical industry, it may very well not be), there are other steps that can be taken to amend the PPSA to improve its ability to achieve the Act’s goals.

B. EXPANDED DEFINITION OF COVERED RECIPIENTS

At a minimum, the definition of “covered recipients” should be expanded to include *all* providers with prescribing privileges, such as NPs and PAs, whose presence is increasingly important in our health care system and who are writing an increasing number of prescriptions. Many patients now rely on mid-level providers for the bulk, if not all, of their primary care, including prescriptions. Providing these patients with information about payments to *physicians* will be of little import to these patients when making health care decisions.

Disclosure laws have obvious connections to the federal Anti-Kickback Statute (AKS). The AKS is quite broad and applies to healthcare professionals *and* non-professionals.¹³⁰ NPs and other mid-level providers can be (and have been)¹³¹ charged with AKS violations. It is thus

¹²⁸ See, e.g., Jason Dana & George Lowenstein, *A Social Science Perspective on Gifts to Physicians from Industry*, 290 J. AM. MED. ASS’N 252 (2003); Dana Katz et al., *All Gifts Large and Small: Toward an Understanding of the Ethics of Pharmaceutical Industry Gift-Giving*, 10 AM. J. BIOETHICS (2010), at 11.

¹²⁹ Marissa King et al., *Medical School Gift Restriction Policies and Physician Prescribing of Newly Marketed Psychotropic Medications: Difference-in-Differences Analysis*, 346 BRIT. MED. J. 1 (2013).

¹³⁰ 42 U.S.C. § 1320a-7b(b) (2010) (“*whoever* knowingly and willfully solicits or receives any remuneration”) (emphasis added).

¹³¹ See Information at 7, *United States v. Castaneda*, No.2011R01368 (D. N.J. Apr. 3, 2012) (finding Jose Castaneda, a nurse practitioner, guilty of violating the federal anti-kickback statute), *available at* http://www.healthlawyers.org/Events/Programs/Materials/Documents/PHY09/benesch_hyman.pdf; Press

logical, and consistent, to apply disclosure laws to mid-level providers with prescribing ability, as they are just as capable of being influenced by the industry as physicians.

C. DIRECT PROVIDER-TO-PATIENT DISCLOSURE

If complete prohibition of provider-industry relationships is not possible, another disclosure method that may be slightly more effective than the PPSA is direct disclosure to the patient via the physician. Although enforceability could be difficult (because the disclosure would occur within a confidential medical appointment), one mechanism to ensure at least a somewhat more *direct* disclosure is to require providers to post signs and provide pamphlets in their offices (and via the mail to patients) regarding any financial ties they have to the industry. Requiring this disclosure to occur in-person provides a better opportunity for patients to ask questions and have a discussion with their providers. Additionally, being honest and open with patients may *improve* the provider-patient relationship and *increase* patient trust and loyalty.¹³²

D. INCREASED PENALTIES

If the PPSA disclosure requirements remain in place, then enforcement must be ensured and penalties should be increased. Failing to comply with the PPSA could be linked to other fraud and abuse laws, such as the AKS and False Claims Act (FCA). By tying violations of the PPSA to violations of these other laws, penalties could be increased and provide greater deterrence greater incentive to decrease the extent and nature of physician-industry relationships.

The database could, in fact, be used to flag potentially problematic relationships (as many already believe will occur). The database, even if it does not improve *patient* knowledge, can

Release, U.S. Atty's Office Dist. N.J., Nurse Practitioner Pleads Guilty to Accepting Kickbacks for Medicare and Medicaid Patient Referrals (Apr. 3, 2012), *available at*

<http://www.justice.gov/usao/nj/Press/files/Castaneda,%20Jose%20Plea%20News%20Release.html>.

