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ANNALS OF HEALTH LAW
Advance Directive

THE STUDENT HEALTH POLICY AND LAW REVIEW OF LOYOLA UNIVERSITY CHICAGO SCHOOL OF LAW

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Beazley Institute for Health Law and Policy

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ANNALS OF HEALTH LAW
Advance Directive

Editors' Note

The Annals of Health Law and Life Sciences is proud to present the first issue of the thirty second volume of our online, student-written publication, *Advance Directive*. This *Fall 2022 Advance Directive* Issue focuses on trending topics at the intersection of healthcare and the law.

The *Fall 2022 Advance Directive* Issue dives into a broad spectrum of topics within the current conversation taking place in the United States at the intersection of law and health care. First, it addresses the novel legal issues presented by the COVID-19 pandemic, including whistleblower retaliation claims regarding pandemic-related labor and employment violations. Then, it both discusses and proposes remedies for the pressing nationwide nursing shortage.

Next, articles in this Issue analyze longstanding problems plaguing United States health care, including cost, regulatory, and accessibility obstacles. The range of topics specifically covered includes: the implications of rising prescription drug costs and accompanying drug patenting processes; regulatory hurdles regarding the enforcement of hospital price transparency rules; and ways to ensure greater healthcare accessibility to DACA recipients. This wide range of topics exemplifies the diverse legal challenges and systemic barriers confronting healthcare in the United States today.

The Annals of Health Law members deserve special recognition for their hard work and dedication to the well-thought articles included in this Issue. We would also like to thank Micaela Enger, our *Annals* Editor-in-Chief, for her leadership and support. We would also like to thank and acknowledge our *Annals* Executive Board Members: Julian Caruso, Danielle Feingold, and Shivani Thakker for their efforts in producing this Issue. Lastly, we must thank the faculty at the Beazley Institute for Health Law and Policy, namely Professor Nadia Sawicki and Kristin Finn, for their continuous guidance and support.

We hope you enjoy this Issue of *Advance Directive*.

Sincerely,

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COVID-19 and Whistleblower Retaliation Claims: Expanding the Illinois Whistle Blower Act to Protect Employees

Paul Achkar

I. INTRODUCTION

Since the beginning of the COVID-19 pandemic, thousands of pandemic-related lawsuits have been filed against employers in response to alleged labor and employment violations.[1] Among these lawsuits are many whistleblower retaliation claims.[2] Prior to 2020, the Occupational Safety and Health Administration (OSHA) received an average of 1,948 whistleblower complaints each year.[3] From 2020 to 2022, OSHA and state affiliated programs received 8,898 COVID-19 related whistleblower complaints.[4] In response to the drastic increase in these types of claims, the State of Illinois should take steps to protect Illinois employees by finding ways to better address and accommodate COVID-19 related whistleblower and retaliatory firing claims. Greater protection can be achieved by expanding the scope of the Illinois Whistleblower Act (IWA), under which many whistleblower and retaliatory firing claims are pursued. The scope of the IWA should be expanded through incorporating claims that are recognized under Illinois common law, and by adding language that addresses whistleblower and retaliatory firing claims in the context of COVID-19.

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[1] Abbye E. Alexander et al., *Health care employers face rise in whistleblower claims during pandemic*, REUTERS (Feb. 24, 2022, 10:12 AM), https://www.reuters.com/legal/litigation/health-care-employers-face-rise-whistleblower-claims-during-pandemic-2022-02-24/.
[2] *Id*.
[3] *Id*.
[4] *Id*.

II. WHISTLEBLOWER CLAIMS GENERALLY

State and federal laws contain provisions that make it unlawful for employers to retaliate against employees "who exercise their protected legal rights or oppose unlawful employer actions."[5] Retaliation claims are fact-intensive and include complex federal, state, and local laws.[6] Generally, a claim of retaliation is established when an employee demonstrates that they engaged in a protected activity, their employer took an adverse action against him or her, and a causal connection exists between the protected activity and the adverse action.[7] Under Illinois Common Law, a prima facie case for retaliatory discharge is established when a plaintiff employee can show that (1) the employer discharged the employee, (2) the discharge was in retaliation for employee activities, and (3) the discharge violates a clear mandate of public policy.[8] In the context of the COVID-19 pandemic, there have been many claims that allege retaliation for "blowing the whistle", namely, objecting to or reporting unsafe working conditions and exposure to COVID-19 in the workplace.[9]

Employees raising concerns surrounding the availability of personal protective equipment, the implementation of facemask policies, or lack of COVID-19 related training has led to many claims of employer retaliation.[10] The increase in pandemic related whistleblowing and retaliation claims has led to an increase in lawsuits as well.[11] From March of 2020 to March of

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[5] Durga Bharam & Matthew O'Malley, *COVID-19 Related Whistleblower and Retaliation Claims*, FOR THE DEF., 44 (2021).
[6] *Id.*
[7] *See id.* (citing *Sweeney v. City of Ladue*, 25 F.3d 702, 703 (8th Cir. 1994)).
[8] Roberts v. Bd. of Trustees of Cmty. Coll. Dist. No. 508, 135 N.E.3d 891, 896 (Ill. 2019); Candice D. Bennett et al., *The Price of Getting Even: An Analysis of Employment-Related Retaliation Claims*, 17 IDC QUARTERLY at 2 (2007).
[9] Bharam, *supra* note 5.
[10] Lisa A. Lucido et al., *Top Ten Issues in Health Law 2022*, HEALTH L. CONNECTIONS (Jan. 1, 2022), https://www.americanhealthlaw.org/content-library/connections-magazine/article/d4c53b68-6b75-4a9f-a56c-5ed7122fc3b0/Top-Ten-Issues-in-Health-Law.
[11] *Id.*

2022, there were 5,659 lawsuits filed in the US against employers based on alleged labor and employment violations related to COVID-19, with at least 3,093 cases that involve retaliation claims.[12] During this period in Illinois, there were sixty-nine COVID-19 related retaliation claims and fourteen whistleblower claims.[13] While COVID-19 poses unique challenges for both employees and employers, employers have long been prohibited from retaliating against employees who raise safety concerns, and these protections still apply when employees raise concerns related to COVID-19.[14]

III. WHISTLEBLOWER CLAIMS UNDER THE ILLINOIS WHISTLE BLOWER ACT

In Illinois, many of the aforementioned whistleblower and retaliatory firing claims are protected under the Illinois Whistleblower Act (IWA).[15] The IWA, established in 2004, prohibits employers from retaliating against an employee for refusing to participate in or reporting an activity that would result in a violation of a state or federal law, rule, or regulation. [16] Generally, claims under the Act involve an employee who alleges they were fired in retaliation for externally reporting an employer's failure to adhere to a

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[12] Littler Mendelson, *COVID-19 Labor & Employment Litigation Tracker: March 2020-March 2022*, LITTLER NEWS & ANALYSIS (April 1, 2022), https://www.littler.com/publication-press/publication/covid-19-labor-employment-litigation-tracker.

[13] *Id.*

[14] Regina L. LaMonica & Sarah E. Flotte, *Illinois Guidance Underscores Whistleblower Protections as Employees Head Back to the Workplace During COVID-19*, PERKINS COIE NEWS AND INSIGHT (Aug. 6, 2022), https://www.perkinscoie.com/en/news-insights/illinois-guidance-underscores-whistleblower-protections-as-employees-head-back-to-the-workplace-during-covid-19.html.

[15] *Id.*

[16] Whistleblower Act, 740 ILL. COMP. STAT. 174/10 (2009); Jackson Lewis, *Whistleblower Act Creates New Liability For Illinois Employers*, JACKSON LEWIS PUBL'NS (Sep. 12, 2003), https://www.jacksonlewis.com/resources-publication/whistleblower-act-creates-new-liability-illinois-employers.

COVID-19 related law, rule, or regulation or, alternatively, allege they were terminated for refusing to participate in an activity that would result in such a violation.[17]

In *Brown v. Biomat USA, Inc.*, the U.S. District Court for the Northern District of Illinois reasoned that non-legislative executive orders that mandate COVID-19 policies qualify as rules under the IWA.[18] Biomat, a plasma donation center, employed Lavonce Brown, who received excellent performance reviews during this time and was promoted to Operational Supervisor.[19] After COVID-19 was declared a public health emergency in January 2020, Governor Pritzker issued an executive order pursuant to the Illinois Emergency Management Agency Act, mandating social distancing and other measures.[20] In March of 2020, Brown reported to the FDA that Biomat was not following the Executive Order's social distancing and capacity-reduction protocols.[21] Brown was terminated a month later and alleged this was because he reported Biomat's safety violations to the FDA.[22] Brown argued that this was a retaliatory firing in violation of the IWA.[23] The court rejected Biomat's arguments that an executive order did not qualify as a law, rule, or regulation under the IWA.[24] Additionally, no case law existed that allowed a plaintiff to assert an IWA claim after reporting an alleged violation of an executive order.[25] The court further reasoned that Brown's discharge violated a clear mandate of public policy such that Brown could state a claim of retaliatory discharge under Illinois law.[26]

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[17] *See* LaMonica & Flotte, *supra* note 14 (Describing the IWA in the context of COVID-19).
[18] Brown v. Biomat USA, Inc., No. 20-CV-05437, at *3 (N.D. Ill. July 28, 2021) (order granting motion to dismiss).
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *Id*. at *1
[23] Brown v. Biomat USA, Inc., No. 20-CV-05437, at *1 (N.D. Ill. July 28, 2021).
[24] *Id.*
[25] *Id*. at *2-*3.
[26] *Id*. at *5.

In the 2021 case, *Bradley Hotel Corp. v. Aspen Specialty Insurance Company*, the Seventh Circuit held that Governor Pritzker's executive order qualified as a "law" in the context of exclusion under an insurance policy.[27] While this case was unrelated to the IWA, the court's interpretation of the executive order as a law supports the *Brown* court's determination that the executive order satisfied the "law, rule, or regulation" requirement of the IWA. This case and *Brown* opened the door for COVID-19 mandate related whistleblower claims under the IWA.

