

Fall 2019

Redefining What It Means to "Furnish Items in Excess of a Patient's Needs": A Federal Tool to Guide Physician Prescribing Behavior and Combat the Opioid Crisis

Carson Schneider

Follow this and additional works at: <https://scholar.law.colorado.edu/lawreview>



Part of the [Health Law and Policy Commons](#)

Recommended Citation

Carson Schneider, *Redefining What It Means to "Furnish Items in Excess of a Patient's Needs": A Federal Tool to Guide Physician Prescribing Behavior and Combat the Opioid Crisis*, 90 U. COLO. L. REV. 1157 (2019).

Available at: <https://scholar.law.colorado.edu/lawreview/vol90/iss4/6>

This Comment is brought to you for free and open access by the Law School Journals at Colorado Law Scholarly Commons. It has been accepted for inclusion in University of Colorado Law Review by an authorized editor of Colorado Law Scholarly Commons. For more information, please contact rebecca.ciota@colorado.edu.

REDEFINING WHAT IT MEANS TO “FURNISH ITEMS IN EXCESS OF A PATIENT’S NEEDS”: A FEDERAL TOOL TO GUIDE PHYSICIAN PRESCRIBING BEHAVIOR AND COMBAT THE OPIOID CRISIS

Carson Schneider*

The United States is in the midst of one of the deadliest drug epidemics in its history: the opioid crisis. The relevant players—prominent physicians, federal investigators, and multiple presidents, to name a few—have demonstrated a desire to combat the crisis, but they have not always focused on addressing one of the crisis’s most prominent causes. This Comment starts by identifying a major cause of the opioid crisis—physician-prescribed opioid painkillers—and then advocates for federal regulation and monitoring through the Department of Health and Human Services (HHS) as a remedy.

Under the current statutory regime, HHS has the power to control aspects of physician behavior, which could include the rate and volume of opioid prescribing. This power derives from HHS’s exclusion authority, which empowers the agency to prevent certain doctors from receiving federal funding. HHS has statutory authority to exclude physicians who furnish items “in excess of their patient’s needs.” This power could serve as a useful tool in combating the crisis, but to achieve the maximum crisis-mitigating effect, the regulations interpreting the statute should be amended to more clearly

* J.D. Candidate, 2019, University of Colorado Law School; Associate Editor, *University of Colorado Law Review*. My sincere thanks to the *University of Colorado Law Review* and all its members who supported my project. In particular, thank you to my editors Marty Whalen Brown and Claire Jarrell for their thoughtful and patient feedback. Lastly, thank you to the handful of medical professionals who humored me and provided meaningful critiques and commentary throughout the writing process.

cover doctors' prescribing habits. Reducing physician-prescribed opioids would have a powerful and mitigating impact on the opioid crisis, and the federal government has the statutory tools to accomplish it.

INTRODUCTION	1158
I. PHYSICIAN-PRESCRIBED PAINKILLERS: THE ROOT OF AMERICA'S OPIOID CRISIS	1163
A. <i>Opioids, the Drugs</i>	1164
B. <i>The Recent History of Pain Relief in America</i>	1165
C. <i>The Troubling Effects of Opioid Overprescription</i> ..	1167
D. <i>Acknowledging the Impact of Opioid-Prescribing Habits</i>	1170
II. HHS'S EXCLUSION AUTHORITY: AN OLD STATUTORY TOOL WITH NEW IMPLICATIONS	1172
A. <i>The United States' History of Regulating the Medical Field Through Funding</i>	1173
B. <i>Two Types of Exclusion: Regulating America's Physicians in the Twenty-First Century</i>	1175
C. <i>The Impetus Behind Regulation of Physician Prescribing Behavior</i>	1179
III. SECTION 1320A-7(B)(6)(B) IN PRACTICE: A DULL INSTRUMENT WITH THE POTENTIAL FOR SHARPENING ...	1181
A. <i>The Difficulties in Bringing Cases Under Section 1320a-7(b)(6)(B)</i>	1182
B. <i>The Need for Stronger, Clearer Guidelines in the Opioid-Prescribing Context</i>	1185
IV. RECOMMENDATION: AMEND 42 C.F.R. § 1001.701 SO HHS CAN HOLD PHYSICIANS ACCOUNTABLE FOR EXCESSIVE OPIOID PRESCRIBING	1188
CONCLUSION	1192

INTRODUCTION

Tens of thousands of people are dying opioid-related deaths every year.¹ In the United States, drug overdoses involving opioids have tripled over the past fifteen years,² and

1. *Overdose Death Rates*, NAT'L INST. ON DRUG ABUSE, <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates> (last modified Aug. 2018) [<https://perma.cc/Y5N4-FDYU>].

2. Molly Schnell & Janet Currie, *Addressing the Opioid Epidemic: Is There a Role for Physician Education?* 1, 3 (Nat'l Bureau of Econ. Research, Working

rates of deaths involving opioids have quadrupled over the past thirty.³ One chronicler of the crisis observed that “[i]f deaths were the measurement, this wave of opiate abuse was the worst drug scourge to ever hit the country.”⁴ The rise of emergency department visits and economic costs associated with opioids are further evidence of the large toll this crisis has taken on the American population.⁵

Several parties are responsible for this crisis, but only one has an affirmative duty to provide care: physicians.⁶ This affirmative duty of care distinguishes physicians from both the patients they serve and the pharmaceutical companies. Pharmaceutical companies do not have a duty to provide care. These companies have mass produced opioids in many forms, and their pharmaceutical business practices deserve scrutiny.⁷ But unfettered development, production, and sales are not too surprising given the duty of loyalty corporate officers owe to their corporations, which arguably requires officers to pursue all available profits and advantages.⁸ Thus, a pharmaceutical company’s duties are not to the consumer, but largely to itself. Additionally, people addicted to opioids are often unable to care for themselves. Addiction can drive them to seek prescription pills and other opioid-based drugs, like heroin, from legal and illegal sources.⁹ Research indicates that people addicted to opioids can lose the ability to resist using the drug, even to their

Paper No. 23645, 2017), <http://www.nber.org/papers/w23645> [<https://perma.cc/5LRZ-FJ3V>].

3. Michael L. Barnett et al., *Opioid-Prescribing Patterns of Emergency Physicians and Risk of Long-Term Use*, 376 NEW ENG. J. MED. 663, 664 (Feb. 16, 2017).

4. SAM QUINONES, DREAMLAND: THE TRUE TALE OF AMERICA’S OPIATE EPIDEMIC 7 (2015).

5. DEPT OF HEALTH & HUMAN SERVS., ADDRESSING PRESCRIPTION DRUG ABUSE IN THE UNITED STATES 3 (2014).

6. See generally *AMA Principles of Medical Ethics*, AMA, <https://www.ama-assn.org/delivering-care/ama-principles-medical-ethics> (last visited Jan. 24, 2019) [<https://perma.cc/3LTY-6U9Y>] (“[A] physician shall be dedicated to providing competent medical care.”).

7. Ohio received enough opioids in 2012 such that every man, woman, and child could have had sixty-eight pills. Alana Semuels, *Are Pharmaceutical Companies to Blame for the Opioid Epidemic?*, ATLANTIC (June 2, 2017), <https://www.theatlantic.com/business/archive/2017/06/lawsuit-pharmaceutical-companies-opioids/529020/> [<https://perma.cc/EQ47-FK36>].

8. See, e.g., *Guth v. Loft, Inc.*, 5 A.2d 503, 510 (Del. 1939).

9. See *infra* Section I.A.

fatal detriment.¹⁰ But between the drug makers and the drug takers there exist the doctors, an important intermediary and gatekeeper, whose motive should not be one of profit or addiction—but rather one of care. Physicians have a duty to responsibly connect the drug maker and drug taker and to foster an effective, care-focused relationship between themselves and their patients.¹¹ In the context of the opioid crisis, this duty has not been adequately fulfilled.

What makes this drug crisis unique is that many overdoses are attributable to legal opioids—namely, those prescribed by a physician.¹² Alongside the rise in opioid-related deaths, rates of opioid prescribing have quadrupled over the last thirty years.¹³ In 2012, there were more opioid prescriptions written in Kentucky and Tennessee than there were people living in those states.¹⁴ One doctor commented that “the heroin problem wouldn’t be one-tenth as bad if we hadn’t primed the pump with prescription opioids.”¹⁵

Pharmaceutical companies need doctors to get their prescription opioids to the public. Those companies are not permitted to sell their pills directly to the American public; they are reliant on an intermediary.¹⁶ They need doctors to prescribe their pills. And in 2010, enough opioids were prescribed to provide every adult in the United States with five milligrams of an opioid drug every four hours for a month.¹⁷ Thus, physicians have been complicit partners in Big Pharma’s pill-pushing

10. See generally Barry J. Everitt et al., *Neural Mechanisms Underlying the Vulnerability to Develop Compulsive Drug-seeking Habits and Addiction*, 363 PHIL. TRANSACTIONS ROYAL SOC’Y 3125 (2008); Andrew Kolodny et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 ANN. REV. PUB. HEALTH 559 (2015).

11. *AMA Principles of Medical Ethics*, *supra* note 6.

12. Schnell & Currie, *supra* note 2, at 2.

13. Barnett et al., *supra* note 3, at 664.

14. See Rich Lord et al., *How Doctors Wrote the Script for an Epidemic*, PITTSBURGH POST-GAZETTE (May 22, 2016), <https://newsinteractive.post-gazette.com/overdosed/> [https://perma.cc/M53W-ZBVM] (noting that OxyContin patients often sold their pills to street customers for one dollar per milligram).

15. *Id.*

16. This fact is evidenced by the great lengths to which the pharmaceutical industry goes to persuade doctors to prescribe their pills. Such persuasive techniques commonly include bribes and financial payments. Scott E. Hadland et al., *Industry Payments to Physicians for Opioid Products, 2013–2015*, 107 AM. PUB. HEALTH ASS’N 1493, 1494 (2017) (finding that one in twelve U.S. physicians received a payment involving an opioid during a twenty-nine-month study).

17. Barnett et al., *supra* note 3, at 664.

agenda. A profession that prides itself on self-regulation¹⁸ has been unable to effectively curtail its prescribing of opioids.

The federal government plays a large role in regulating the healthcare industry, and the scope of such regulation includes physician behavior.¹⁹ Effective, physician-focused federal regulation is possible because the vast majority of physicians receive some federal funds for their services,²⁰ and those funds come with strings attached—strings that can be pulled to shape physician behavior. Importantly, the Department of Health and Human Services (HHS), the federal agency that disperses funds throughout the healthcare industry, has the authority to exclude physicians from participating in federal programs if they do not comply with certain regulations.²¹ Exclusion can mean the end of a doctor's career. In addition to the collateral consequences (reputational and otherwise) that accompany exclusion, many doctors rely on federal dollars to stay in business.²² The threat of exclusion, then, strongly incentivizes compliance with HHS regulations.