¹³² See, e.g., Steven D. Pearson et al., *A Trial of Disclosing Physicians' Financial Incentives to Patients*, 166 ARCHIVES INTERNAL MED. 623 (2006) (finding that mailed disclosure letters from their physicians did not harm patient trust and *strengthened* patient loyalty).

improve the government’s and/or prosecutors’ knowledge and provide evidence of remunerations/payments that may violate the AKS. And even if there are legitimate and lawful reasons for the payments, the “one purpose” test finds an AKS violation where any *one purpose* of the remuneration may be to induce or reward the referral or recommendation of business payable in whole or in part by a Federal health care program.¹³³ The important implication of the one-purpose test is that “a lawful purpose [e.g., supporting bona fide research] will not legitimate a payment that also has an unlawful purpose” (such as inducing/rewarding a physician for prescribing the studied drug).¹³⁴ If the AKS is violated, FCA liability is also possible, because under the 2010-amended FCA, any claim involving a kickback is considered a false claim. Therefore, if a physician submits a reimbursement claim for a drug or device manufactured by a company with whom the physician has financial ties to, there may be a potential AKS violation and thus an FCA violation as well.¹³⁵

The disclosures could also be used to enforce of Stark Law violations, by “creating a road map” to prohibited physician referrals of Medicare beneficiaries to entities in which they (or an immediate family member) have a financial relationship, for certain services such as clinical laboratory services, physical and occupational therapy services, and durable medical equipment and supplies, among other services.¹³⁶

By specifically tying the PPSA to these other fraud and abuse laws, and honestly stating CMS’s intent to use the disclosures to detect potentially illegal remunerations and value

¹³³ United States v. Greber, 760 F.2d 68, 69 (3d Cir. 1985).

¹³⁴ 68 Fed. Reg. 23731, 23734 (May 5, 2003).

¹³⁵ According to Tracy Miller, senior member of the Health Care Group at Cadwalder, Wickersham & Taft LLP, disclosures may trigger investigation of potential violations of the AKS and FCA, and under the amended FCA, “violations of the [AKS] can serve as the basis for [FCA] violations for all claims submitted that resulted from illegal remuneration.” Tracy E. Miller, *The Payment Sunshine Act: Assessing the Compliance Risks for Healthcare Providers*, 15 AHLA CONNECTIONS, Aug. 2011, at 24, 24.

¹³⁶ 42 U.S.C. § 1395nn (2010); Miller, *supra* note 135, at 24.

transfers, possible penalties will be greatly increased and thus hopefully deter and dis-incentivize these problematic relationships. For example, the Secretary may exclude individuals or entities from participation in any Federal health care program if they have committed acts related to fraud, kickbacks, and “other prohibited activities.”¹³⁷ Exclusion, which has been described as the “death penalty” for entities and individuals, can provide significant incentive to comply with the law and reduce the possibility of violations.¹³⁸ This, in turn, could incentivize manufacturers to limit their relationships with physicians.

CONCLUSION

The PPSA has laudable goals—informed patients and strengthened provider-patient relationships based on trust are certainly important. The PPSA, however, does not go far enough to achieve its goals. The lack of uniformity among disclosure laws and regulations, such as the PPSA, state laws, and industry codes, complicates enforcement and compliance and provides some individuals with greater information than others. Furthermore, significant evidence raises serious questions about the likely success of mandatory disclosure laws in health care and other areas of law. Patients are unlikely to access the information, understand the information, and/or know how to appropriately use the information as it will be provided by the PPSA. Given this reality, the PPSA’s goal of improving patient knowledge about potential physician biases is unlikely to be achieved. To achieve its goals, the law should be expanded, its penalties should be increased, and the government must strictly and uniformly enforce the law.

¹³⁷ 42 U.S.C. § 1320a-7(b)(7) (2012).

¹³⁸ Stephanie L. Trunk, Note, *Sounding the Death Toll for Health Care Providers: How the Civil Claims Act has a Punitive Effect and why the Act Warrants Reform of its Damages and Penalties Provisions*, 71 GEO. WASH. L. REV. 159, 165 (referring to exclusion as a “so-called ‘death penalty’”).