IV. EXPANSION OF THE WHISTLEBLOWER ACT TO COVER INTERNAL CLAIMS

While COVID-19-related claims have been recognized under the IWA, certain types of claims may not be covered.[28] Before the IWA, whistleblower claims would be pursued under Illinois common law doctrine.[29] Common law whistleblower tort claims are much broader and allow for claims where an employee made a complaint internally to their employer.[30] Common law also covered claims where the subject of the complaint is a violation of internal company policy, rather than a state or federal regulation.[31] Under the IWA, there is no cause of action where an employee reveals information only to the employer.[32] This comparative narrowness of the IWA is

[27] Bradley Hotel Corp. v. Aspen Specialty Ins. Co., 19 F.4th 1002, 1008 (7th Cir. 2021).
[28] Sang-Yul Lee *et al.*, *The Illinois Whistleblower Act's Impact on Common Law Claims*, 97 Ill. B.J. 90, 91 (2009).
[29] *Id.* at 90.
[30] *Id.*
[31] *Id.*
[32] *Id.*; Zelman v. Hinsdale Twp. High Sch. Dist. 86, No. 10 C 00154, at *2 (N.D. Ill. Nov. 12, 2010) (holding that, under the IWA, there is no cause of action where an employee reveals information only to his or her employer).

problematic because Illinois courts provide no uniform guidance on IWA preemption of common law claims.[33]

The Illinois Supreme Court has yet to answer the question of whether the IWA codifies or preempts the common law retaliatory discharge cause of action for whistleblowing.[34] When the IWA preempts common law, internal violation complaints will not form a basis of a claim in Illinois.[35] In the context of COVID-19 claims, an employee may have great incentive to report safety concerns to their employer. In the 2020 case *Mazurkiewicz v. Northwestern Memorial Hospital*, a nurse was terminated from Northwestern Memorial Hospital after she sent an email to supervisors and co-workers stating N95 facemasks were safer and more effective than employer supplied masks.[36] The nurse, who had been exposed to patients with novel coronavirus, was terminated the following day and asserted a claim against the hospital for retaliatory discharge.[37] Initially making claims under both the IWA and common law retaliatory discharge, the plaintiff nurse agreed to voluntarily dismiss the claim under the IWA, with the court allowing the common law retaliatory discharge claim to proceed.[38]

To better protect Illinois employees after a pandemic and at a time of economic uncertainty, the IWA must be expanded to included internal complaints. Although there may be a claim under common law for cases like *Mazurkiewicz*, there are disadvantages to not being able to pursue a claim such as this under the IWA. Under common law, remedies include punitive

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[33] *Id*. at 92.
[34] Bennett supra note 8 at 6.
[35] Sang-Yul Lee et al., *supra* note 28.
[36] Mazurkiewicz v. Northwestern Mem. Hosp., No. 2020 L 3511, at *1 (D. Ill. Sept. 15, 2020) (order granting motion to dismiss).
[37] *Id*.; Melinda S. Kollross & Mara Goltsman, *Illinois Coronavirus Lawsuit Implicates Healthcare and Employment Practices Liability Concerns*, CLAUSEN MILLER NEWS (Apr. 6, 2020), https://www.clausen.com/illinois-coronavirus-lawsuit-implicates-healthcare-and-employment-practices-liability-concerns/.
[38] *Id*. at *1-*2.

damages and compensatory damages, such as future wages, back pay, and attorney fees.[39] Under the IWA, a successful claim can result in not only the same punitive and compensatory damages, but also in reinstatement with the same level of seniority they employee would have had the violation not occurred.[40] The opportunity for reinstatement under the IWA provides a valuable safeguard for employees who were legitimately retaliated against for expressing reasonable safety concerns during the uncertainty of a pandemic. This remedy also better serves the needs and goals of employees who raise concerns with the intention of increasing workplace safety. Whistleblowers who raise concerns internally want to improve their workplace rather than leave it or hamper it by reporting its actions to an outside agency.[41] Further, accommodating internal complaints and providing the remedy of reinstatement would not only benefit employees, but also further State goals of combating workplace shortages.[42] By extending the IWA to internal complaints, individuals with legitimate safety concerns can be incentivized to report unsafe conditions to their employers without fear of losing employment. Allowing employees to put their trust in superiors and express safety concerns will create safer workplaces where open dialogue and cooperation is encouraged, and safety issues can be addressed and

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[39] Sang-Yul Lee et al., supra note 28; *What You Need to Know About Retaliatory Discharge in Illinois*, L. OFF. OF MICHAEL T. SMITH & ASSOC. (Oct. 13, 2020) https://www.lawofficemichaelsmith.com/resources/blog/what-you-need-to-know-about-retaliatory-discharge-in-illinois/#:~:text=In%20Illinois%2C%20retaliatory%20discharge%20is,violates%20public%20and%20company%20policy.

[40] *Id*.; Whistleblower Act, 740 Ill. Comp. Stat. 174/30 (2009).

[41] *See* David I. Kelch, *Internal investigations: Their risks and benefits*, PORTER WRIGHT (Jul. 11, 2019), https://www.porterwright.com/media/internal-investigations-their-risks-and-benefits/ (highlighting the benefits of conducting an internal investigation in response to internal whistleblowing claims, including limiting government involvement).

[42] *See* Curtis Dubay, *How Fixing Our Worker Shortage Can Fight Inflation*, U.S. CHAMBER OF COMM. (July 7, 2022), https://www.uschamber.com/workforce/how-fixing-our-worker-shortage-can-fight-inflation (describing the private and public interest in reducing workplace shortages).

resolved internally. Empowering employees to advocate for safety could efficiently mitigate safety issues before involvement of outside entities, such as OSHA, is necessary. Further the exacerbation of workplace shortages, especially in sectors such as healthcare, can be limited through reinstatement remedies.

The plaintiff's abandoned claim under the IWA in *Mazurkiewicz* could be distinguished from other IWA claims where plaintiffs argue that the quality or effectiveness of masks is not a direct violation of a "law, rule, or regulation" under the IWA. Despite this distinction, the *Brown* court found social distancing requirements to be a rule under the IWA because they were included in Governor Pritzker's Executive Order.[43] Although mask wearing and quality of masks in hospitals were not part of this Executive Order and thus not a rule, it is possible that an employee in similar circumstances could interpret something such as mask wearing as a rule.[44]

Further, this IWA claim in the context of COVID-19 presents other novel questions. Section 15 of the IWA provides that an employer may not retaliate against an employee for reporting to a government or law enforcement agency information that the employee has *reasonable cause* to believe discloses a violation of a state or federal law, rule, or regulation.[45] There is the unexplored possibility that the nurse in *Mazurkiewicz* could have had reasonable cause to believe that the information she reported internally was in violation of a COVID-19 related law, rule, or regulation. Judicial interpretation of "reasonable cause" under the IWA could further extend protection to employees when no law, rule or regulation has been violated but there are countervailing COVID-19 safety concerns. Further, the

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[43] *See* Brown v. Biomat USA, Inc., No. 20-CV-05437, at *2 (N.D. Ill. July 28, 2021) (holding that the Governor's executive order constituted "rules" under the IWA).
[44] *See* Ill. Exec. Order No. 2020-10 (March 20, 2020) (including no provision regarding mask wearing or quality of masks).
[45] Whistleblower Act, 740 Ill. Comp. Stat. 174/15(b) (2009).

legislator could also change the language of the IWA to provide a clearer definition of what reasonable cause means in relation to COVID-19 mandates and what constitutes a law, rule, or regulation under the IWA.

The IWA also prohibits an employer from retaliating against an employee who refuses to participate in an activity that would result in a violation of a State or federal law, rule, or regulation.[46] In *Sharenow v. Drake Oak Brook Resort LLC*, the U.S. District Court for the Northern District of Illinois held that an employee who was fired for refusing to participate in an activity that would violate Illinois Department of Commerce and Economic Opportunity (DCEO) COVID-19 guidelines had a sufficient claim under the IWA.[47] In this case, the Plaintiff, Sharenow, refused to book wedding events with more than fifty guests per DCEO guidelines, despite her employer insisting otherwise, and was fired.[48] The court held that Sharenow made a sufficient claim under the IWA for retaliatory discharge, agreeing with the argument that violating the DCEO guidelines would result in a violation of a state or federal law, rule, or regulation.[49]

As displayed in *Sharenow*, Section 20 of the IWA allows for a retaliation claim when there has been no external reporting to a government or law enforcement agency.[50] Therefore, it is not inconsistent with the current function of the IWA if the statute is expanded to include claims related to internal complaints. Afterall, refusal to engage in an activity required by the employer is internal in nature and similar to an employee filing an internal complaint related to health and safety concerns. Incorporating such a

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[46] *Id*.
[47] Sharenow v. Drake Oak Brook Resort LLC, No. 20 CV 06337, at *3 (N.D. Ill. July 13, 2022) (order denying motion to dismiss).
[48] *Id*. at *1.
[49] *Id*. at *2.
[50] *See* 740 Ill. Comp. Stat. 174/20 (2009) (having no language related to COVID-19).

provision to the IWA will expand employee protection and encourage employees to express concerns directly to their employers.

V. LOOKING TO OTHER LAWS AND REGULATIONS TO EXPAND WHISTLEBLOWER PROTECTIONS

The IWA could provide greater protections for employees by incorporating COVID-19 specific language. The IWA does not mention COVID-19 and has been interpreted to extend to COVID-19 related claims by Illinois courts.[51] By amending the IWA to include COVID-19 specific language, legislators could offer more guidance to the courts when they are tasked with making unprecedented fact-specific judicial determinations in interpreting legislation, such as the IWA, that predates the existence of COVID-19. Other ordinances, state law, and proposed federal law could be used as guidance for developing language to add to the IWA.

In Illinois, the city of Chicago created a COVID-19 anti-retaliation ordinance that prohibits employers from retaliating against employees for obeying an order issued by the Mayor, Governor, Chicago Department of Public Health, or healthcare provider having to do with COVID-19.[52] While this ordinance is concerned with retaliation due to an employee obeying a quarantine order or providing care to someone obeying such an order, it could serve as a model for a corresponding state law.[53] Similarly, the Employee Protections in Connection with COVID-19 Emergency Health Order by the City of Philadelphia provides COVID-19 specific employee protections.[54] The order prohibits retaliation against employees who disclose information related to employer non-compliance with COVID-19 public-health order or

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[51] *See generally* Brown v. Biomat USA, Inc., No. 20-CV-05437, at *2 (N.D. Ill. July 28, 2021) (allowing a COVID-19 related claim to proceed under the IWA).
[52] Chicago, IL., Ordinance 2020-2343 (July 1, 2020).
[53] *Id*.
[54] Philadelphia, Pa., Ordinance 200328 (June 12, 2020).

refuse to work in unsafe conditions related to COVID-19.[55] Adding language to the IWA that addresses COVID-19 whistleblowing retaliation, as well as clarifying aforementioned IWA language as it relates to COVID-19, could provide another avenue for claims that may not currently be covered or are deserving of adequate recourse under the IWA.