One of HHS's statutory powers is the authority to exclude doctors who "furnish items or services in excess of the patient's needs."²³ HHS has explicitly refused to further define the contours of that authority.²⁴ Although there is little case law on the scope of this authority, the statute could—and should—be used to exclude doctors who overprescribe opioids. The statute could be a powerful tool to curb physician prescribing habits and have a profound impact on the number of Americans who suffer opioid addiction in the future.

This Comment begins by identifying physician overprescribing habits as a major cause of the opioid crisis and then argues for federal regulation and monitoring by HHS as a remedy. Part I illustrates how America's opioid addictions are

18. See David Orentlicher, *The Role of Professional Self-Regulation*, in REGULATION OF THE HEALTHCARE PROFESSIONS 129 (Timothy S. Jost ed., 1997) (noting that independence and discretion are the presumptive staples of the profession).

19. See *infra* Sections II.A, II.B.

20. Editorial Board, *Doctors and Their Medicare Patients*, N.Y. TIMES (Aug. 31, 2013), www.nytimes.com/2013/09/01/opinion/sunday/doctors-and-their-medicare-patients.html [<https://perma.cc/PBX3-RRB7>].

21. 42 C.F.R. § 1003.100 (2018).

22. See *infra* Part III.

23. 42 U.S.C. § 1320a-7(b)(6)(B) (2012).

24. See *infra* notes 131–134 and accompanying text.

largely traceable to physician-prescribed painkillers. Part II describes HHS's exclusion authority—that is, its ability to exclude doctors from receiving federal dollars through Medicare and Medicaid. Part II also explores how HHS's authority to exclude doctors who furnish items “in excess of their patient's needs” could serve as a useful tool in combating the crisis. Part III analyzes how the exclusion tool has been used in practice and discussed in academic literature. This leads to the recommendations in Part IV, which argues that the exclusion tool's enabling statute should either be amended to more clearly cover over-prescribing habits, or interpreted more strictly by HHS enforcers.

Ultimately, this Comment proposes reforming HHS's exclusion authority to aid patient-focused doctors in fighting the opioid epidemic. Some physicians act in immoral and illegal ways, but this Comment is not about them. “Pill-mill” operations are already being targeted by federal²⁵ and state investigations,²⁶ and, moreover, these operations constitute only a fraction of the crisis. It is the regular, well-meaning, and patient-focused doctor on whom this Comment is centered. This Comment's proposed changes would help physicians provide better care. Further, the changes would help insulate physicians from the pressures of competing with peers whose prescribing habits are inappropriate.²⁷

When it comes to government regulation of healthcare professionals, one scholar said it best:

The reexamination of the role of regulation in the health professions should not be looked at like a chore—it is an opportunity. We have better safety for the public, with less

25. Press Release, U.S. Dep't of Justice, Attorney General Sessions Announces Opioid Fraud and Abuse Detection Unit (Aug. 2, 2017), <https://www.justice.gov/opa/pr/attorney-general-sessions-announces-opioid-fraud-and-abuse-detection-unit> [<https://perma.cc/5EW7-5RZ2>].

26. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 5, at 16 n.118.

27. See THE LIFE AND SELECTED WRITINGS OF THOMAS JEFFERSON 440 (Adrienne Koch & William Peden eds., 1944). As Thomas Jefferson acknowledged, an “energetic government . . . is always oppressive.” *Id.*; see also *infra* Section II.C (discussing the business pressures around prescribing that physicians may experience).

regulation and less cost to the consumer and less hassle to the profession—if we do this right.²⁸

In the opioid context, doing this right involves setting better guidelines for prescribing. Once set, these guidelines should be treated as de facto mandatory by using deviations from the guidelines as a basis for exclusion under the “in excess of the patient’s needs” provision. Compliance will lead to changes in prescribing behavior, with those doctors who fail to comply being excluded. The stakes in this context—abuse, addiction, and death²⁹—are too high not to change how opioid prescribing is regulated.

I. PHYSICIAN-PRESCRIBED PAINKILLERS: THE ROOT OF AMERICA’S OPIOID CRISIS

Sam Quinones’s book *Dreamland*, a preeminent historical account of the opioid crisis, opens by chronicling several stories, each of a similar structure: a middle-class, educated adult seeks a doctor for help with a relatively benign ailment.³⁰ As one example, Quinones tells the story of a young man with carpal tunnel syndrome.³¹ For this ailment, his physician wrote him a prescription for OxyContin,³² a powerful opioid pain reliever.³³ This initial prescription grew into an addiction from which the man would never recover.³⁴ As his dependency grew, his prescription slowly became insufficient to meet his addiction, and the man looked for more OxyContin on the streets, away from doctors and pharmacies.³⁵ When he failed to find more, the man, like many others, turned to another opioid—

28. Richard D. Lamm, *Foreword* to REGULATION OF THE HEALTHCARE PROFESSIONS ix (Timothy S. Jost ed., 1997).

29. This mantra was aptly used by Jane C. Ballantyne & Mark D. Sullivan, *Intensity of Chronic Pain—The Wrong Metric?*, 373 NEW ENG. J. MED. 2098 (2015).

30. QUINONES, *supra* note 4, at 6–8.

31. *Id.* at 8.

32. *Id.*

33. *Oxycodone*, U.S. NAT’L LIBR. MED.: MEDLINEPLUS, <https://medlineplus.gov/druginfo/meds/a682132.html> (last visited Jan. 24, 2019) [<https://perma.cc/BLK7-3X9B>].

34. QUINONES, *supra* note 4, at 8.

35. *Id.*

heroin. Five years after the carpal tunnel patient's first OxyContin prescription, he died of a heroin overdose.³⁶

Similar accounts are all too common,³⁷ and these stories illustrate part of what has made the opioid crisis so hard to control. The patient-turned-addict's first painkillers are often prescribed by physicians for legitimate reasons.³⁸ Quinones notes how families are often confused by the addiction's roots. Doctor-facilitated pain relief seems so benign.³⁹ In fact, HHS has found that patients are not discussing alternatives to opioids with their physicians because of a growing belief that prescription drugs are not dangerous.⁴⁰ The agency found that this belief was a factor in the recent increase in prescription drug use.⁴¹ Thus, medical patients have been primed to ask for opioid prescriptions, and the physicians, in historic numbers, have obliged.⁴² Contrary to the general belief that prescription drugs are safe, history shows that prescription opioids are incredibly dangerous.

A. *Opioids, the Drugs*

Prescription opioids are particularly dangerous because they are very powerful and very addictive.⁴³ Prescription opioids, like Purdue Pharma's OxyContin, work by binding to opioid receptors in the brain and spinal cord.⁴⁴ This binding blocks pain signals to the brain, causing the patient to experience less

36. *Id.*

37. *Id.* at 7.

38. *Id.*; see also Sarah Kliff, *The Opioid Crisis Changed How Doctor's Think About Pain*, VOX (June 5, 2017, 6:30 AM), <https://www.vox.com/2017/6/5/15111936/opioid-crisis-pain-west-virginia> [<https://perma.cc/3UFK-N34U>] (citing lower-back pain of coal miners in West Virginia as one example).

39. QUINONES, *supra* note 4, at 7.

40. DEPT OF HEALTH & HUMAN SERVS., *supra* note 5, at 21.

41. *Id.* at 3.

42. *Prescription Opioid Data*, CTRS. DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/drugoverdose/data/overdose.html> (last updated Dec. 19, 2018) [<https://perma.cc/Y4CC-C3JG>].

43. See *Pain Relievers*, U.S. NAT'L LIBR. MED.: MEDLINEPLUS, <https://medlineplus.gov/painrelievers.html> (last updated Aug. 29, 2018) [<https://perma.cc/47NY-4Y2L>]; see also *Opioid Abuse and Addiction*, U.S. NAT'L LIBR. MED.: MEDLINEPLUS, <https://medlineplus.gov/opioidabuseandaddiction.html> (last updated Nov. 30, 2018) [<https://perma.cc/Q56U-545N>].

44. See generally B. N. Dhawan et al., *International Union of Pharmacology. XII. Classification of Opioid Receptors*, 48 PHARMACOLOGICAL REV. 567 (1996).

pain.⁴⁵ Opioids are strikingly more effective at pain relief than over-the-counter drugs like acetaminophen or naproxen.⁴⁶ Further, opioids come in a variety of forms. The five forms of opioids that were most heavily promoted by pharmaceutical companies were Fentanyl, Hydrocodone, Buprenorphine, Tapentadol, and Oxycodone.⁴⁷ The intricacies of these drugs are beyond the purview of this Comment and the expertise of this author.

Although the pain relief from each of these drugs is powerful, patients develop a tolerance to them over time.⁴⁸ It is widely recognized that continued pain relief from opioids requires increasingly larger doses.⁴⁹ Thus, use of one of these extremely effective painkillers, provided by the authority figure of a doctor, can lead to reliance and addiction because the drug's continued effectiveness is reliant on ever-increasing dosages.

Quinones described the effect of opioids in this manner: "Like a lover, no other molecule in nature provided such merciful pain relief, then hooked humans so completely, and punished them so mercilessly for wanting their freedom from it."⁵⁰ To stop using opioids is far more difficult than "just say no" politics would tell you. But if these drugs are so addictive, one may wonder why and how they came to be used with such frequency in the first place.

B. The Recent History of Pain Relief in America

The goal of comprehensive pain relief was once embraced not only by patients but also by the medical community as a whole.⁵¹ This goal has its origins in the 1990s, the decade when

45. *Opioid (Narcotic) Pain Medications*, WEDMD, <https://www.webmd.com/pain-management/guide/narcotic-pain-medications#1> (last updated Sept. 20, 2018) [<https://perma.cc/EE9A-D8CQ>].

46. *Id.*

47. Hadland et al., *supra* note 16, at 1494.

48. *Opioid (Narcotic) Pain Medications*, *supra* note 45.

49. *Id.*

50. QUINONES, *supra* note 4, at 38–39 (describing morphine molecules, one of the major molecules that opioids derive from).

51. Kliff, *supra* note 38. For a more recent iteration of the trends Kliff identified, see generally Phillip A. Pizzo & Noreen M. Clark, *Alleviating Suffering 101—Pain Relief in the United States*, 366 NEW ENG. J. MED. 197 (2012) (asserting that effective pain management is a moral imperative and a

many of today's practicing physicians were trained, and when there was a movement in medicine to focus on treating pain.⁵² This focus was to be achieved largely by relying on opioids.⁵³ "Pain scales" were invented and some groups of physicians were encouraged to treat pain as a vital sign alongside heart rate, temperature, and others.⁵⁴ Today, it is likely that more patients are treated for pain than would be the case if doctors did not specifically ask about it.⁵⁵ Thus, pain garnered more attention from doctors, more concern from patients, and more opioid prescriptions to be filled.