Guidance for how to incorporate this language may also be found by evaluating COVID-19 related amendments implemented in other states. In New York, the state amended a whistleblower law, Section 740 of the Labor Law, effective January of 2022.[56] Previously, Section 740 provided narrow whistleblower rights, prohibiting retaliation only against employees who complained of practices that actually constitute a "substantial and specific danger to the public health or safety."[57] With the 2022 amendment in effect, employers are prohibited from retaliating against an employee for disclosing or threatening to disclose *any* conduct that they reasonably believe violates any law, rule, or regulation, executive order, or any judicial or administrative decision, ruling, or order; or that they reasonably believe constitutes a substantial and specific danger to the public health or safety.[58] This language is similar to the "law, rule, or regulation" requirement under the IWA, but New York's whistleblower laws go a step further.[59] Under the newly amended Section 740, executive orders are explicitly included in the definition of laws rules and regulation, answering a question for the judiciary that Illinois courts have recently grappled with in cases such as *Brown v.*

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[55] *Id.*
[56] N.Y. Lab. Law § 740 (2022).
[57] Philip Berkowitz & Jeanie Conley Daves, *New York Dramatically Expands Whistleblower Rights*, LITTLER NEWS & ANALYSIS, (Nov. 10, 2022), https://www.littler.com/publication-press/publication/new-york-dramatically-expands-whistleblower-rights.
[58] *Id*.
[59] 740 Ill. Comp. Stat. 174/10 (2009).

Biomat USA, Inc.[60] Additionally, under Section 740, the complained of conduct does not need to constitute a public health or safety risk or violate a law rule, or regulation; the employee needs only to have a reasonable belief that the conduct is unlawful or dangerous, and do not have to be correct in that belief to be protected against retaliation.[61] Under this lowered standard, a case in New York containing facts analogous to *Mazurkiewicz* can result in a sufficient whistleblower claim despite no law, rule, or regulation being violated. This language in the New York law is more accommodating of COVID-19 related cases where there is no violation of a law, rule, or regulation but countervailing public health and safety concerns are present.

These amendments to Section 740 have only recently gone into effect and courts have not yet ruled on cases that turn on the provisions in the new amendments.[62] Illinois legislators should watch New York cases under this amendment with careful interest. The IWA is similar to New York's whistleblower law and if time shows that Section 740's amendments help to accommodate the rise in whistleblower claims, increase employee protection, or make for safer and healthier workplaces, Illinois should look to amend its own whistleblower and anti-retaliation laws in the same manner as New York.

Legislation that has been introduced by Congress in the House of Representatives could also offer guidance for how to amend the IWA. The Whistleblower Protection Act was introduced in the House of Representatives in February of 2021 and provides whistleblower protections for government contractors and private sector workers who may witness

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[60] N.Y. Lab. Law § 740(1)(c) (2022); *See* Brown v. Biomat USA, Inc., No. 20-CV-05437, at *3 (N.D. Ill. July 28, 2021) (holding that COVID-19 related executive orders are rules under the IWA).
[61] Berkowitz & Daves, *supra* note 57.
[62] Rachel E. Greene, *Updates: New York Whistleblower Law Expansions During COVID-19*, NAT'L L. REV. (June 21, 2020) https://www.natlawreview.com/article/updates-new-york-whistleblower-law-expansions-during-covid-19.

waste, fraud, or experience misconduct related to a COVID-19 related program.[63] The bill would prevent employers from discharging, demoting, or discriminating against employees who "disclose information concerning fraud, misuse, or other misconduct related to COVID-19 program funds.[64] While this bill is orientated towards workplaces were government funding is involved, it provides a template for whistleblower law that specifically addresses COVID-19. Section 3 of the bill provides: "A protected individual may not be discharged . . . for disclosing . . . information that the protected individual reasonably believes is evidence of misconduct that violates, obstructs, or undermines any statute, rule, or regulation with respect to any Coronavirus pandemic-related program."[65]

In amending the IWA, this language could be used more generally without tying it to federal funding. The "statute, rule, or regulation" language used in this bill is similar to the "law, rule, or regulation" language in Section 10 of the IWA. A COVID-19 specific provision added to the IWA could mirror the language, intent, and function of Section 10 of the IWA. Adding this more specific language could help to guide the courts in determining if common law or the IWA should apply, and more employees would be offered the benefit of reinstatement under the IWA rather than being limited to common law remedies.

VI. CONCLUSION

As the law in the United States continues to catch up with the consequences of the COVID-19 pandemic, employee rights and safety

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[63] Cong. Rsch. Serv., *H.R.846 – COVID-19 Whistleblower Protection Act, Summary*, CONGRESS.GOV, https://www.congress.gov/bill/117th-congress/house-bill/846, (last visited Oct. 21, 2022).
[64] *Id*.
[65] H.R. 846, 117th Cong. § 3 (2021).

should be prioritized in the changing landscape of health and labor law. To accommodate the rise in whistleblower cases, Illinois should reevaluate its whistleblower and anti-retaliation laws in the context of COVID-19 to best protect employees, their rights, and their safety in the workplace. This could be achieved by expanding the scope of the IWA to cover complaints made internally to the employer and by explicitly expanding the meaning of a "law, rule, or regulation" under the act. Additionally, the IWA could be amended to add language that specifically addresses whistleblower claims in the context of COVID-19 to better guide the judiciary and more effectively accommodate the many unique circumstances that could lead to whistleblower retaliation caused by an unprecedented pandemic. In the wake of COVID-19, Illinois should put employees first by reevaluating laws that predate the pandemic to protect those who expose themselves to potential harm in trying to challenge unlawful employer actions or advocate for greater workplace safety.

Illinois' Nursing Crisis: Applying the State's Behavioral Health Approach to the Nursing Shortage

Grace Connelly

I. INTRODUCTION

The COVID-19 pandemic placed an extreme burden on the healthcare workforce nationwide, and consequently caused labor shortages throughout the healthcare industry.[1] Illinois, in particular, presently faces a shortage of healthcare workers, including behavioral health workers[2] and nurses.[3] Despite the labor shortages, more people are seeking mental health care than ever before, which further strains the workforce.[4] Accordingly, to combat behavioral health worker shortages in Illinois, Governor J.B. Pritzker signed Senate Bill 3617 (SB 3617) into law in June 2022.[5] Like the shortage of behavioral health workers, a nursing shortage existed before the pandemic; however, the aggravated problem is now at the forefront of nationwide discussions.[6] Therefore, Illinois needs to take initiative and address the nursing shortage akin to the way it took steps to ameliorate the behavioral health worker shortage. First, this article will discuss how SB 3617 addresses

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[1] *Impact of the COVID-19 Pandemic on the Hospital and Outpatient Clinician Workforce*, ASSISTANT SEC'Y FOR PLAN & EVALUATION (May 3, 2022), https://aspe.hhs.gov/sites/default/files/documents/9cc72124abd9ea25d58a22c7692dccb6/aspe-covid-workforce-report.pdf (explaining that COVID-19 caused extreme stress to the health care workforce in the entire United States).

[2] *Addressing Illinois' Behavioral Health Workforce Shortage*, BEHAV. HEALTH & ECON. NETWORK. https://www.bhecon.org/wp-content/uploads/2019/06/IL-Workforce-Fact-Sheet.pdf (last visited Sept. 16, 2022).

[3] Karen B. Lasater et al., *Chronic Hospital Nurse Understaffing Meets COVID-19: An Observational Study*, 30 BMJ QUALITY & SAFETY 639, 643-45 (2020) (discussing Illinois' shortage of behavioral health workers and nurses).

[4] *Worsening mental health crisis pressures psychologists workforce*, AM. PSYCH. ASS'N (Oct. 19, 2021), https://www.apa.org/pubs/reports/practitioner/covid-19-2021.

[5] S.B. 3617, 102nd Gen. Assemb., Reg. Sess. (Ill. 2022); *Bill Status of SB3617*, Ill. Gen. Assemb., https://www.ilga.gov/legislation/BillStatus.asp?DocNum=3617&GAID=16&DocTypeID=SB&SessionID=110&GA=102 (last visited Oct. 10, 2022).

[6] Lasater et al., *supra* note 3, at 639.

the shortage of behavioral healthcare workers. Next, it will discuss the nursing shortage and the lack of remedial action. Finally, this article will propose legislation that, like SB 3617's attempts to combat the behavioral healthcare worker shortage, aims to rectify the nursing shortage crisis plaguing Illinois.

II. BACKGROUND AND ILLINOIS SENATE BILL 3617

In 2019, the United States' behavioral health workforce could only care for approximately 22% of the population's needs.[7] Notably, in Illinois, 38% of the population lives in an area where there is a shortage of behavioral health professionals.[8] Additionally, the COVID-19 pandemic decreased the number of behavioral health providers while increasing the need for mental health services.[9] In 2021, psychologists reported that they were treating depression and anxiety at a much higher rate than prior to the pandemic.[10] With the mental health crisis growing and suicide continually being a leading cause of death in the United States,[11] behavioral health workers are needed now more than ever.