The nearly one-to-one correlation between opioid use and pain treatment is partly the result of the perceived lack of other adequate treatments.⁵⁶ Admitting that not all pain should be treated with opioids begs difficult questions. What level of pain is okay to leave untreated? And are there other ways of treating pain besides opioids? Patients come to a doctor's office, describe their pain, and discover that their treatment choices are limited. Often, powerful OxyContin and the like are the only immediate answers.⁵⁷ There are alternative methods of pain treatment, such as diet, exercise, and habit

professional responsibility of physicians, and that opioids provide one of the best ways to treat pain).

52. Kliff, *supra* note 38.

53. See Ballantyne & Sullivan, *supra* note 29 (noting how during the 1980s and 90s, large-scale opioid-based pain relief was argued for on moral grounds, and explaining that the medical community was ultimately persuaded); Kliff, *supra* note 38.

54. See generally DEP'T VETERANS AFFAIRS, PAIN AS THE 5TH VITAL SIGN TOOLKIT (rev. ed. 2000), https://www.va.gov/PAINMANAGEMENT/docs/Pain_As_the_5th_Vital_Sign_Toolkit.pdf [<https://perma.cc/M7N4-XS82>] (the revised edition of the manual for VA physicians about how to address pain as the fifth vital sign). A vital sign is a measure used by medical professionals to gauge the body's most basic functions. The four main vital signs are body temperature, pulse rate, respiration rate, and blood pressure. *Vital Signs (Body Temperature, Pulse Rate, Respiration Rate, Blood Pressure)*, JOHNS HOPKINS MED., https://www.hopkinsmedicine.org/healthlibrary/conditions/cardiovascular_diseases/ (last visited Mar. 19, 2018) [<https://perma.cc/87Z8-323K>].

55. Kliff, *supra* note 38.

56. See DEP'T OF HEALTH & HUMAN SERVS., *supra* note 5, at 3; see also *The Weeds: Is Google in an "Ideological Echo Chamber"?*, VOX (Aug. 9, 2017), <https://art19.com/shows/the-weeds/episodes/d5b9d925-42eb-4ef2-9b5a-5bf9fda15abe> [<https://perma.cc/NF57-6WTP>] (noting that "we are at a loss when it comes to how to treat back pain").

57. See DEP'T OF HEALTH & HUMAN SERVS., *supra* note 5, at 3 (noting the frequently unmet need for adequate pain treatment).

formation, but even the best alternative pain treatments do not produce the immediate pain alleviation that opioids do.⁵⁸

Importantly, however, immediate pain relief needs to be seen in the context of a patient's long-term health. One of Quinones's reflections in *Dreamland* captures the danger of relief by opioids: "Children of the most privileged group in the wealthiest country in the history of the world were getting hooked and dying in almost epidemic numbers from substances meant to, of all things, numb pain."⁵⁹ Clearly then, there has been a sacrifice of patients' long-term health for short-term relief. However admirable the medical profession's initial pursuit of a pain-free world may have been, it has become clear that the collateral, opioid-related consequences of the pursuit are vast.

C. *The Troubling Effects of Opioid Overprescription*

Atul Gawande, a thoracic surgeon and a staff writer for the *New Yorker* magazine, pulls no punches in his assessment of the opioid crisis, stating "[w]e as a profession have caused an epidemic that is bigger than the HIV epidemic."⁶⁰ Gawande thinks that the cause of the crisis started with doctors, like himself, who failed to recognize the risk of catalyzing long-term addiction with prescription painkillers.⁶¹ He notes that patients who take opioids for seven days have an 8 percent chance of still being on those pills a year later.⁶² Other studies have found stronger correlations. One study from the Center for Disease Control and Prevention estimates that patients given a ten-day supply of opioids have a roughly 25 percent chance of becoming long-term users.⁶³

58. Ballantyne & Sullivan, *supra* note 29.

59. QUINONES, *supra* note 4, at 8.

60. Sarah Kliff, "We Started It": Atul Gawande on Doctors' Role in the Opioid Epidemic, *VOX* (Sept. 8, 2017, 5:25 PM), <https://www.vox.com/2017/9/8/16270370/atul-gawande-opioid-weeds> [https://perma.cc/9UYJ-PH3S].

61. *Id.*

62. *Id.*

63. Anuj Shah et al., *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use—United States, 2006–2015*, *CTRS. DISEASE CONTROL & PREVENTION* (Mar. 17, 2017), https://www.cdc.gov/mmwr/volumes/66/wr/mm6610a1.htm#F1_up [https://perma.cc/92X8-YSW2] (in figure one, charting the probabilities of continued opioid use by the number of days' supply of the first opioid prescription). For a less verbose discussion of the CDC's findings, see Beth Mole, *With a 10-Day Supply of Opioids, 1 in 5 Become Long-Term Users*,

There is additional circumstantial evidence that supports Gawande's professional assessment. The rate of opioid prescribing has increased since the 1990s, coinciding with a rise in addiction and opioid-related deaths. As to overprescribing, rates of opioid prescription have quadrupled over the last thirty years.⁶⁴ And it is not just the volume of prescriptions that is growing excessively, but also the number of pills per prescription. For example, studies have shown that after thyroid surgery or breast cancer surgery the average patient received more than fifty opioid pills, but that ten pills would have covered the needs of more than 80 percent of patients.⁶⁵ Alongside this rise in opioid prescriptions has been an increase in prescription-opioid-related deaths.⁶⁶ In 1999, deaths from opioid prescription painkillers accounted for 30 percent of all overdose deaths, but in 2010 that percentage had risen to over 60.⁶⁷ In fact, the anecdote that began this Part is misleading in that heroin is not close to being the most destructive force in this crisis. In 2013, overdose deaths from opioid painkillers outnumbered overdose deaths involving all illicit drugs combined, including heroin and cocaine.⁶⁸ Thus, in accord with Gawande's insight, the crisis was catalyzed by the doctors who wrote the prescriptions.

There are additional correlations between prescription opioids and addiction. A study of Medicare Part D patients showed that the intensity of physicians' opioid prescribing was positively associated with the probability that their patient would become a long-term opioid user sometime during the following year.⁶⁹ Although causality cannot be established from an observational study, the results of the research suggest that for every forty-eight patients who are prescribed an opioid, one will become a long-term user.⁷⁰ Other studies have found evi-

ARS TECHNICA (Mar. 18, 2017, 9:00 AM), <https://arstechnica.com/science/2017/03/with-a-10-day-supply-of-opioids-1-in-5-become-long-term-users/> [https://perma.cc/XXZ9-KY5Z].

64. Barnett et al., *supra* note 3, at 664 (citing *Prescription Opioid Data*, *supra* note 42).

65. Kliff, *supra* note 60.

66. DEPT OF HEALTH & HUMAN SERVS., *supra* note 5, at 3.

67. *Id.*

68. *Id.*

69. Barnett et al., *supra* note 3, at 672. The correlation between the number of opioids prescribed by a physician and the likelihood of long-term opioid use was consistent across numerous subgroups. *Id.* at 667

70. *Id.*

dence that even short-term use may increase the chances of opioid dependence.⁷¹ As noted by one Harvard medical researcher, there has been a sharp increase in opioid-overdose mortality that is closely linked to increases in opioid overprescribing for nonchronic, noncancer pain.⁷²

Overprescribing contributes to the opioid crisis in three ways. First, the patient himself may take more pills than he would otherwise need or think to use simply because they are available. The results of this overabundance are damaging. The more opioid pills a patient takes, the more likely it is that the patient will suffer addiction later in life.⁷³ Second, excess pills often find their way to the black market and into the hands of nonpatients for recreational use.⁷⁴ This too fuels addictions and drug-seeking behavior. Third, and most generally speaking, overprescribing perpetuates the “pain-free” culture that gathered steam in the 1990s. In discussing pain, Gawande noted that “we have to teach people that the goal is not zero [pain]”—rather, physicians should strive to help people explore alternatives, such as targeted physical activity.⁷⁵ In that endeavor, some pain will have to be tolerated, and fewer pills prescribed.

Notably, there is high variability in opioid prescribing habits among physicians.⁷⁶ For instance, in Kentucky in 2009, roughly 80 percent of controlled substance prescriptions came from the top 20 percent of prescribers.⁷⁷ Moreover, one study in the *New England Journal of Medicine* found substantial variation in the opioid prescribing patterns of emergency-room phy-

71. Megan M. Butler et al., *Emergency Department Prescription Opioids as an Initial Exposure Preceding Addiction*, 68 ANNALS EMERGENCY MED. 202, 207 (2016).

72. Richard G. Frank, *Targeting the Opioid Drug Crisis: A Health and Human Services Initiative*, HEALTH AFF. BLOG (Apr. 3, 2015), <https://www.healthaffairs.org/doi/10.1377/hblog20150403.046076/full/> [<https://perma.cc/B6SX-VZ5J>]; see also DEP'T OF HEALTH & HUMAN SERVS., *supra* note 5, at 13 (noting the link between opioid-related morbidity and mortality and the increase in opioid prescribing for nonchronic, noncancer pain).

73. Shah et al., *supra* note 63.

74. See Lord et al., *supra* note 14.

75. Kliff, *supra* note 60. See generally Ballantyne & Sullivan, *supra* note 29.

76. Barnett et al., *supra* note 3, at 664.

77. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 5, at 16–17. Such data may be of little relevance because some medical disciplines necessarily address pain more frequently, thus accounting for disparities. Further research, however, has shown that such disparities exist even within the same specialty areas of medicine at the same hospital.

sicians within the same hospital.⁷⁸ There are often no regulations or established practices on the amount to prescribe,⁷⁹ so the key to understanding doctors' future prescribing behaviors is the prescribing habits that they learn early in their careers, such as those learned during residency.⁸⁰ But this custom of "learned behavior" has not generated uniform prescribing behaviors. And some of the learned behaviors are more dangerous than others.

Consequently, the apparent randomness in opioid prescribing habits among medical professionals has effectively changed treatment into addiction roulette. One study found that among doctors in the same practice area in the same hospital, opioid prescribing rates varied by a factor of more than three.⁸¹ And among patients treated in the same emergency room, those patients treated by a physician with a higher prescribing rate are significantly more likely to be dependent on opioids twelve months later.⁸² Thus, physician prescribing behavior in the opioid context has resulted in addiction and pain with fierce, detrimental randomness.

D. Acknowledging the Impact of Opioid-Prescribing Habits

It is not novel or unique to assert that physicians' prescribing behaviors have been a direct and substantial cause of

78. Barnett et al., *supra* note 3, at 669.

79. See *infra* Section III.B. (discussing why there should be a rulebook).

80. See Schnell & Currie, *supra* note 2, at 4 (noting the training a physician receives while at medical school has an effect on prescribing habits); see also DEP'T OF HEALTH & HUMAN SERVS., *supra* note 5, at 15 ("The majority of opioid analgesics in the U.S. are prescribed by primary care physicians and internists and most were not trained in pain management or addiction." (citations omitted)); Atul Gawande, *The Cost Conundrum*, NEW YORKER (June 1, 2009), <https://www.newyorker.com/magazine/2009/06/01/the-cost-conundrum> [<https://perma.cc/HE7P-U6KW>].

81. Barnett et al., *supra* note 3, at 672. Many factors impact physician prescribing behavior. As mentioned, training is an important factor in doctor behavior. A paper from the National Bureau of Economic Research found that doctors from lower ranked medical schools write more opioid prescriptions than their peers in the same county and specialty practice area who are from higher ranked schools. See Schnell & Currie, *supra* note 2. Physicians from lower ranked medical schools were more likely to write opioid prescriptions in the first place, and (conditional upon being an opioid prescriber) physicians from lower ranked schools prescribed more opioids on average. *Id.* at 4. These relationships were found even among specialists who practice in the same hospital or clinic. *Id.* at 24.

82. Barnett et al., *supra* note 3, at 667.

the opioid crisis.⁸³ The Department of Justice (DOJ) has acknowledged that doctors have played a role. For example, former Attorney General Jeff Sessions announced a new “data analytics program” designed to gather information on prescription opioids.⁸⁴ The program is designed to identify, among other things, doctors whose patients die within sixty days of receiving an opioid prescription.⁸⁵ In addition to the DOJ, many other scholars, practitioners, and commentators have identified physicians as a cause of the crisis.⁸⁶

Establishing a strong empirical basis for the dangers of physicians’ prescribing habits is necessary because responses to these dangers from the medical community have been far from uniform. Backlash to a 2015 article arguing that doctors should think less about treating pain⁸⁷ is indicative of the 1990s pain-treatment philosophy that still exists in some sects of the medical community. Two University of Washington professors’ banal argument that focusing on reducing pain intensity can be counterproductive for a patient over the long term⁸⁸ was met with disdain.⁸⁹ The University received letters calling for one of the authors’ resignation.⁹⁰

Singularly focused finger-pointing is not the goal of this Comment. The opioid crisis has many causes.⁹¹ That said, physician prescribing behavior is one major cause that should receive more attention at the federal level. Federal prosecutors are going after a few big fish, such as black-tar heroin sects, Oxycodone dens, and prescription-pill mills.⁹² But as shown by the medical research discussed above, many smaller fish—such as family physicians, orthodontists, surgeons, and nurses—also

83. See DEPT OF HEALTH & HUMAN SERVS., *supra* note 5, at 13–16; Frank, *supra* note 72 (noting that “the sharp increase in opioid overdose mortality is closely linked to increases in inappropriate prescribing of opioid drugs”).

84. Press Release, *supra* note 25.

85. *Id.*

86. For a sampling of authority in support of this proposition, see Schnell & Currie, *supra* note 2; Barnett et al., *supra* note 3; DEPT OF HEALTH & HUMAN SERVS., *supra* note 5; Lord et al., *supra* note 14; Kliff, *supra* note 38; Kliff, *supra* note 60.

87. Ballantyne & Sullivan, *supra* note 29.

88. *Id.*

89. Kliff, *supra* note 38.

90. *Id.*

91. See *supra* Introduction.

92. Press Release, *supra* note 25.

have big impacts.⁹³ As one commentator notes, it may be hard for physicians to admit that they cannot solve all of a patient's pain problems, but "the alternative—the drug deals, the overdoses, the debilitation of [their] cities—is worse."⁹⁴ The federal government can and should help us avoid that alternative.

II. HHS'S EXCLUSION AUTHORITY: AN OLD STATUTORY TOOL WITH NEW IMPLICATIONS

The opioid crisis is a national one. Although the Rust Belt, including Kentucky, West Virginia, Ohio, and Michigan, has arguably been hit hardest,⁹⁵ populations in Denver, Los Angeles, rural Oregon, and Alaska are also suffering.⁹⁶ And although some states have created programs to enhance prescription drug monitoring and information sharing,⁹⁷ this crisis requires more than a piecemeal attack. A national problem merits a national solution. This Part analyzes the federal government's bases and mechanisms for regulating the medical profession so that regulation in the context of the opioid crisis can be understood and justified. It focuses on the exclusion authority, which is HHS's mechanism to prevent physicians from receiving federal funds.⁹⁸ An underlying purpose of this authority is to protect patients and assure that physicians are providing quality care.⁹⁹ Understood in light of its purpose, this mechanism equips HHS to make a difference in stemming the opioid crisis.

93. The term "physician" is predominantly used throughout this Comment, but the discussion of the origins of the crisis and the proposed solutions are equally applicable to these other kinds of medical professionals. This includes, but is not limited to, nurses, physician assistants, and dentists.

94. Kliff, *supra* note 38.

95. Yousur Al-Hlou et al., *The Facts on America's Opioid Epidemic*, N.Y. TIMES, <https://www.nytimes.com/video/health/policy/100000005515818/the-opioid-epidemic-what-you-need-to-know.html> (last visited Jan. 24, 2019) [<https://perma.cc/R539-9P22>].

96. See generally QUINONES, *supra* note 4, at 7.

97. See generally Leonard J. Paulozzi et al., *Prescription Drug Monitoring Programs and Death Rates from Drug Overdose*, 12 PAIN MED. 747 (2011) (noting that state monitoring programs are having a minimal impact on overall opioid consumption).

98. See *infra* Section II.B.

99. See *id.*

A. The United States' History of Regulating the Medical Field Through Funding

This Comment considers how one federal tool—the Department of Health and Human Service’s authority to exclude physicians from receiving payments from federal programs—can be used to control physician prescribing behavior and stem the tide of the opioid crisis. This regulatory tool has been developed by statutory and regulatory reforms throughout a long history of funding and regulating the medical field. But to fully understand this tool and its implications, an explanation of how and why the federal government regulates America’s physicians is in order.

The federal government is, and has been, deeply involved in healthcare. From President Johnson’s Great Society to President Obama’s (comparatively modest) Affordable Care Act, the United States has shown that healthcare is a field deserving of government resources.¹⁰⁰ In conjunction with and in response to these proffered resources, the United States has consistently considered healthcare a field that it can and should regulate on a national level. These regulations, generally speaking, manifest as conditions that must be met to receive federal funds through the Medicaid or Medicare programs. More specifically, the Department of Health and Human Services has been given the power to exclude entities and individuals from receiving federal funds through these healthcare programs if they misbehave in certain ways.¹⁰¹ Through these exclusion authorities and other federal programs,¹⁰² the federal role in regulating healthcare has grown dramatically over the course of the twentieth century.¹⁰³

Even at the beginning of the United States’s foray into the healthcare sector, there were protections designed to encourage the responsible use of federal funds, although such protections were relatively limited. There were provisions in President

100. See generally Sarah Helene Duggin, *From the New Deal to the New Healthcare: A New Deal Perspective on King v. Burwell and the Crusade Against the Affordable Care Act*, 23 U. MIAMI BUS. L. REV. 317, 324–25 (2015).

101. 42 U.S.C. § 1320a-7 (2012).

102. See, e.g., *supra* Section I.D (discussing DOJ’s recent efforts to track physician prescribing behavior).

103. Mark R. Yessian & Joyce M. Greenleaf, *The Ebb and Flow of Federal Initiatives to Regulate Healthcare Professionals*, in REGULATION OF THE HEALTHCARE PROFESSIONS 170–71 (Timothy S. Jost ed., 1997).

Roosevelt's Social Security Act of 1935 that excluded specific items or services from being reimbursed with federal dollars.¹⁰⁴ Notably, the approach taken by Congress was to exclude payments for specific items or services, and not to exclude individuals or entities that prescribed those items or services.¹⁰⁵

As regulation of Medicare and Medicaid expanded in the 1980s, the focus changed from the items to the prescribers. The Medicare and Medicaid Amendments of 1980 first codified an exclusionary principle that focused on specific providers.¹⁰⁶ These amendments instructed HHS to exclude from federal funding individuals or entities convicted of crimes related to the delivery of medical services.¹⁰⁷

Federal regulation expanded again with the Medicare and Medicaid Patient and Program Protection Act of 1987.¹⁰⁸ These amendments added exclusionary principles to cover non-criminal activities.¹⁰⁹ They expanded many of the protections from the Social Security context to apply explicitly to Medicare and Medicaid. And they added to HHS's discretionary authority.¹¹⁰ Importantly, the Senate Report professed that the purpose of the bill was twofold: to protect federal healthcare programs from misuse and to "protect the beneficiaries of those programs from incompetent practitioners and from inappropriate or inadequate care."¹¹¹ The Senate's stated purpose for the bill is noteworthy because it goes beyond simply protecting the integrity of the federal programs by underscoring a desire to protect patients from "incompetent practitioners."¹¹² Commentators tend to approve of the dual purposes of the regulation, noting that the United States, as the largest purchaser of healthcare services in the world, should be interested in both upholding

104. Section 1862 of the Act, now codified at 42 U.S.C. § 1395y (2012).

105. *See id.*

106. An Act to Provide for Reconciliation Pursuant to Section 3 of the First Concurrent Resolution on the Budget, Pub. L. No. 96-499, § 913, 94 Stat. 2599, 2619-21 (1980).

107. *Id.*

108. Medicare and Medicaid Patient and Program Protection Act, Pub. L. No. 100-93, § 1(a), 101 Stat. 680 (1987); *see also* S. REP. NO. 100-109, at 1 (1987) ("[This bill] also broadens the grounds for the discretionary exclusion of health care providers from Medicare and Medicaid.").

109. *See* Pub. L. No. 100-93, § 1(a), 101 Stat. 680.

110. Pub. L. No. 100-93, § 1(a), 101 Stat. 680, 690.

111. S. REP. NO. 100-109, at 1 (1987).

112. *Id.*

the integrity of its healthcare systems and promoting quality care.¹¹³

B. Two Types of Exclusion: Regulating America's Physicians in the Twenty-First Century

Additionally, the 1987 amendments codified the two broad categories of exclusion that are still in effect: mandatory and permissive.¹¹⁴ Under a mandatory exclusion framework, HHS must exclude physicians¹¹⁵ who are convicted of program-related crimes,¹¹⁶ patient abuse,¹¹⁷ or various other felonies.¹¹⁸ Criminality-based exclusions, however, are inadequate for mitigating the cause of the opioid crisis. One modern exclusionary principle is instructive. Under 42 U.S.C. § 1320a-7(a)(4), HHS must exclude an individual or entity who has been convicted of a felony relating to controlled substances.¹¹⁹ Prescription opioid drugs are all Schedule II controlled substances,¹²⁰ but most doctors' prescribing habits, however destructive, fall far short of criminality. The vast majority of overprescribing practices would largely evade implicating § 1320a-7(b)(3) and other similar provisions.¹²¹

Importantly, HHS has the permissive (i.e., discretionary) authority to exclude in a wider variety of situations.¹²² Many of

113. Alexander D. Eremia, *When Self-regulation, Market Forces, and Private Legal Actions Fail: Appropriate Government Regulation and Oversight is Necessary to Ensure Minimum Standards of Quality in Long-Term Health Care*, 11 ANNALS HEALTH L. 93, 95 (2002).