SB 3617 provided general findings about the behavioral health workforce shortage[12] to highlight the urgent need for change in Illinois.[13] In particular, the bill explained that although the behavioral health provider shortage

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[7] *See Mental Health Care Professional Shortage Areas (HPSAs)*, KAISER FAM. FOUND., https://www.kff.org/other/state-indicator/mental-health-care-health-professional-shortage-areas-hpsas/ (last updated Sept. 30, 2022) (noting the mental health care health professional shortages in each state).
[8] *Addressing Illinois' Behavioral Health Workforce Shortage*, *supra* note 2.
[9] Stacy Weiner, *A growing psychiatrist shortage and an enormous demand for mental health services*, ASS'N OF AM. MED. COLL. (Aug. 9, 2022), https://www.aamc.org/news-insights/growing-psychiatrist-shortage-enormous-demand-mental-health-services.
[10] *Worsening mental health crisis pressures psychologists workforce*, *supra* note 4.
[11] *Suicide*, NAT'L INST. OF MENTAL HEALTH (June 2022), https://www.nimh.nih.gov/health/statistics/suicide.
[12] Ill. S.B. 3617 §1-5 (discussing findings about behavioral health workforce shortage).
[13] *Governor Pritzker Signs Legislation Increasing Mental Health Workforce in Illinois* (June 10, 2022), https://www.illinois.gov/news/press-release.25035.html.

existed before the pandemic, the pandemic immensely aggravated the problem.[14] According to Mercer's 2021 External Healthcare Labor Market Analysis, Illinois will likely face over 8,000 job vacancies in the mental health workforce by 2026.[15] The Illinois General Assembly also reported challenges in finding supervision for training and noted that fees complicate the licensure process for many individuals.[16] To address the crisis, SB 3617 took various steps, including waiving certain fee requirements for licensure and providing funding for training and supervising programs, to both ease licensure for behavioral health professionals and increase the number of providers.[17]

Specifically, SB 3617 provided grants to mental health centers and clinics to enhance professional development, training, and supervision for interns.[18] The grants strive to "establish new, or enhance existing, training, and supervision of interns and behavioral health providers-in-training."[19] Moreover, SB 3617 removed barriers to those wishing to re-enter the behavioral health workforce, such as no longer requiring continuing education credits, additional certifications and fee payments.[20] Additionally, under SB 3617, clinical professionals who obtained their license in another U.S. jurisdiction were no longer required to provide proof of completion of education or supervised employment.[21] This change made it more flexible

[14] Ill. S.B. 3617 §1-5(1).
[15] *Id.* at §1-5(3) (discussing the potential vacancies in the Illinois behavioral health workforce).
[16] *Id*. at §1-5(5) (discussing obstacles new behavioral health care professionals face with supervision fees).
[17] *Id.*
[18] *Id.* at §1-10 (discussing the new grants for student training and supervision).
[19] Ill. S.B. 3617 §1-15(a) (discussing the requirements eliminated by SB 3617).
[20] *Id.* at §5-15(a), §5-15(h).
[21] *Id.* at §15-20 (discussing flexibility for out-of-state practitioners).

for out-of-state professionals to practice in Illinois.[22] Professionals whose licenses have lapsed in the past five years were also able to be reinstated so long as they have not faced disciplinary action.[23] Accordingly, SB 3617 implemented the aforementioned measures to both increase access to care and ease the behavioral health worker crisis.[24]

III. THE NURSING SHORTAGE

Akin to the behavioral health provider shortage, the nursing shortage existed long before the COVID-19 pandemic,[25] but COVID-19 aggravated the problem.[26] While there is no single definition for what constitutes a nursing shortage, there are common indicators,[27] including self-reported shortage statuses by hospital chief executive officers and the vacancy rates of nursing jobs.[28] In particular, in 2020, the American College of Healthcare Executives (ACHE) surveyed hospital executives regarding personnel shortages.[29] 81 percent of the executives surveyed listed registered nursing staff shortages among their top three staffing concerns.[30] Moreover, in 2021, 62 percent of U.S. hospitals reported a vacancy rate among nursing positions

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[22] *Id.*
[23] *Id.* at §13(b).
[24] *Governor Pritzker Signs Legislation Increasing Mental Health Workforce in Illinois*, *supra* note 13.
[25] Rebekah L. Fox PhD & Kathleen Abrahamson PhD, RN, *A Critical Examination of the U.S. Nursing Shortage: Contributing Factors, Public Policy Implications*, 44 NURSING FORUM 235, 244 (2009) (discussing the decades-long nursing shortage).
[26] Lasater et al., *supra* note 3 (discussing how COVID-19 exacerbated the existing nursing shortage).
[27] Kristin M. Mannino, *The Nursing Shortage: Contributing Factors, Risk Implications, and Legislative Efforts to Combat the Shortage*, 15 LOY. CONSUMER L. REV. 143, 145 (2003).
[28] *Id.* at 145.
[29] *Addressing Personnel Shortages in Hospitals*, AMER. COLL. OF HEALTHCARE EXEC. (2020), 2, https://www.ache.org/-/media/ache/learning-center/research/2020-ceo-circle-white-paper.pdf (analyzing the nursing shortage in 2020).
[30] *Id.*

above 7.5 percent.[31] These rates are indicative of a nursing shortage.[32] In 2009, Rebekah Fox, Assistant Professor of Communication Studies at Texas State University, also listed the following factors as influencing the shortage: demographic factors, nursing education, nursing work, and nursing wages.[33] The demand for more healthcare services and an increase in the number of people with insurance coverage also contributed to the shortage of nurses.[34] The common indicators make it evident that there is a shortage of nursing staff.

The U.S. was faced with widespread nursing burnout and understaffing in hospitals prior to the start of the pandemic.[35] Nursing burnout is likely to continue to complicate the nursing staffing hardships by resulting in nurses opting to leave their jobs.[36] In March 2022, McKinsey, a global management consulting firm,[37] surveyed nurses and found that 29 percent of the survey participants were likely to leave their jobs in direct patient care, and 15 percent said they were leaving the nursing profession

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[31] *Registered Nurse Vacancy Rate in U.S. Based Hospitals 2021*, STATISTA (Aug. 6, 2021), https://www.statista.com/statistics/1251419/vacancy-rate-of-registered-nurses-in-hospitals-in-the-united-states.
[32] *See* Mannino, *supra* note 27, at 145 (listing common indicators of a nursing shortage); *see also Addressing Personnel Shortages in Hospitals*, *supra* note 29, at 2 (indicating that hospital executives have reported personnel shortages); *see also Registered Nurse Vacancy Rate in U.S. Based Hospitals 2021*, *supra* note 31 (reporting rates of nurse vacancies).
[33] Fox & Abrahamson, *supra* note 25, at 238-39 (discussing factors increasing the nursing shortage).
[34] Anthony P. Carnevale et al., *Nursing Supply and Demand Through 2020*, GEO. UNIV. CTR. ON EDUC. & THE WORKFORCE, 2, 7 (2015).
[35] Lasater et al., *supra* note 3, at 640.
[36] *Id.* at 639.
[37] *McKinsey & Company*, DEVEX, https://www.devex.com/organizations/mckinsey-company-24493 (last visited Oct. 31, 2022) (explaining what McKinsey & Company is).

completely.[38] By 2025, Illinois is predicted to have a shortage of about 15,000 nurses.[39]

The increased need for mental health services prompted psychologists to address the shortage of behavioral health workers,[40] which subsequently engendered state action to try to alleviate the nursing shortage.[41] Moreover, the nursing shortage must be addressed because of the detrimental impact it has on patient care and safety.[42] Since the early 2000s, studies have shown that nursing understaffing affects the quality of care that patients receive.[43] A 2002 study published by the New England Journal of Medicine found that a greater number of hours of nursing care received by patients correlated to lower rates of poor health outcomes.[44] More recently, a 2019 study concluded that low registered nurse staffing levels are associated with fewer interactions between nurses and patients in addition to lower quality interactions.[45] When hospitals are short-staffed, nurses often work overtime which leads to more nursing errors and adverse patient outcomes.[46] Notably, errors occurring as a result of understaffing have the

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[38] Gretchen Berlin et al., *Assessing the lingering impact of COVID-19 on the nursing workforce*, MCKINSEY & CO. (May 11, 2022), https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/assessing-the-lingering-impact-of-covid-19-on-the-nursing-workforce.
[39] *ANA- Illinois Calls For Action On Nursing Shortage at Illinois Senate Health Committee Meeting*, AM. NURSES ASS'N ILL. (Apr. 4, 2022), https://www.ana-illinois.org/news/ana-illinois-calls-for-action-on-nursing-shortage-at-illinois-senate-health-committee-meeting.
[40] *Worsening mental health crisis pressures psychologists workforce*, *supra* note 4.
[41] *Governor Pritzker Signs Legislation Increasing Mental Health Workforce in Illinois*, *supra* note 13 (citing Representative Deb Conroy who discussed the strain on the mental health workforce trying to meet demands).
[42] Lasater et al., *supra* note 3, at 640 (noting that nurse understaffing has public health impacts include patient safety risks).
[43] Jack Needleman et al., *Nurse-Staffing Levels and the Quality of Care in Hospitals*, 346 NEW ENG. J. MED. 1715, 1718 (2002); *see also* Jackie Bridges et al., *Hospital Nurse Staffing & Staff-Patient Interactions: An Observation Study*, 28 BMJ QUALITY & SAFETY 706, 711 (2019) (discussing how nursing shortages can impact the quality of patient care).
[44] Needleman et al., *supra* note 43, at 1718.
[45] Bridges et al., *supra* note 43, at 711.
[46] Ann E. Rogers et al., *The Working Hours of Hospital Staff Nurses and Patient Safety*, 23 HEALTH AFF. 202-03, 210 (2004) (discussing the greater risk of error by nurses who work long hours due to understaffing).

potential to contribute to malpractice suits.[47] The nursing staff shortage presents risks to patients and alleviating the staff shortage in the nursing industry is likely to help hospitals and health systems prevent avoidable legal consequences. Illinois addressed the behavioral health worker shortage, citing that it "threatens access to care, increases hospital stays, and contributes to an overuse of the legal system"[48] and similar threats are present in the nursing industry, warranting needed change.

IV. PROPOSAL FOR ILLINOIS LEGISLATION

Proposed legislation to address Illinois' nursing shortage includes (1) the elimination or minimization of continuing education requirements for nurses wishing to re-enter the workforce; (2) membership in the Nurse Licensure Compact; and (3) dedicating grants and funding for nursing education.