114. Pub. L. No. 100-93, § 1(a), 101 Stat. 680.

115. The language used through the modern statutes and regulations is that HHS excludes "individuals and entities." See, e.g., 42 U.S.C. § 1320a-7(a)(1) (2012). Throughout, I will reference HHS's power to exclude physicians, both for simplicity and because physicians are the focus of this paper, recognizing that HHS's exclusion power is much broader.

116. *Id.*

117. *Id.* § 1320a-7(a)(2).

118. *Id.* § 1320a-7(a)(3)–(4).

119. Additionally, HHS has permissive authority to exclude individuals who have been convicted of misdemeanors relating to a controlled substance. *Id.* § 1320a-7(b)(3).

120. *Drug Scheduling*, U.S. DRUG ENFT ADMIN., <https://www.dea.gov/druginfo/ds.shtml> (last visited Jan. 24, 2019) [<https://perma.cc/C9FU-ZFS7>].

121. Robert A. Berenson & Dean M. Harris, *Using Managed Care Tools in Traditional Medicare- Should We? Could We?*, 65 L. & CONTEMP. PROBS. 139, 155–56 (2002).

122. Compare 42 U.S.C. § 1320a-7(b)(2) (2012) (permissive exclusion of physicians who obstruct an audit), with *id.* § 1320a-7(b)(6)(B) (permissive

these permissive exclusions are related to the obstruction of HHS information-gathering processes. For example, one permissive exclusion provision targets physicians who obstruct an investigation or audit.¹²³ Other provisions target physicians who fail to supply payment information¹²⁴ or any other relevant information to the agency.¹²⁵

Focusing on different criteria, § 1320a-7(b)(6)(B) gives HHS the discretionary authority to exclude physicians who “furnished items or services (whether or not eligible for benefits under [Medicare] or under a state health care program) substantially in excess of the needs of such patients or of a quality which fails to meet professionally recognized standards of health care.”¹²⁶ This permissive exclusion bucks the trend in that it is not related to either criminality or compliance with program procedures. Rather, the regulation is directed at the substance of a doctor’s duties. This permissive exclusion provision addresses how doctors are to provide medical services to their patients—namely, it prohibits doctors from providing items or services in excess of the patient’s needs. Notably, exclusion under this provision requires HHS’s Office of the Inspector General (OIG) to prove that the requisite bad behavior occurred, as opposed to simply referencing some previously established criminal record.¹²⁷ Further, this provision embodies the spirit of the law as announced by the Senate committee report in that it seeks to protect patients regardless of whether or not their medical care is being covered by a federal program.¹²⁸

exclusion of physicians who furnished unnecessary items or services to patients), and *id.* § 1320a-7(b)(14) (permissive exclusion of physicians who default on educational loans).

123. *Id.* § 1320a-7(b)(2).

124. *Id.* § 1320a-7(b)(11).

125. *Id.* § 1320a-7(b)(12).

126. *Id.* § 1320a-7(b)(6)(B). As noted in the 1987 Medicare and Medicaid Patient and Program Protection Act of 1987, this section was largely borrowed from similar protections that were developed in the social security context. *See id.* § 1395y(a)(1)(A) (stating that no payment shall be made for items or services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury”).

127. The requisite proof is a preponderance of the evidence standard. 42 C.F.R. § 1001.2007(c) (2018).

128. *See generally* U.S. DEPT OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., PROTECTING PUBLIC HEALTH AND HUMAN SERVICES PROGRAMS: A 30-YEAR RETROSPECTIVE (2006), <https://oig.hhs.gov/reports-and-publications/retrospective.asp> [<https://perma.cc/QP7F-ABWJ>] (describing how HHS mission includes insuring better quality of care for the patient).

For example, if a physician overprescribed painkillers (an “item,” as defined in HHS regulations)¹²⁹ to a patient not covered by Medicare or Medicaid, that physician could still be excluded from participating in those programs. Commenting on the regulations that interpreted this statutory authority, HHS noted that:

The Department has a very strong interest in ensuring that program beneficiaries receive quality health care. The OIG believes that poor quality care or substantially excessive services are at least as great a threat to the programs and their beneficiaries as the types of behavior that underlie the convictions that serve as a basis for exclusion.¹³⁰

The regulations promulgated by HHS under its § 1320a-7(b)(6)(B) authority simply reaffirmed the enabling statute’s language without altering or explaining any of its ambiguous terms.¹³¹ Thus, the regulation, 42 C.F.R. § 1001.701(a)(2), seems nearly copied and pasted from 42 U.S.C. § 1320a-7(b)(6)(B).¹³² A number of commenters during the notice-and-comment period called attention to the unresolved ambiguities in the language “substantially in excess of the patient’s needs,” but HHS noted that they have had many cases under that provision already and have found it unnecessary to define it further.¹³³ More specifically, HHS responded by noting that cases brought under § 1001.701 are based on a holistic, fact-specific inquiry and, further, that the determination “is always made on the basis of expert medical opinion.”¹³⁴

129. 42 C.F.R. § 1003.110 (2018) (defining an item as including any drug).

130. Health Care Programs: Fraud and Abuse; Amendments to OIG Exclusion and CMP Authorities Resulting from Public Law 100-93, 55 Fed. Reg. 12205, 12208 (Apr. 2, 1990) (to be codified at 42 C.F.R. pts. 1000–1007).

131. In practice, cases appear to be brought under both the statutory authority and the regulatory authority. See *infra* Part III. I will refer to both interchangeably, except in Part IV, *infra*, where only the regulations are referenced because the proposed changes could only take place at the regulatory level.

132. See *infra* Part IV for a discussion of how this abdication of regulatory explanation may impact HHS’s ability to utilize this provision more forcefully in the future.

133. Health Care Programs: Fraud and Abuse; Amendments to OIG Exclusion and CMP Authorities Resulting from 100-93, 57 Fed. Reg. 3298, 3306 (Jan. 29, 1992).

134. *Id.*

The “in excess of a patient’s needs” provision is a recent and pertinent example of the twentieth-century trends of federal regulation in the healthcare industry. Three principles have emerged from this history of federal regulation. First, the federal government has slowly yet consistently expanded its power to regulate physicians over the course of the twentieth century. Second, this regulation has been targeted not only at maintaining the integrity of the federal programs, but also at protecting patients. Third, such regulation has reached the substance of physicians’ work—namely, treating patients. In relation to the opioid crisis, such principles indicate that the federal government can regulate physician opioid-prescribing behavior.

This recent regulatory history points to a concrete solution to the opioid epidemic. The OIG could potentially exclude physicians under 42 U.S.C. § 1320a-7(b)(6)(B) for furnishing items in excess of their patients’ needs when they overprescribe opioids. Prescription drugs already qualify as “items” under the regulatory definition.¹³⁵ “Substantially in excess of the patient’s needs” is the more difficult interpretive issue, which is explored in Part IV.

Such a solution merits attention because if the OIG could apply § 1320a-7(b)(6)(B) to cases in the opioid-prescribing context, then physician behavior would adjust accordingly. Research demonstrates that standards and information alone are insufficient to shape physician behavior and that the standards should be “supplemented by incentives or mandates to ensure compliance.”¹³⁶ Potential exclusion from federal funding is a strong incentive. Most physicians would not be able to stay in practice if they were excluded from participating in federal programs—exclusion has been colloquially called “the kiss of death.”¹³⁷ The proposed solution would be effective at regulat-

135. 42 C.F.R. § 1003.110 (2018).

136. Orentlicher, *supra* note 18, at 129.

137. SCOTT MCBRIDE & SUMMER D. SWALLOW, BUREAU OF NAT’L AFFAIRS, INC., *THE KISS OF DEATH: OIG’S EXCLUSION AUTHORITY 1* (2011); Thomas Sullivan, *HHS OIG: Medicare and State Healthcare Programs: Fraud and Abuse—OIG Proposes Revisions to Exclusion Authorities and “Early Reinstatement” for Certain Healthcare Providers*, POLICY & MED., <http://www.policymed.com/2014/05/hhs-oig-medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-the-office-of-inspector-generals-exclusion.html> (last updated May 6, 2018) [<https://perma.cc/3WD5-UUNL>] (noting that OIG’s exclusion authority is

ing the majority of America's physicians because although only 26 percent of the population is enrolled in a federally funded healthcare program, more than 90 percent of physicians receive income from federal-dollar patients.¹³⁸ Thus, federal funds comprise part of their business. More importantly, the effects of exclusion go far beyond losing business. If HHS excludes a practitioner, the agency is required to notify the physician's state and local agencies and recommend that the physician be sanctioned in accordance with state law.¹³⁹ Additionally, the regulations specify ten other entities that are to receive notice of a doctor's exclusion, including hospitals and practices where the doctor might work, the national practitioner database, and medical and professional societies.¹⁴⁰ There is no way to hide the scars of federal exclusion, such that the threat of exclusion would be a sufficient incentive to control physician prescribing behavior.

C. *The Impetus Behind Regulation of Physician Prescribing Behavior*

Some pressures, like a doctor's self-interest and patients' personal preferences, may pressure a doctor to act in ways that are not in the patient's best interest. These counterproductive pressures demonstrate why a federal strong-arm approach is sometimes necessary to control physician behavior. These pressures are particularly powerful in the context of physician opioid-prescribing behavior. Physicians may dismiss borderline drug-seeking behavior as legitimate because filling the prescriptions provides work for the doctor.¹⁴¹ In addition to any possible financial incentives, the patients themselves can be a powerful pressure on a physician's decision to prescribe opioids. It takes gumption to say no to someone requesting pain relief when a simple stroke of the doctor's pen would provide immediate (albeit temporary) relief. As noted by Andrew Gurman, president of the American Medical Association, patients expect that doctors will alleviate their pain, and doctors largely "went

known colloquially as a "kiss of death" and a "death sentence" among doctors because federal programs are "often vital revenue sources").

138. Editorial Board, *supra* note 20.

139. 42 C.F.R. §§ 1001.2004, 1001.2005 (2018).

140. *Id.* § 1001.2006.

141. *See generally* Gawande, *supra* note 80.

into medicine to alleviate suffering.”¹⁴² Moreover, patient preference works in tandem with a physician’s personal interest because if a doctor develops a reputation for being unwilling to overprescribe opioids, her patients may decide to seek out doctors who are freer with their pen.¹⁴³ Only powerful counter-influences will overcome such pressures on physician behavior.