As SB3617 illustrated, it is possible to minimize or eliminate continuing education requirements for health professionals that are re-entering the workforce.[49] Similarly, to help address the nursing shortage, Illinois should permanently adopt the continuing education waiver that was issued as part of the Gubernatorial COVID-19 Disaster Proclamation.[50] The waiver allows nurses that are re-entering the workforce to reinstate their license without

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[47] Mannino, *supra* note 27, at 157 (explaining there is evidence available to courts that demonstrate the connection between fewer nurses and adverse patient outcomes which can lead to patient malpractice claims).
[48] *Addressing the Behavioral Health Workforce Crisis in Illinois*, ILL. DEP'T OF HUM. SERV., https://www.dhs.state.il.us/page.aspx?item=137782 (last visited Nov. 3, 2022).
[49] S.B. 3617, 102nd Gen. Assemb. Reg. Sess. §5-15(h) (Ill. 2022) (suspending previous requirements for license reinstatement); *see also* S.B. 3617, 102nd Gen. Assemb. Reg. Sess. §5-15(a) (Ill. 2022) (explaining continuing education requirement for license reinstatement).
[50] Deborah L. Gersh et al., *Reinstatement of Illinois Medical & Other Health Care Licenses & the Introduction of Temporary Practice Permits for Out-of-State Practitioners*, ROPES & GRAY, https://www.ropesgray.com/en/newsroom/alerts/2020/04/Illinois-Medical-License-Reinstatement-COVID-19 (April 3, 2020).

meeting various continuing education requirements, as long as their license had lapsed within the past five years.[51]

Waiving the continuing education requirement for nurses who want to re-enter the workforce would remove a barrier that may be preventing nurses with inactive licenses from re-entering the workforce. Continuing education can be a barrier to nurses with inactive licenses due to costs, lack of time, scheduling issues, or lack of knowledge about available opportunities.[52] SB 3617 removes continuing education requirements for behavioral health workers looking to re-enter the workforce if less than five years have passed since their license has expired.[53] Similar to SB 3617, Illinois legislation should recognize the need to remove barriers to re-entering the workforce for healthcare professionals and remove continuing education requirements for nurses wanting to reinstate their licenses.

The ability to make this change is feasible, as it is already integrated into the March 19, 2020 Executive Order 2020-09.[54] The Executive Order waives the continuing education requirement for registered nurse licensure reinstatement.[55] Illinois legislators must make this a permanent change so more nurses are able to re-enter the workforce and begin to alleviate the staffing shortage. While continuing education is important for nurses to develop their skills and expertise,[56] waiving the requirement will only apply to nurses whose licenses have lapsed within the past five years. Further,

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[51] *Id.*
[52] Jacqueline A. Dean, *Perceived Benefits of and Barriers to Continuing Education Among Hospital Employed Registered Nurses* (June 2, 2004) (M.S.N. thesis, Grand Valley State University) (on file with Grand Valley State University Libraries) at 9.
[53] S.B. 3617 §5-10(b).
[54] Gersh et al., *supra* note 50.
[55] *See id.* (explaining that Executive Order 2020-09 waived the continuing education requirement for licensure reinstatement).
[56] Ann Feeney, *The Nurse's Guide to Continuing Education*, NURSE J., https://nursejournal.org/resources/nurses-continuing-education-guide/ (last updated Aug. 29, 2022).

Illinois requires nurses to receive continuing education while working;[57] hence, nurses will still receive necessary education once their licenses have been reinstated. By making this change, Illinois would make it easier for nurses whose licenses have lapsed within the past five years to work as a nurse again.

To prevent experienced nurses who have been licensed outside of Illinois from having to undergo further licensure to practice in Illinois, Illinois legislation should adopt membership in the Nurse Licensure Compact.[58] The Nurse Licensure Compact provides nurses the ability to obtain a singular nursing license that allows them to practice in other states that are part of the Compact.[59] Presently, there are thirty-nine participating states.[60] Illinois legislators have proposed membership of the Nurse Licensure Compact since 2017 but have continually faced opposition.[61] The opposition mainly comes from nurses' labor unions that are concerned that joining the Nurse Licensure Compact will result in out-of-state nurses easily replacing in-state nurses.[62] The understaffing crisis, however, must be addressed to ensure patient and

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[57] *Illinois RN Continuing Education Frequently Asked Questions (FAQs)*, ILL. DEP'T OF FIN. & PRO. REGUL., https://nursing.illinois.gov/PDF/2021-01_IL_RN_CE_Relicensure_FAQ.pdf (last visited Nov. 3, 2022) (explaining that all nurses must complete continuing education to renew their Illinois licenses).

[58] *Nurse Licensure Compact*, NAT'L COUNCIL OF STATE BD. OF NURSING, https://www.ncsbn.org/compacts/nurse-licensure-compact.page (last visited Oct. 11, 2022) (showing that Illinois is pending NLC legislation).

[59] *Nurse Licensure Compact*, NURSECOMPACT.COM, https://www.nursecompact.com/files/Updated_onepaged_NLC.pdf (last visited Oct. 11, 2022).

[60] *Id.* (showing that there are thirty-nine member states as of October 2022).

[61] *Healthcare License Compacts in Illinois: Where We Are, Where We're Going*, JACKSON LLP, https://jacksonllp.com/healthcare-license-compacts-illinois/ (last visited Nov. 3, 2022).

[62] Joe Tabor, Chicago's COVID-19 Nurse Shortage Shows Why Illinois Must Join the Nurse Licensure Compact, ILL. POL'Y (Aug. 19, 2021) https://www.illinoispolicy.org/chicagos-covid-19-nurse-shortage-shows-why-illinois-must-join-nurse-licensure-compact/ (explaining the opposition to Illinois joining the Nurse Licensure Compact mainly comes from labor unions).

nurse safety and membership of the Nurse Licensure Compact makes it easier for more nurses to practice in Illinois, and the shortage makes it clear that there are positions for both in-state and out-of-state nurses, [63] showing that the benefits of membership outweigh the potential competitive drawbacks.

There is currently pending legislation in Illinois regarding potential membership.[64] By passing the proposed bill and making Illinois a member of the Nurse Licensure Compact, Illinois can mitigate the shortage by making it easier for out-of-state nurses to practice in Illinois. Membership can be easily adopted by Illinois, as the idea has already been introduced to legislators.[65] HB4269 was first introduced to the Illinois House of Representatives in January 2022.[66] To become a member of the Nursing Licensure Compact, Illinois could incorporate the model legislation provided by the National Council of State Boards of Nursing (NCSBN) into this bill addressing the nursing shortage.[67]

Overall, like SB 3617's approach to mitigating the shortage of behavioral health workers by accelerating the process for out-of-state behavioral health workers to get their Illinois license, state membership in the Nurse Licensure Compact would make it easier for out-of-state nurses to practice in Illinois.[68]

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[63] *Illinois Grappling with Nurse Shortage which Officials Say Will Get Worse*, 97.7 WMOI (Sept. 20, 2022) https://977wmoi.com/2022/09/illinois-grappling-with-nurse-shortage-which-officials-say-will-get-worse/ (quoting Susan Swart, the executive director of the Illinois Nurses Foundation, as projecting that Illinois will be short 15,000 nurses by 2025).
[64] *Bill Status of HB4269*, Ill. Gen. Assemb., https://www.ilga.gov/legislation/billstatus.asp?DocNum=4269&GAID=16&GA=102&DocTypeID=HB&LegID=137325&SessionID=110 (last visited Oct. 11, 2022).
[65] *Id. (*demonstrating that the bill allowing Illinois to join the Nurse Licensure Compact has been introduced to the Illinois House of Representatives).
[66] *Id.* (indicating that the first reading of the proposed bill was in January 2022).
[67] *Nurse Licensure Compact*, NAT'L COUNCIL OF STATE BD. OF NURSING, https://www.ncsbn.org/compacts/nurse-licensure-compact.page (last visited Oct. 11, 2022); *see also NLC Model Legislation*, NAT'L COUNCIL OF STATE BD. OF NURSING, https://www.ncsbn.org/public-files/NLC_Final_050415.pdf (last visited Oct. 11, 2022) (proposing model legislation for state membership of the Nurse Licensure Compact).
[68] *Nurse Licensure Compact*, *supra* note 59 (explaining that the NLC gives nurses the ability to have one license that allows them to practice in member states without obtaining additional licenses).

In doing so, Illinois would expand the number of nurses eligible to work in the state.[69]

Illinois legislation should also include investments in nursing education programs, like SB 3617 does for behavioral health.[70] SB 3617 provides funds to be used to "establish new, or enhance existing, training, and supervision of interns and behavioral health providers-in-training" to build a stronger workforce.[71] Proposed legislation provides grants and awards dedicated to enhancing existing training and creating new training through expanded clinical placement opportunities for nursing students. Grants and awards should also be utilized to adequately pay nurse preceptors to train and supervise students.

Not only is there a shortage of nurses, but there is also a shortage of nurse preceptors.[72] Nurse preceptors are registered nurses who supervise nursing students or new graduates.[73] Without enough nurses, there are not enough preceptors.[74] The shortage of preceptors leads to fewer students receiving clinical placements for hands-on training.[75] The lack of clinical placements can lead to fewer nursing students.[76] By emulating the funding provisions of

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[69] *Urge IL House Legislators to Support & Cosponsor Nurse Licensure Compact Legislation HB 4269*, ILL. HEALTH & HOSP. ASS'N, (Feb. 14, 2022), https://www.team-iha.org/advocacy-policy/state-issues/advocacy-tab-(1)/urge-il-house-legislators-to-support-hb-4269 (explaining that Illinois' membership in the NLC would increase access to nurses in the state).

[70] S.B. 3617, 102nd Gen. Assemb. Reg. Sess. §1-15 (Ill. 2022).

[71] *Id.*

[72] Marina Zhavoronkova et al., *How to Ease the Nursing Shortage in America*, THE CTR. FOR AM. PROGRESS (May 23, 2022), https://www.americanprogress.org/article/how-to-ease-the-nursing-shortage-in-america/.

[73] *Id.* (explaining the role of nurse preceptors).

[74] *Id.* (discussing how the shortage of nurse preceptors contributes to the nursing shortage).

[75] *Id.*

[76] *Id.*; *see also Preparing Nurse Faculty, & Addressing the Shortage of Nurse Faculty and Clinical Preceptors*, NAT'L ADVISORY COUNCIL ON NURSE EDUC. & PRAC. 8, 5 (Jan. 2021), https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/nursing/reports/nacnep-

SB 3617, Illinois legislation can grant funds to health care institutions in order to enhance nursing preceptor programs and alleviate the nursing shortage.