External regulation of physician behavior can be a powerful counterinfluence and has been effective before at the federal level. For example, after the federal government tightly regulated the use of antipsychotic drugs in primary-care homes, there was a substantial decrease in antipsychotic drug use.¹⁴⁴ Additionally, an analysis of past American drug crises concluded that drug regulation can shift economic incentives in ways that cut off the supply of the drug.¹⁴⁵ That insight is applicable here. The proposed regulatory instrument would put the physician’s entire practice at stake in cases of opioid overprescription.¹⁴⁶ Thus, the proposal is an example of federal regulation and economic incentives working in tandem to cut off the drug’s supply. If employed, this federal tool would affect physician prescribing behavior. Such tools should be considered and applied to address the nation’s “unprecedented drug overdose epidemic.”¹⁴⁷ However, the question remains: Could a case of overprescribing opioids actually be brought against a physician under § 1320a-7(b)(6)(B) for furnishing items substantially in excess of a patient’s needs?

142. Kliff, *supra* note 38.

143. *See id.* (noting that patients shop around for doctors who will fill their prescriptions at the most liberal rate).

144. Orentlicher, *supra* note 18, at 140 (citing R.I. Shorr et al., *Changes in Antipsychotic Drug Use in Nursing Homes During Implementation of the OBRA-87 Regulations*, 271 J. AM. MED. ASS’N 358 (1994)).

145. Mike Stobbe, *Opioid Epidemic Shares Chilling Similarities with the Past*, SPOKESMAN-REV. (Oct. 28, 2017, 9:22 PM), <http://www.spokesman.com/stories/2017/oct/28/opioid-epidemic-shares-chilling-similarities-with/> [<https://perma.cc/GUE6-E3JW>] (extrapolating lessons from America’s past drug crises that may provide context and guidance to the current opioid crisis).

146. *See* DEP’T OF HEALTH & HUMAN SERVS., OFFICE OF THE INSPECTOR GEN., EDUCATIONAL MATERIALS 8, https://oig.hhs.gov/compliance/physician-education/roadmap_speaker_notes.pdf (last visited Jan. 24, 2019) [<https://perma.cc/BX3T-NFBH>] (referring to exclusions as a “financial death sentence”).

147. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 5, at 3.

III. SECTION 1320A-7(B)(6)(B) IN PRACTICE: A DULL INSTRUMENT WITH THE POTENTIAL FOR SHARPENING

HHS has not often used section 1320a-7(b)(6)(B) (hereinafter, (b)(6)(B)) when exercising its exclusion authority.¹⁴⁸ Section A begins this Part by analyzing cases brought under (b)(6)(B), showing why it will be difficult under the current regulatory regime to bring cases against doctors in the context of the opioid crisis. Then, Section B discusses the need for descriptive and clear guidelines.

But first, a quick note on how these cases work. To begin, HHS's OIG decides to investigate a physician.¹⁴⁹ This decision is normally triggered by a tip from a state healthcare or state licensing agency.¹⁵⁰ Sometimes the OIG will receive a tip from within HHS if its own monitoring catches anything abnormal, such as a physician who is receiving large reimbursements through Medicare.¹⁵¹ Next, after a complex set of regulation-required notice¹⁵² and discovery procedures,¹⁵³ the OIG can exclude the physician from participating in federal healthcare programs.¹⁵⁴ If excluded, the physician has sixty days to request a hearing before an administrative law judge (ALJ), who will issue a ruling.¹⁵⁵ Then, either party can appeal an unfavor-

148. See William H. Dow & Dean M. Harris, *Exclusion of International Medical Graduates from Federal Healthcare Programs*, 40 MED. CARE 68, 69 (2002).

149. 42 C.F.R. § 1001.2002 (2018). The exclusion authority has been delegated by HHS to its OIG. Delegation of Authority to the Inspector General, 53 Fed. Reg. 12993 (Apr. 20, 1988). Many federal agencies have an Office of the Inspector General that is tasked with enforcing the agency's controlling law. See e.g., 49 C.F.R. § 1.73 (2018) (describing the authority of the inspector general in the Department of Transportation). In this Comment, OIG will refer exclusively to HHS's OIG.

150. See e.g., Bruce Vest, M.D., Dep't Health & Human Servs., Departmental Appeals Board, Docket No. C-95-035 (Dec. 1, 1995), <https://www.hhs.gov/sites/default/files/static/dab/decisions/alj-decisions/1995/cr405.pdf> [<https://perma.cc/S4SK-GLJ6>].

151. See generally *Exclusions FAQ*, OFFICE OF INSPECTOR GEN.: DEP'T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/faqs/exclusions-faq.asp> (last visited Jan. 24, 2019) [<https://perma.cc/RP7M-WACU>].

152. 42 C.F.R. §§ 1001.2001, 1001.2002, 1001.2003 (2018). After receiving "notice of intent to exclude," the doctor may send information to the OIG for reconsideration, which in some cases can justify the doctor's practices and prevent exclusion. See *id.*

153. *Id.* § 1005.7.

154. *Id.* §§ 1001.2001, 1001.2002.

155. *Id.* § 1001.2007.

able ALJ ruling to HHS's Departmental Appeals Board (DAB).¹⁵⁶ Finally, the case can be appealed to federal court.¹⁵⁷

Opinions from ALJs, the DAB, and federal courts in (b)(6)(B) cases are the starting point for analyzing whether the provision can be a useful tool in combatting the opioid crisis. As shown below, past success in excluding some doctors under (b)(6)(B) does not sufficiently demonstrate that the provision can be used as a tool to combat the crisis.

A. The Difficulties in Bringing Cases Under Section 1320a-7(b)(6)(B)

A couple examples will highlight the difficulties associated with bringing (b)(6)(B) cases. Dr. Lahiri was permanently excluded from participating in federal programs under (b)(6)(B) authority.¹⁵⁸ Dr. Lahiri was an oncologist in California who grossly mistreated at least seven patients over a period of many years by furnishing them items and services that were in excess of their needs.¹⁵⁹ For example, Dr. Lahiri often gave chemotherapy treatment to patients who had a cancer that would not respond to chemotherapy.¹⁶⁰ That, in combination with many other needless treatments and appointments, led HHS's DAB to conclude that Dr. Lahiri subjected his patients to treatments that neither cured nor soothed them, and that he was more focused on maximizing his Medicare billing than providing care to his patients.¹⁶¹ On appeal from an ALJ's holding, the DAB affirmed Dr. Lahiri's lifetime exclusion.¹⁶²

In contrast, Dr. Vest had his exclusion overruled by the DAB.¹⁶³ The ALJ originally affirmed the OIG's decision to exclude Dr. Vest for five years because the OIG presented evi-

156. *Id.* § 1005.21. See generally Dep't Health & Human Servs., *Organizational Overview*, HHS.GOV, <https://www.hhs.gov/about/agencies/dab/about-dab/organizational-overview/index.html> (last updated Nov. 9, 2016) [<https://perma.cc/3B6P-SJ2Z>].

157. 42 C.F.R. § 1005.21(k) (2018).

158. Lahiri, M.D., Dep't Health & Human Servs., Departmental Appeals Board, Docket No. C-92-088, at 131 (Dec. 12, 1994), <https://www.hhs.gov/sites/default/files/static/dab/decisions/alj-decisions/1994/cr348.PDF> [<https://perma.cc/Y684-KGXA>].

159. *Id.* at 10.

160. *Id.* at 19.

161. *Id.* at 130–31.

162. *Id.* at 131.

163. Bruce Vest, M.D., *supra* note 150, at 1.

dence from Dr. Vest's Medicare carrier showing that he rendered seventy-seven services (mostly diagnostic procedures) that were found to be medically unnecessary, and that on average Dr. Vest rendered 95 percent more services and items to his patients than did his peers in the same region.¹⁶⁴ More generally, the Medicare carrier complained that Dr. Vest had a concerning history—over a six-year period, he was the highest user of services in their region.¹⁶⁵ The ALJ found that all of this evidence supported Dr. Vest's exclusion under (b)(6)(B).¹⁶⁶ But the DAB disagreed.¹⁶⁷

On appeal, the DAB concluded that the OIG failed to meet its burden of proof in Dr. Vest's case.¹⁶⁸ The DAB found that the seventy-seven services could not be conclusively deemed unnecessary because the OIG's experts did not examine Dr. Vest's patient files in their entirety.¹⁶⁹ Context, the DAB noted, is crucial in determining whether items or services were excessive.¹⁷⁰ Further, the DAB found that the statistic that he provided 95 percent more services than his peers was also unreliable because the OIG never defined Dr. Vest's peer group.¹⁷¹ This was, in fact, a difficult task because Dr. Vest was both a general practitioner and a certified radiologist.¹⁷² The DAB also concluded that a mere pattern of high use of federal services was insufficient to show overuse under (b)(6)(B).¹⁷³

For the purposes of (b)(6)(B), the act of prescribing opioids is likely to be treated more like Dr. Vest's abundance of diagnostic procedures than like Dr. Lahiri's unnecessary chemotherapy treatments. Subjecting a patient to chemotherapy when their cancer is known to be unresponsive to such treatment is a black-and-white case of furnishing unnecessary items and services. The treatment was unnecessary, and Dr. Lahiri furnished it. In another case brought under (b)(6)(B), a physician was excluded for providing multiple unnecessary endo-

164. *Id.* at 2–3, 9.

165. *Id.* at 9.

166. *Id.* at 2.

167. *Id.* at 4.

168. *Id.* at 1.

169. *Id.* at 27.

170. *Id.*

171. *Id.* at 9–10.

172. *Id.* at 10.

173. *Id.* at 9.

scopic procedures over a two-year period.¹⁷⁴ Again, the analysis is relatively simple and binary—the endoscopic procedures were unnecessary when less costly and less invasive exoscopic procedures would have sufficed.

Opioid prescribing, in contrast, is more nuanced. Opioid prescribing tends to fall into a gray area because dosage, the history and severity of a patient's pain, and alternative treatment options all need to be considered when determining whether a prescription was in excess of patient needs. It is a truly holistic diagnosis. Thus, physicians under investigation can more easily make contextual and entirety-of-care arguments in defense of their opioid prescription decisions, like the arguments Dr. Vest made in his case.

Further, even if it were possible to exclude some physicians in these cases, it would be an extremely time-consuming endeavor for the OIG. One scholar reflected that “[t]he ambiguous nature of medical treatment, combined with patients who are often weak and vulnerable, enable health care providers to bill unnecessary tests and useless equipment to the programs.”¹⁷⁵ In other words, the necessity of any aspect of medical treatment is in some sense subjective and difficult to challenge in a courtroom. To the degree that opioid prescribing is an especially virulent example of this subjectivity, challenges to opioid prescribing will be even more difficult and time consuming to conduct.

Finding exclusions under (b)(6)(B) is likely to be difficult because it is simply hard to know whether such prescribing was excessive. One scholar noted that “the bases to judge either over- or under-utilization have been, at best, implicit and subjective.”¹⁷⁶ So under (b)(6)(B), where all exclusion determinations are made on the basis of expert opinion, the experts often can do nothing more than look at the billed items and services and shrug. Not surprisingly then, cases under (b)(6)(B) have been few and far between.¹⁷⁷ HHS has the authority to bring

174. *Thorbus v. Bowen*, 848 F.2d 901, 902 (8th Cir. 1988).