Illinois should allocate funding to hospitals, health systems, and nursing programs to provide clear paths for certified nursing assistants (CNAs) to become registered nurses. CNAs work under registered nurses and provide basic patient care, such as bathing patients, checking vitals, and helping patients move.[77] Registered nurses are able to provide more sophisticated patient care and report to doctors.[78] Most CNAs do not go on to become nurses.[79] By specifically including funding for programs to be implemented that give CNAs clear steps to further their education and become nurses, the nursing shortage can be eased.[80]

Further, funding should be used to pay nurse preceptors to train and supervise students. Currently, nurse preceptors usually do not get paid any more than their normal wage to train and supervise nurses.[81] By appropriately compensating preceptors for their training, there will likely be more nurses willing to take on these responsibilities.[82] As a result, there will be more clinical placement opportunities and nursing programs will have capacity to educate more students.[83] With greater enrollment capacity in

17report-2021.pdf (explaining how the lack of nursing educators leads to the decrease in nurses).

[77] Maureen Malone, *The Difference Between Certified Nurses Assistant & Registered Nurse*, CHRON (Feb. 10, 2022), https://work.chron.com/difference-between-certified-nurses-assistant-registered-nurse-3630.html.

[78] *Id.*

[79] Iris Palmer, *We need to fix the broken nursing career pathway—here's how*, NEW AM. (April 5, 2021), https://www.newamerica.org/education-policy/edcentral/we-need-to-fix-the-broken-nursing-career-pathwayheres-how/ (citing a California study that found only about 20 percent of CNAs go on to become RNs).

[80] Zhavornokova et al., *supra* note 72.

[81] *Id.*

[82] *Id.*(suggesting that more pay may be needed to encourage more nurses to serve as preceptors).

[83] *See id.*(explaining that the shortage of nurse educators causes a shortage of clinical placements and increased pay is a potential solution).

nursing programs, there will be more nurses graduating and entering the workforce, remedying some of Illinois's problem.[84]

V. CONCLUSION

The COVID-19 pandemic has detrimentally impacted the healthcare workforce, including behavioral health workers and nurses.[85] Nursing shortages lead to poor patient outcomes and, often times, medical errors.[86] Illinois took steps to mitigate the shortage of behavioral health professionals by passing legislation (SB 3617) that approaches the issue from various angles.[87] Key provisions from SB 3617, such as eliminating barriers to reinstatement of licensure, making it easier for out-of-state professionals to practice in Illinois, and investing in training for people entering the profession, should be incorporated into legislation to remedy Illinois' nursing staff shortage.[88] Additionally, Illinois should pass legislation to join the Nurse Compact Licensure which makes it easier for out-of-state nurses to work in Illinois. Furthermore, investing in the training and education of nursing students and CNAs can increase the number of practicing professionals. Illinois can use the approach taken by SB 3617 and make modifications specific to nursing to lessen the nursing shortage and ensure better patient outcomes.

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[84] *Id.* (recommending the expansion of capacity in nursing programs to alleviate the nursing shortage).
[85] Lasater et al., *supra* note 3; *see also Impact of the COVID-19 Pandemic on the Hospital and Outpatient Clinician Workforce*, *supra* note 1 at 2 (discussing the shortages of healthcare workers, including behavioral health workers).
[86] Bridges et al., *supra* note 45; *see also* Rogers et al., *supra* note 46 (discussing the greater risk of error by nurses who work long hours due to understaffing).
[87] *Governor Pritzker Signs Legislation Increasing Mental Health Workforce in Illinois*, *supra* note 13.
[88] S.B. 3617, 102nd Gen. Assemb., Reg. Sess. (Ill. 2022).

Treading Lightly: Reversing the Exclusion of DACA Recipients from Federally Subsidized Healthcare Insurance

Manuel Franco

I. INTRODUCTION

The Obama administration zealously advocated for increased accessibility to healthcare, as observed by the enactment of the Affordable Care Act ("the ACA") in 2010.[1] Particularly, the ACA strove to increase healthcare equity by reducing the overall cost of healthcare and increasing the number of insured individuals.[2] Moreover, advocates of the ACA pledged to increase healthcare coverage for the nation's most vulnerable populations.[3] The Obama administration also championed for progressive immigration policies such as the Deferred Action for Childhood Arrivals ("DACA") program.[4] Announced in 2012, DACA is grounded upon the Department of Homeland Security's ("DHS") right to exercise prosecutorial discretion.[5] Under DACA, DHS exercises prosecutorial discretion by deferring removal proceedings against undocumented individuals that meet the strict requirements for DACA.[6] Moreover, DACA recipients receive limited benefits such as U.S. Work Authorization and social security numbers.[7]

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[1] Fatma Marouf, *Alienage Classifications and the Denial of Health Care to Dreamers*, 93 WASH. U. L. REV. 1271, 1278 (2016).
[2] *Id.*
[3] *See* Clarissa A. Gomez, *The Paradox between U.S. Immigration Policy and Health Care Reform: Deferred Action for Childhood Arrivals*, 38 SETON HALL LEGIS. J. 101, 113 (2014) (explaining that the ACA purports to provide expanded access to insurance coverage and to make care more accessible for vulnerable uninsured populations).
[4] Marouf, *supra* note 1, at 1280.
[5] Gomez, *supra* note 3, at 106.
[6] *See* Medha D. Makhlouf & Patrick J. Glen, *A Pathway to Health Care Citizenship for DACA Beneficiaries*, 12 CALIF. L. REV. ONLINE 29, 32-33 (2021-2022) (describing the five eligibility criteria to qualify for DHS's deferment of prosecutorial action under DACA).
[7] *See* CCF Admin, *For DACA Grantees, Health Insurance is (Only) a Dream*, GEO. UNIV. HEALTH POL'Y INST.: CTR. FOR CHILD. AND FAM. (April 11, 2014), https://ccf.georgetown.edu/2014/04/11/for-daca-youth-health-insurance-is-only-a-dream/(describing that DACA grantees are eligible for a Social Security number and an employment authorization document also known as an "EAD," or a "work permit").

Although both DACA and the ACA emanated from the Obama administration's agenda, legislators have failed to incorporate DACA recipients into the scope of the ACA.[8]

The ACA's benefits are statutorily limited to individuals that are "a citizen or national of the United States or…lawfully present in the United States."[9] Congress specifically tasked the Department of Health and Human Services ("HHS") with defining the term "lawfully present" prior to the implementation of the ACA in 2010.[10] Prior to DACA, HHS broadly defined the term "lawfully present" to include "all aliens currently in deferred action status."[11] However, two months after the announcement of DACA, HHS published an interim final rule ("IFR") which amended the 2010 definition of "lawfully present" to specifically exclude individuals that received deferred action through DACA.[12] HHS's exclusion of DACA recipients was codified as follows:

> Exception. An individual with deferred action under the Department of Homeland Security's *deferred action for childhood arrivals* process, as described in the Secretary of Homeland Security's June 15, 2012, memorandum, shall not be considered to be lawfully present with respect to any of the above categories in paragraphs (1) through (7) of this definition.[13]

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[8] *See id.* (describing that individuals with DACA status are ineligible for benefits under the Affordable Care Act).
[9] *Tips for Addressing Immigrant Families' Concerns when Applying for Health Coverage Programs*, NAT'L IMMIGR. L. CTR. (October 2017), https://www.nilc.org/wp-content/uploads/2017/10/Health-Care-Assister-Handout-2017.pdf.
[10] Marouf, *supra* note 1, at 1279.
[11] *See id.* at 1275-76 (stating that in 2020 HHS included all individuals with deferred action status in its definition of "lawfully present").
[12] *See id*. at 1279 (explaining that HHS's interim final rule amended the definition of "lawfully present" to exclude individuals that received deferred action through DACA but not individuals that received deferred action through other means).
[13] *See* 45 C.F.R. § 152.2 (4)(vi), (8) (2022)(emphasis added)(granting eligibility to "aliens currently in deferred action status" at subsection (4)(vi), but then making an exception which excludes individuals who received deferred action through DACA in subsection (8)).

Since HHS's new definition of "lawfully present" excluded DACA from the benefits of the ACA, DACA recipients were rendered healthcare pariahs, even among the marginalized community of other noncitizens with temporary protection from deportation.[14] Furthermore, the label of DACA recipients as not "legally present" has consequently excluded this group from a plurality of other healthcare programs such as the Pre-Existing Condition Insurance Plan ("PCIP"), Children's Health Insurance Program ("CHIP"), and Medicaid.[15] In addition, DACA recipients are prohibited from using options that are progeny of the ACA, such as the health insurance marketplaces, leaving them vulnerable to high health care costs due to their lack of ability to purchase subsidized health insurance.[16]

II. TAILORING AN AMENDMENT TO THE DELICATE NATURE OF DACA

This paper proposes a limited amendment to HHS's exclusionary definition of "lawfully present." Specifically, this paper proposes that HHS must clearly re-define the exclusion of DACA recipients from the ACA codified in 45 C.F.R. § 152.2 (8) as follows:

> Exception. An individual with deferred action under the Department of Homeland Security's deferred action for childhood arrivals process, as described in the Secretary of Homeland Security's June 15, 2012, memorandum, shall not be considered to be lawfully present with respect to any of the above categories in paragraphs (1) through (7) of this definition, *except for the purpose*

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[14] Makhlouf & Glen, *supra* note 6, at 39.
[15] *See* Marouf, *supra* note 1, at 1280-81 (stating that HHS's change made DACA recipients ineligible for the PCIP, Affordable Insurance Exchanges, premium tax credits, and cost-sharing reductions because all these programs rely on the same definition of lawfully present).
[16] *See* Drew Joseph, *Young Immigrants Excluded from ACA Benefits*, Physicians for a Nat'l Health Program (Feb. 19, 2013), https://pnhp.org/news/young-immigrants-excluded-from-aca-benefits/ (explaining that eligibility to affordable insurance exchanges rely on HHS's definition of "lawfully present," thereby also excluding DACA recipients from this option).

> *of purchasing insurance from federally subsidized insurance exchange markets*.[17]

Unlike previously proposed amendments to the ACA itself, the amendment proposed in this paper focuses solely on HHS's codified definition of "lawfully present" and is aimed at granting DACA recipients the right to purchase insurance from federally subsidized insurance exchange markets only. Further, in contrast to proposals suggesting that congressional action is necessary to effectuate health care rights for DACA recipients, the proposed amendment promotes achieving the same goal through action promulgated by HHS.[18] Contrary to existing proposals for a blanket repeal of HHS's exclusion, the proposed amendment postulates that entirely repealing HHS's exception is not the only effective method to grant DACA recipients rights under the ACA.[19]

The proposed amendment's limited nature would more appropriately address recent political skepticism surrounding the DACA program when compared to a broader amendment or repeal of the exclusion.[20] The DACA program has survived various lawsuits brought during President Trump's presidency, largely surviving on the ground that the rights for DACA recipients are limited and not equivalent to permanent residents or United

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[17] *Cf.* Makhlouf & Glen, *supra* note 6, at 40-41 (alteration in original)(emphasis added)(proposing that HHS's secretary under the Biden administration should repeal HHS's exclusion of DACA recipients from the ACA in its entirety, but not proposing a limited amendment).

[18] *See id*. (arguing that DACA beneficiaries can be put on the path to "health care citizenship" through an HHS Interim Final Rule, also known as an IFR).

[19] *See* Gomez, *supra* note 3, at 128 (proposing that the inclusion of DACA recipients in the health insurance market is a much more productive and effective way to advance both our nation's immigration and health policies); *but see id*. at 130 (suggesting that Congress should take legislative action to effectuate this goal rather than HHS taking action as suggested in this paper).

[20] See Gomez, *supra* note 3, at 125-128 (describing that allowing DACA recipients to participate in health insurance exchanges is an effective method to address the ongoing divide in sentiments surrounding immigration policies).

States citizens.[21] Most recently, the Fifth Circuit remanded a lawsuit against the program for further review on the legality of its scope of protection, leaving DACA recipients in limbo about the future of the program.[22] Consequentially, in order to protect the DACA program from further scrutiny about the scope of rights that recipients receive, a full grant of rights under the ACA would be inappropriate.[23] Nonetheless, reform of the current policy is needed to appropriately guarantee that DACA recipients have better access to healthcare than they currently have.[24] This delicate balance can best be achieved by amending HHS's definition of "lawfully present" for the limited purpose of allowing DACA recipients to purchase subsidized medical insurance in marketplace exchanges, as proposed here, while still limiting greater benefits such as full Medicaid coverage.[25] This approach would further the social policy goals of HHS while re-enforcing the legal immigration restrictions of DACA.[26]

Unlike blanket repeals of HHS's exclusion, the proposed amendment's aim to only grant DACA recipients the right to purchase insurance from federally subsidized insurance exchange markets would be consistent with

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[21] Urial J. Garcia, *DACA Remains Intact as Appeals Court Sends Case Challenging its Legality to Lower Court in Texas*, THE TEX. TRIB. (Oct. 5, 2022), https://www.texastribune.org/2022/10/05/texas-daca-appeals-court-ruling/.

[22] *See id*. (reporting that the 5th U.S. Circuit Court of Appeals said in its ruling that implementation of DACA in 2012 was illegal, but remanding the case to the lower court to analyze the latest rule that the Biden administration has implemented in an effort to save the program from future legal challenges).

[23] See Gomez, *supra* note 3, at 125-126 (postulating that allowing DACA recipients to access health insurance exchanges would effectively defeat arguments about potential negative economic effects to the United States because the DACA program is available only to a very narrowly defined group of undocumented individuals).

[24] Makhlouf & Glen, *supra* note 6, at 40-41 (proposing that the definition of "lawfully present" as applied to DACA recipients should be modified to reverse the health-related and social marginalization problems associated with the DACA carve-out).

[25] *Id*.

[26] *See* Gomez, *supra* note 3, at 118 (describing that that including DACA recipients in the health insurance exchanges poses little risk to immigration policies)

HHS's original rationale for enacting the exclusionary amendment.[27] Arguably, the exclusion of DACA recipients from the ACA by HHS was key to ensuring the success of both programs amidst tensions between President Obama and Congress at the time.[28] In fact, the DACA program was developed as a response to halted immigration reform by a conservative Congress.[29] Rather than continuing to pursue a grant of immigration rights through Congressional action after multiple failed attempts, the Obama administration pursued relief under DHS's limited discretionary power.[30] However, DHS was wary of granting extensive rights to DACA recipients as is evident by DHS public statements that DACA would confer no substantive rights or pathway to citizenship.[31] Thus, it was made clear that DHS wanted to avoid bringing too much light to the program.[32] In retrospect, it becomes apparent that DACA recipients became caught in the political battles of the time, which created a plurality of inconsistent policies.[33]

Despite effectuating only the right to purchase subsidized insurance, HHS would still need to properly support its rationale for amending the exclusion of DACA recipients from the ACA as proposed in this paper.[34]

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[27] *See* Sara N. Kominers, *Caught in the Gap between Status and No-Status: Lawful Presence Then and Now*, 17 RUTGERS RACE & L. REV. 57, 74-75 (2016) (describing the refusal of HHS to grant DACA recipients substantive rights in the memorandum which enacted the program).
[28] *See id*. at 72-73 (describing the dynamics that arise when there is tension between a progressive President and a conservative Congress).
[29] *Id*. at 72.
[30] *See id*. at 73 (describing that the creation of DACA stemmed from the Senate's failure to pass the Development, Relief, and Education for Alien Minors Act (DREAM Act) in December 2010).
[31] *Id*. at 74-75 (quoting Secretary of Homeland Security Janet Napolitano's statement that DACA "confers no substantive right, immigration status or pathway to citizenship").
[32] *See* Gomez, *supra* note 3, at 128 (describing that the Obama Administration had to consider all the conflicting views surrounding immigration and what balanced action would best serve the interests of all when taking action to pass DACA).
[33] Kominers, *supra* note 27, at 59.
[34] *See generally* Dan Bosch, *Interim Final Rules: A Primer*, AM. ACTION F. (Nov. 18, 2020), https://www.americanactionforum.org/insight/interim-final-rules-a-primer/ (stating that the

The mechanisms available to amend the ACA include amending the law through an expansive notice-and-comment rulemaking procedure or through an interim final rule ("IFR").[35] The latter was the method used to create the DACA exclusion.[36] An IFR becomes effective immediately upon publication by the agency in contrast to the traditional notice-and-comment rulemaking process, which can subject proposals to a greater degree of scrutiny.[37] Further, agencies are free to make amendments via IFRs if the agency believes that there is good cause to forego the traditional notice-and-comment rulemaking process.[38] The proposed amendment would allow HHS to appropriately use the IFR mechanism because there is support that continuing to prevent DACA recipients from purchasing health insurance is contrary to the public interest.[39]

III. LESSONS FROM THE PANDEMIC

HHS can amply support amending the ACA through an IFR by highlighting the urgent need to prevent the propagation of hardships faced by uninsured patients, such as DACA recipients, during the COVID-19 pandemic.[40] Specifically, the rapid onset of the pandemic created a period of

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Administrative Procedure Act requires agencies such as HHS to provide an explanation supporting the reasons for issuing rules such as amendments and exceptions to existing policies).

[35] Makhlouf & Glen, *supra* note 6, at 40-41 (explaining that the DACA carve-out was immediately effective through an interim final rule, so this mechanism may be appropriate to reverse the same).

[36] *See id*. (stating that HHS issued an interim final rule to clarify whether eligibility status of DACA recipients).

[37] *See* Bosch, *supra* note 34 (describing that interim final rules have immediate effect while public comment is obtained and considered even though few interim final rules are ever modified based on comments).

[38] *See id.* (explaining that an agency is permitted to issue a rule without notice if the agency finds good cause that the notice process is impracticable, unnecessary, or contrary to the public interest).

[39] *See id*. (describing that the public interest and emergencies are adequate grounds for issuing an interim final rule).

[40] *Id*.

time when testing and treatment options were not free and far from accessible to DACA recipients that were uninsured as a result of the DACA exclusion.[41] Terrifyingly, it is estimated that 74 million individuals residing in the United States were uninsured at the start of the pandemic: a number that was only compounded by the mass unemployment that occurred as the pandemic progressed.[42] In addition, the lack of testing accessibility to the uninsured population resulted in increased infections and hospitalizations.[43] It is estimated that the average cost of treatment for patients that suffered major complications from COVID-19 is $74,310.[44] Conversely, the average cost of treatment for patients infected with COVID-19 who did not suffer from complications or comorbidities but nonetheless required hospitalization for cure was $42,486.[45] Estimates have also revealed that most insurers would not pay for the total cost of COVID-19 treatment, which caused larger obstacles for poorly uninsured patients.[46] In addition to this, the disparity of treatment for uninsured patients resulted in the increase of costs for safety net providers and the increase in premiums for everyone that did qualify for benefits under the ACA.[47] Allowing DACA recipients to access marketplace

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[41] *See* Tanvi Misra, *Democrats Demand Healthcare Benefits for DACA Recipients*, CONG. Q.: ROLL CALL (April 22, 2020), https://www.westlaw.com/Document/I8744c6d484cb11ea80afece799150095/View/FullText.html?transitionType=Default&contextData=(sc.Default)&VR=3.0&RS=cblt1.0 (suggesting that the lack of access to healthcare left DACA recipients without the ability to receive testing and treatment for COVID-19).

[42] Creola Johnson, *Crushed by COVID-19 Medical Bills, Coronavirus Victims Need Debt Relief Under the Bankruptcy Code and Workers' Compensation Laws*, 125 PENN ST. L. REV. 453, 457 (2021).

[43] *Id*. at 453.

[44] *Id*. at 470.

[45] *Id*.

[46] *Id*.