175. Lewis Morris & Gary W. Thompson, *Reflections on the Government's Stick and Carrot Approach to Fighting Health Care Fraud*, 51 ALA. L. REV. 319, 320 (1999).

176. Alice G. Gosfield, *Value Purchasing in Medicare Law: Precursor to Health Reform*, 20 AM. J.L. & MED. 169, 182 (1994).

177. *DAB Decisions*, HHS.GOV, <https://www.hhs.gov/about/agencies/dab/decisions/index.html> (last visited Jan. 24, 2019) [<https://perma.cc/8ZYC-W32G>]. This site is a database comprising all DAB and ALJ decisions. When searching for

(b)(6)(B) claims only in theory because “except in the most egregious of cases . . . it is difficult to exclude physicians and institutions from participating in the program on those grounds.”¹⁷⁸ In fact, less than 5 percent of exclusions are based on any sort of quality-of-care issue.¹⁷⁹ Although HHS has shown resistance to establishing clearer standards for (b)(6)(B) exclusions,¹⁸⁰ in the context of the opioid crisis such standards are necessary for maximizing the success of these laws.

B. The Need for Stronger, Clearer Guidelines in the Opioid-Prescribing Context

Where there are no objective standards for the prescription of certain medications, by definition there are no objective standards for the overprescription of those medications under (b)(6)(B).¹⁸¹ Thus, the biggest problem for OIG in bringing these claims against physicians for opioid overprescription is that there are few clinical guidelines on their appropriate use.¹⁸² Where there is little guidance or national consensus on opioid prescribing, such prescribing cannot be treated like a Lahiri situation. While there are some guidelines found in a few narrowly defined contexts, this Section’s exploration of those guidelines demonstrates that they need to be clearer and stronger if they are to be effective in the (b)(6)(B) context.

In the prescription-drug context generally, the Medicare Benefit Policy Manual provides some insight into what constitutes an unnecessary item or service; but it does not do so in the opioid context specifically. Unnecessary injections and drugs that are ineffective at treating a particular illness are

the exclusions under this provision, using either the statutory law or the regulatory law as search terms, only three cases were found.

178. Berenson & Harris, *supra* note 121, at 155–56.

179. Dow & Harris, *supra* note 148, at 69 tbl. 1 (cited in Berenson & Harris, *supra* note 121, at 156 n.99).

180. See Health Care Programs: Fraud and Abuse; Amendments to OIG Exclusion and CMP Authorities Resulting from 100-93, 57 Fed. Reg. 3298, 3306 (Jan. 29, 1992) (“In our opinion, it is unnecessary to define the phrase ‘substantially in excess of the patient’s needs’ or to limit by regulations the OIG’s discretion to initiate cases that are not based on a pattern of violations.”).

181. Cf. Berenson & Harris, *supra* note 121, at 159 (arguing that Medicare should include objective standards and clinical guidelines to enhance the efficacy of exclusion on quality-of-care grounds).

182. Barnett et al., *supra* note 3, at 664.

specifically mentioned.¹⁸³ Notably, excessive medications are also discussed: “Medications administered for treatment of a disease and which exceed the frequency or duration of injections indicated by accepted standards of medical practice are not covered.”¹⁸⁴ A few types of drug treatment, such as vitamin B12 injections to treat anemia, are specifically mentioned; opioid-based pain relief is not.¹⁸⁵ Thus, the Medicare Benefit Policy Manual still leaves open the question as to what excessive medication looks like in the opioid context.

Some opioid-specific guidelines, and accompanying enforcement of the guidelines, have existed effectively at the state level, but a national crisis will not be fully addressed by the actions of a few states. In Kentucky, one of the centers of this crisis, there was a massive crackdown on doctors between 2011 and 2015.¹⁸⁶ There, twelve out of every one thousand doctors were disciplined for opioid-related offenses during that time period, and as a result, opioid overdoses “bucked the national trend by edging downward.”¹⁸⁷ Another crackdown in Washington State provided similar mitigating effects.¹⁸⁸ But many states have not been so reactive to the crisis, and the federal government should not wait for them to get on board, particularly when doctor-regulation efforts have been effective in this context.

Some opioid-prescribing guidelines for particular hospital systems exist but are simply inadequate. The inspector general for the Department of Veteran’s Affairs investigated improper opioid prescription renewal practices in San Francisco.¹⁸⁹ Even though the inspector general found that many physicians were

183. MEDICARE BENEFIT POLICY MANUAL ch. 15, § 50.4.3 (1)-(2), <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf> (last visited Mar. 5, 2019) [<https://perma.cc/UWF5-NA3K>] (“Medications given for a purpose other than the treatment of a particular condition, illness, or injury are not covered (except for certain immunizations).”).

184. *Id.* § 50.4.3 (3).

185. *Id.*

186. Lord et al., *supra* note 14.

187. *Id.* A key to Kentucky’s efforts was its electronic reporting system, which logged complaints against doctors and allowed state officials to see patterns of overprescribing. *Id.*

188. See Frank, *supra* note 72 (citing a study out of Washington State where guidelines did have a mitigating effect on doctors’ prescribing habits in workers’-compensation cases).

189. DEP’T OF VETERANS AFFAIRS, OFFICE OF THE INSPECTOR GEN., HEALTHCARE INSPECTION: ALLEGED IMPROPER OPIOID PRESCRIPTION RENEWAL PRACTICES NO. 13-00133-12 (2013).

tasked with evaluating and renewing numerous opioid requests for patients with whom they were unfamiliar, the inspector general concluded that there was no wrongdoing because their Veteran's Health Administration (VHA) policy allowed for such practice.¹⁹⁰ The VHA policy allowed for a provider to renew opioid prescriptions *for patients the practitioner had never met before*.¹⁹¹ This was permitted because the physicians were expected to review the patients' files.¹⁹² The thoroughness of the VA physician's review, however, was questionable given that they often relied merely on the pharmacist's patient review and recommendation.¹⁹³ This paper-review practice probably contributed to the inspector general's other finding: VA physicians were not properly documenting patients' adherence to their treatment plans or patients' potentials for misuse and addiction.¹⁹⁴

While conceding that the VA's practices may be a reflection of an on-the-ground necessity of providing treatment in a timely manner, the drugs in play here are simply too powerful and too prone to abuse to be dealt with in such a flippant manner. It should also be noted that the veteran population is probably more predisposed to need pain treatment.¹⁹⁵ But such a reality should require the treating physician to exercise *more* care in watching for signs of misuse and addiction, not less merely in the name of efficiency.

The call of this Section is not unique because there have been many pushes for federal guidelines to address opioid overprescription. HHS's Subcommittee on Prescription Drug Abuse recommended that HHS "develop indicators of inappropriate prescribing," as well as pain management guideline recommendations.¹⁹⁶ And Harvard Professor Richard Frank has called for better defined opioid-prescribing practices to remedy the crisis.¹⁹⁷ Additionally, DOJ data on opioid-prescribing lev-

190. *Id.* at 2.

191. *Id.*

192. *Id.* at 3.

193. *See id.* ("[I]t was the general consensus of the [physicians] that the clinical pharmacist's preliminary review of the [patient] was extremely helpful.").

194. *Id.*

195. *Transforming VA Pain Care*, DEP'T VETERANS AFFAIRS, <https://www.va.gov/painmanagement/> (last visited March 19, 2018) [<https://perma.cc/ZF4F-8FH9>].

196. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 5, at 31.

197. Frank, *supra* note 72.

els, which is currently being compiled, will be helpful for determining an empirical basis for appropriate levels.¹⁹⁸

The push for more and better guidelines is admirable, and potentially helpful,¹⁹⁹ but the federal guidelines this Comment advocates for need to be more than guiding. Opioid-prescribing guidelines will compel maximum compliance if they are employed objectively and consistently in (b)(6)(B) cases. "Market forces, self-regulation, and private litigation have not been successful at ensuring quality health care,"²⁰⁰ and research has shown that physicians are generally unable to police themselves in the opioid-prescribing context.²⁰¹ If employed in (b)(6)(B) cases, the guidelines will become de facto mandatory, and a strong message will be sent to the medical community: overprescribe at your own risk.

IV. RECOMMENDATION: AMEND 42 C.F.R. § 1001.701 SO HHS CAN HOLD PHYSICIANS ACCOUNTABLE FOR EXCESSIVE OPIOID PRESCRIBING

Temporary, emergency rulemaking²⁰² to address physician prescribing behavior is an appropriate measure to combat the opioid crisis for two reasons. First, the relevant federal actors have called the crisis a public health emergency. Second, and most importantly, the longer it takes to rein in prescribing habits, the greater the number of people who will be exposed to opioid-related harm.²⁰³ Section 553(b)(1)(B) of the Administrative Procedure Act provides that an agency may skip notice-and-comment rulemaking when "an agency for good cause finds

198. DEPT OF HEALTH & HUMAN SERVS., *supra* note 5, at 31 (describing the forthcoming fraud and abuse detection unit, and part of their efforts at quantifying opioid prescribing levels).

199. See Frank, *supra* note 72 (citing a study out of Washington State, which found that guidelines did have a mitigating effect on doctors' prescribing habits in workers'-compensation cases).

200. Eremia, *supra* note 113, at 96.

201. See *supra* Section I.D.

202. Interpretive rulemaking under § 553(b)(1)(A) of the Administrative Procedure Act would probably not be an option because courts are hesitant to let agencies "interpret" a flexible standard into a bright-line rule. See *Hector v. U.S. Dep't of Agric.*, 82 F.3d 165 (7th Cir. 2014). Such a rule would probably need to go through notice and comment (unless, as suggested in this Section, emergency procedures are applied).

203. See *supra* Section I.D.

that notice and comment are impracticable.”²⁰⁴ In this context, President Trump has called the opioid crisis a “public health emergency,”²⁰⁵ and his former attorney general has said that the crisis is one that is “gripping our entire nation.”²⁰⁶ In 2017, approximately 115 Americans died every day from opioid drugs.²⁰⁷ If the federal government does not take action now, it risks subjecting future generations of Americans to similar levels of tragedy. Thus, “for good cause,” HHS could find that ordinary notice and comment is impracticable.²⁰⁸

New rulemaking is important for another reason. As 42 C.F.R. § 1001.701 starts to be used more frequently to combat the crisis, the absence of any standards in this provision may draw the attention of the courts as an abdication of the agency’s rulemaking authority.²⁰⁹ The D.C. Circuit has expressed concern about agencies “promulgating mush” because doing so can allow agencies to tinker with the regulation in the adjudicatory context as they see fit.²¹⁰ Additionally, individual justices on the Supreme Court have noted their displeasure with agencies when they abdicate their interpretive duties.²¹¹ In this case, HHS has been explicit about its abdication. The agency concluded that the determination of whether such items or services were in excess of a patient’s needs is always made on a case-by-case basis while consulting medical experts, so a

204. 5 U.S.C. § 553(b)(1)(B) (2012).

205. Julie Hirschfeld Davis, *Trump Declares Opioid Crisis a “Health Emergency” but Requests No Funds*, N.Y. TIMES (Oct. 26, 2017), <https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html> [<https://perma.cc/X56X-JJK5>].

206. Press Release, *supra* note 25.

207. *Understanding the Epidemic*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugoverdose/epidemic/index.html> (last updated Dec. 19, 2018) [<https://perma.cc/7MQK-JSAC>].

208. In the alternative, the agency should commence notice and comment on this provision immediately to mitigate future delays.

209. Again, § 1001.701 is the regulation implementing 42 U.S.C. § 1320a-7 (b)(6)(B), and, as previously discussed, the regulation parrots the language from the statute without addition. This Section focuses on § 1001.701, and not (b)(6)(B), because the proposed solution is to occur at the regulatory level, not statutory. See *supra* Section II.B for a discussion of the interplay between the statutory language and the regulation.

210. *Paralyzed Veterans of Am. v. D.C. Arena L.P.*, 117 F.3d 579, 584 (D.C. Cir. 1997).

211. *Decker v. Northwest Envtl. Def. Ctr.*, 568 U.S. 597, 617–21 (2013) (Scalia, J., dissenting).

better-defined rule is unnecessary.²¹² Even conceding that point, certainly some baseline levels of excessive “furnishing” in different contexts should be established; the current crisis presents an opportunity and a need to define such a baseline in the context of prescribing opioid painkillers.

The emergency rulemaking should define that certain levels of opioid prescribing are presumptively “in excess of their patient’s needs” under § 1001.701 for patients treated for non-cancer-related, nonacute pain.²¹³ These presumptive levels may be drawn from state guidelines or another source that HHS deems appropriate and reliable. The agency should further establish that deviation from the guidelines must be supported by justifications in explanatory paperwork. In this way, a strong and presumptive federal standard can be established. Further, by targeting opioids prescribed for non-cancer-related and nonacute pain, the regulations could be appropriately tailored to address the situations where immediate, fast-acting pain relief is going to be less necessary and where opioid alternatives would be more appropriate. DHS has recognized that “[a]ny such strategy must also balance the legitimate needs of patients and ensure that access to pain treatment is not unnecessarily restrained”;²¹⁴ focusing on non-cancer-related and nonacute pain achieves this balance. In a similar vein, the regulations should be targeted largely at outpatient prescriptions. General practitioners prescribe 50 percent of all opioids,²¹⁵ and doctors in those settings have the best opportunity and ability to discuss alternatives to medication with their patients. By contrast, inpatient treatment, perhaps for someone who just had surgery, should

212. See Health Care Programs: Fraud and Abuse; Amendments to OIG Exclusion and CMP Authorities Resulting from 100-93, 57 Fed. Reg. 3298 (Jan. 29, 1992).

213. 42 C.F.R. § 1001.701 (2018). Notably, such pain would rise to a different medical threshold and be distinguishable from other sorts of pain, which should be treated much more sparingly with opioids. At a general level, acute pain means pain that is extreme, severe, and temporary. Examples include fracturing a bone or recovering from invasive surgery. See Katherine Kam, *Is Your Pain Acute or Chronic?*, WEBMD, <https://www.webmd.com/pain-management/features/types-pain#1> (last updated Feb. 18, 2011) [<https://perma.cc/N77F-AMNK>]; cf. Kliff, *supra* note 38 (“Chronic pain was not a gash or a broken bone that demanded immediate attention. It was invisible and subjective, and for centuries, eliminating it was not a top priority.”).

214. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 5, at 6.

215. Schnell & Currie, *supra* note 2, at 3.

still be focused on maximum pain mediation. The regulations should be strictly enforced under § 1001.701 against doctors who overprescribe opioids for noncancerous, nonacute pain.

That said, strict enforcement should not mean a rule of per se exclusion for every violation. Such punitive measures need not be the norm because any good prosecutor should exercise a degree of discretion in the pursuit of justice. The Senate Committee that originally passed the (b)(6)(B) exclusionary provision recognized this, stating in its report that “[w]here it appears that the underlying violation by the . . . physician . . . is an isolated or inadvertent instance, the Committee would expect the Secretary not to exclude, but rather to insist on prompt corrective action.”²¹⁶ Thus, it appears that a middle ground was desired wherein the guidelines could be enforced effectively without becoming draconian.²¹⁷ A few instances of overprescribing need not, without more justification, ruin a physician’s livelihood—such results are not argued for by this Comment. However, multiple instances of bad behavior must be met with a firm threat of exclusion and, if necessary, actual exclusion. The harm from prescription-caused opioid abuse is too great to ignore any longer.

It is likely that many doctors would take issue with these proposals, and not without cause. As a baseline, federal regulation of American physicians should be sparing. The longstanding “bias toward inaction”²¹⁸ concerning regulation of the healthcare industry rests upon two justifications that are antithetical to this Comment’s thesis but that should presumptively be respected. First, fiercely held American values of individualism and limited government would lead some away from federal regulation as a general matter. As Thomas Jefferson acknowledged, an “energetic government . . . is always oppressive.”²¹⁹ Second, a hands-off approach has been particularly expected in the medical community because of the intricacies of the profession.²²⁰ The physicians are the experts, and they exist to care for the general population. They are well-intentioned

216. S. REP. NO. 100-109, at 9 (1987).

217. See e.g., U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 128, at 36 (describing OIG’s “integrity agreements” wherein the doctor admits to fraudulent behavior and voluntarily enters into mandated compliance programs).

218. Yessian & Greenleaf, *supra* note 103, at 169.

219. THE LIFE AND SELECTED WRITINGS OF THOMAS JEFFERSON, *supra* note 27, at 440.

220. See Yessian & Greenleaf, *supra* note 103, at 169.

specialists. Such a profession needs no watchdog, and (so the argument goes) the government would not know how to regulate such a complex profession, regardless. But as shown, the federal government has a long and consistent history of regulating medical professionals when the need arises,²²¹ and the opioid crisis presents another situation calling for federal intervention.

Moreover, the proposals here are as much directed at protecting the livelihoods of more careful doctors as they are at reining in careless prescribing habits. If one doctor says no to patients asking for a prescription, “[t]hey’ll go somewhere else, to someone who writes more of that medication, or try multiple physicians to try and score different types of medication.”²²² Much like the role of the Securities and Exchange Commission in protecting the integrity of the financial markets, HHS can protect the integrity of its healthcare markets by punishing negligent behavior and encouraging proper behavior. Without watchdogs in both the financial markets and the healthcare markets, financial incentives encourage foul play such that the participants who have more integrity are harmed.²²³ By regulating, HHS can ensure that care-focused physician’s feel less pressure to overprescribe.

CONCLUSION

The opioid crisis presents a sufficiently perilous situation that justifies federal regulation of the healthcare industry. The historical “bias toward inaction” concerning regulation of the healthcare industry should presumptively be respected. But when the sense of peril is sufficient to overcome the inaction bias, the federal government needs to step in. This is one of those perilous times.

In the midst of the cocaine epidemic, this presumption favoring inaction was overcome. When the Boston Celtics first-round draft pick Len Bias overdosed in 1986, Congress was called to address the inescapable grip that crack cocaine had on America.²²⁴ This Comment does not support Congress’s par-

221. See *supra* Sections II.A, II.B.

222. Kliff, *supra* note 38.

223. See *supra* notes 141–143 and accompanying text.

224. Joie Chen, *How a Basketball Player’s Drug Overdose Led to Today’s Mandatory Minimums*, ALJAZEERA AM. (Nov. 5, 2015), <http://america.aljazeera.com>.

ticular actions, such as mandatory minimums and sentencing disparities,²²⁵ but it does applaud Congress's effort to try and do *something*. In this situation, Congress's impetus for action is lessened because they have already delegated the necessary authority to the Department of Health and Human Services. HHS, the federal experts in the healthcare field, *can* act to mitigate the opioid crisis; it is time for them to do so.

The action here should be targeted at an underlying cause of the crisis: physician opioid-prescribing behavior. For sure, there are other causes of the crisis besides prescribing, like pill mills, medically criminal behavior, and treatment programs are all important, but the pill mills and criminality exist on the fringes of a much larger problem that has infected the American medical community. To focus solely on treatment would be to clean the lake without plugging the pipe that is polluting the water. Prescribing habits need to be reined in so that fewer patients are exposed to the risk of long-term addiction.

The threat of exclusion and, in some cases, actual exclusion under § 1001.701 should curtail habits of overprescribing. Guidelines for opioid prescribing need to be implemented at the federal level, and they need to be treated as *de facto* mandatory. In this way, the medical community can force itself to learn new ways to address pain management, learn to rely less on opioids, and protect future generations of Americans from addiction and death. At the state level, there is strong evidence that "getting tough on doctors works."²²⁶ It's time to get the rest of the states on board via federal guidelines and federal enforcement.

In the 1970s, when one of the leading causes of American deaths was automobile accidents,²²⁷ the Department of Trans-

com/watch/shows/america-tonight/articles/2015/11/5/how-a-basketball-players-drug-overdose-led-to-mandatory-minimum-laws.html [https://perma.cc/765Z-LT89]; see also BILL SIMMONS, *THE BOOK OF BASKETBALL* 206–09 (2009) (noting that Len Bias's death changed the course of professional basketball in 1980s, and the course of drug reform in America well into the twenty-first century).

225. Stobbe, *supra* note 145 (noting that, as a part of the "new drug war," Congress imposed harsh jail sentences for the sale and possession of crack cocaine that were more severe than the sentences for regular cocaine) (hardcopy available with the author).

226. Lord et al., *supra* note 14.

227. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983).

portation mandated seat belts in all cars.²²⁸ The reaction to these rules was not a happy one. As a result, multiple cases progressed all the way to the Supreme Court.²²⁹ But, in the end, safety won out, and deaths from car accidents subsided substantially.²³⁰ In 2009, the number of deaths from drug overdoses outnumbered the number of deaths from car accidents.²³¹ Here, like in the 1990s, a government agency needs to take drastic steps to redefine an industry. We need not wait for another celebrity death to spark radical changes in drug policy—the opioid crisis is taking thousands of American lives every year. HHS has the authority to make that change by amending its regulations. That change will protect American patients nationwide from opioids.

228. Federal Motor Vehicle Safety Standards, 42 Fed. Reg. 34289 (July 5, 1977).

229. *See, e.g., State Farm*, 463 U.S. 29.

230. *Seat Belt Use*, DEP'T TRANSP., <https://www.transportation.gov/mission/health/seat-belt-use> (last updated Feb. 2, 2016) [<https://perma.cc/6565-KBSE>].

231. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 5, at 3.