[47] *See* Misra, *supra* note 41 (quoting a letter addressed to HHS secretary Alex Salazar written by the Congressional Hispanic Caucus, in which they wrote "without access to affordable health care, DACA recipients are left without the ability to receive testing and treatment for COVID-19, driving up health care costs on to our own safety net providers and increasing premiums for everyone").

insurance would decrease the uninsured population and the negative economic effects that arise when this population is forced to seek healthcare in a global health emergency such as COVID-19.[48]

IV. SUPPLEMENTING SCARCE RESOURCES AVAILABLE TO DACA RECIPIENTS

Moreover, the proposed amendment would be beneficial to the public interest because allowing DACA recipients to purchase subsidized health insurance is essential to reducing high emergency care costs.[49] The exclusion from HHS's definition of "lawfully present" prohibits DACA recipients from seeking preventative care.[50] As a result, this leaves DACA recipients with scarce options for affordable and comprehensive health insurance, forcing many to wait for medical emergencies to arise before receiving care.[51] Accordingly, many DACA recipients are forced to seek unsustainable coverage under the mercy of laws such as the Emergency Medical Treatment and the Labor Act, which forbids the rejection of undocumented immigrants from receiving emergency room treatment.[52] The only other option for DACA recipients seeking healthcare aside from emergency-room care, community health centers, and free clinics is purchasing private health

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[48] *See* Johnson, *supra* note 42, at 498 (describing that under the flawed U.S. healthcare system, uninsured individuals treated for infectious diseases incur enormous medical debt); *see also* Marouf, *supra* note 1, at 1286-87 (describing that safety-net providers and emergency rooms are unable to meet the needs of those excluded from the ACA).
[49] Gomez, *supra* note 3, at 101 (describing that the treatment of DACA recipients in emergency situations is absorbed by tax dollars paid by insured workers); *see also id*. at 108 (stating that reliance on emergency-care services creates a burden on DACA recipients and Americans alike).
[50] *See* Marouf, *supra* note 1, at 1285-86 (describing the limited healthcare options for DACA recipients).
[51] *See* Jeffrey T. Kullgren, *Restrictions on Undocumented Immigrant's Access to Health Services: The Public Health Implications of Welfare Reform*, 93 AM. J. OF PUB. HEALTH 1630, 1632 (2003) (arguing that the restriction of preventative care while requiring institutions to provide emergency care is not the most cost-effective use of these services).
[52] *Id*.

insurance directly from insurance companies and brokers without the benefit of subsidies, and in rare occasions, being able to qualify for insurance through an employer.[53] However, the high costs associated with unsubsidized private insurance makes this option virtually unattainable.[54] Additionally, employer-based health insurance options are scarce, and the availability of this option is declining, which prevents this from being a sustainable option for DACA recipients.[55] As a result, DACA recipients have no economically-feasible or sustainable options for purchasing health insurance.[56]

Not only have DACA recipients been deprived of a sustainable healthcare system, but the likelihood of disease and treatment expenses have also grown as a result of the DACA population's exclusion from the ACA.[57] Specifically, the increase in treatment expenses arises because uninsured individuals tend to avoid routine check-ups and otherwise relatively inexpensive preventative care until they have developed an illness that has significantly advanced and resulted in a need for urgency of treatment.[58] As a result, emergency room services—a resource that has also been stretched thin— are the most viable option for care to DACA recipients.[59] The rate of emergency room visits has been on the rise since before the COVID-19 pandemic, provoking other limited resources, such as safety net providers, to

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[53] Joseph, *supra* note 16.
[54] *See* Gomez, *supra* note 3, at 114-115 (proposing that while undocumented individuals are not prevented from purchasing unsubsidized insurance, they are usually left with virtually no opportunity or economic means to do so).
[55] *See id*. at 108 (stating that DACA recipients are usually blocked from purchasing employer-subsidized insurance plans); *see also* Marouf, *supra* note 1, at 1285-86 (explaining that DACA recipients who have been able to obtain employer-based insurance may become uninsured in the future because employer-based insurance options are declining).
[56] *See* Marouf, *supra* note 1, at 1286-87 (proposing that the scarce healthcare insurance options for DACA recipients leaves them at the mercy of safety-net providers which are losing funding).
[57] Gomez, *supra* note 3, at 108.
[58] Makhlouf & Glen, *supra* note 6, at 39.
[59] Marouf, *supra* note 1, at 1288.

be worn thin.[60] Notably, greater eligibility to healthcare for DACA recipients is beneficial to the insured American population because allowing the young DACA population to access preventative care in the present would reduce the overall need to access late emergency care.[61] As the general population ages, individuals become more susceptible to risk factors and illnesses that, if left untreated, could result in an emergency room visit.[62] The proposed amendment would directly address the aforementioned issues because federally subsidized insurance options offered through marketplace exchanges must provide a number of essential benefits.[63] All marketplace insurance must cover preventative care and well-woman visits.[64] Additionally, marketplace insurance options must cover prescription drugs and laboratory services, which are often responsible for high costs associated with preventative care.[65] These insurance options must also cover some emergency services, which would help reduce the high toll that providing emergency medical care to uninsured DACA recipients creates.[66] By granting DACA recipients the option to purchase insurance which covers these essential services, the access to healthcare could be increased while reversing some of the negative effects that excluding this option for DACA recipients has caused.[67]

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[60] Misra, *supra* note 41.
[61] Marouf, *supra* note 1, at 1287.
[62] Gomez, *supra* note 3, at 118.
[63] *See* DEP'T OF HEALTH AND HUM. SERV., MARKETPLACE COVERAGE AND ESSENTIAL BENEFITS (July 28, 2022), https://www.healthcare.gov/blog/marketplace-coverage-essential-health-benefits/ (describing that there are 10 categories of benefits that marketplace insurance must cover).
[64] DEP'T OF HEALTH AND HUM. SERV., MARKETPLACE, THE BENEFITS OF HEALTH INSURANCE THROUGH THE MARKETPLACE (Aug. 7, 2015), https://www.healthcare.gov/blog/benefits-of-health-insurance-through-marketplace/.
[65] Dep't of Health and Hum. Serv, *supra* note 63.
[66] *Id.*
[67] *See* Marouf, *supra* note 1, at 1323 (proposing that allowing DACA recipients to access healthcare under the ACA would decrease the high cost of delayed care and reduce the

The proposed amendment would also address the lack of non-federal insurance options for DACA recipients. As a response to the lack of access available to DACA recipients, some states have developed alternative limited opportunities for DACA recipients to receive healthcare with the hope of avoiding the ultimate burden on taxpayers, who absorb the high costs of emergency care that is inevitable when preventive care is not an option.[68] Nonetheless, only a handful of states have sufficient revenue to support these fully state-funded initiatives.[69] For example: only twelve states and the District of Columbia currently support insurance marketplaces that are exclusively subsidized by state funds.[70] Therefore, even though some individual states have taken action to aid DACA recipients federal action must still be taken so that DACA recipients in all states have access to care.[71] HHS's decision to bar a decent percentage of the population under a large national program from accessing key healthcare resources only created discrepancy in federal laws that must be fixed prior to bringing uniformity to the United States healthcare system.[72] Allowing DACA recipients to purchase subsidized federal insurance through the proposed amendment would address the scarce level of state-funded options currently available for DACA recipients, which is key since not every state can afford to support such options for individuals that do not qualify for federal marketplace insurance.[73]

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administrative costs of healthcare by making it easier to determine who qualifies for specific programs under the ACA).

[68] See Kullgren, *supra* note 51, at 1632 (arguing that the restriction of preventative care while requiring institutions to provide emergency care is not the most cost-effective use of these services).

[69] Marouf, *supra* note 1, at 1325-26.

[70] *Id*. at 1278.

[71] Gomez, *supra* note 3, at 124.

[72] *Id*.

[73] Marouf, *supra* note 1, at 1278.

V. CONCLUSION

The exclusion of DACA recipients from the ACA has had significant impacts on the United States healthcare system. The effects of the exclusion can be driven back by a limited reversal of the DACA carve-out. Accordingly, allowing DACA recipients to purchase health insurance would provide adequate access to preventative care and ultimately reduce the stress that HHS's exclusion of DACA recipients from the ACA causes to safety-net providers and emergency rooms.

Adopting Collective Purchasing to Lower the Cost of Prescription Drugs

Jenna Miller

I. INTRODUCTION

Prescription drug prices in the United States have continued to rise over the last few decades, contributing to both a reduction in consumer access and strain upon the federal budget.[1] However, many of these prescription drugs are needed to improve the quality of life for many patients.[2] With prices averaging 2.56 times higher than those of 32 other nations,[3] cost is one of the main barriers preventing access.[4] Currently, the federal government has little involvement in negotiating prices of prescription drugs.[5] The Social Security Act lays out the "noninterference clause," which prevents the Health and Human Services (HHS) Secretary from interfering with negotiations between drug manufacturers and pharmacies, including Medicare Part D drugs.[6] The Inflation Reduction Act (IRA), recently passed by the Biden Administration, created carve-out for Medicare by requiring federal government to negotiate high-cost drug prices covered under Medicare, as well as hold drug

[1] *Prescription Drugs: Spending, Use, and Prices,* CONG. BUDGET OFF. (Jan. 2022), https://www.cbo.gov/publication/57772.
[2] *Id.*
[3] Andrew Mulcahy, *Prescription Drug Prices in the United States Are 2.56 Times Those in Other Countries,* RAND CORP. (Jan. 28, 2021), https://www.rand.org/news/press/2021/01/28.html.
[4] *Prescription Drugs: Spending, Use, and Prices, supra* note 1.
[5] Juliette Cubanski et al., *Drug Price Negotiation Doesn't Mean the Government Will Restrict Access to Medicines,* KFF (Oct. 7, 2021), https://www.kff.//org/policy-watch/drug-price-negotiation-doesnt-mean-the-government-will-restrict-access-to-medicines/ (describing the current prohibitions regarding the federal government involvement with the pricing of drugs).
[6] Social Security Act § 1680D-11, 42 U.S.C. § 1395w-111. Medicare Part D is a voluntary outpatient prescription drug benefit for people with Medicare that helps cover the cost of some prescription drugs. *An Overview of the Medicare Part D Prescription Drug Benefit,* KFF (Oct. 19, 2022), https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/.

manufacturers accountable for pricing to Medicare beneficiaries.[7] While this Act is a step in the right direction for lowering drug costs for consumers, it does not tackle the problem for consumers not covered by Medicare.[8] Adopting a different strategy surrounding drug negotiation—namely, a more international approach including aggregate purchasing to gain more negotiating leverage with drug companies—will alleviate some of the burden.[9]

Changing the government's negotiation strategy will allow for more affordable prices for consumers and increase access.[10] This article will discuss how prescription drug pricing is currently determined, negotiated, and implemented. It will then describe the different proposals and bills that have been introduced in attempt to remedy continually increasing prices. Further, it will analyze how other developed countries negotiate drug pricing in comparison to the United States. Finally, this article will propose that the United States adopt a collective purchasing, or aggregate model, of drug pricing negotiation to begin to lower prescription drug prices and gain more negotiating leverage with drug manufacturers.[11] In addition, these aggregate

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[7] Juliette Cubanski et al., *How Will the Prescription Drug Provision in the Inflation Reduction Act Affect Medicare Beneficiaries,* KFF (Aug. 18, 2022), https://www.kff.org/medicare/issue-brief/how-will-the-prescription-drug-provisions-in-the-inflation-reduction-act-affect-medicare-beneficiaries/.

[8] On face value, the Inflation Reduction Act looks like a step in the right direction, but there are questions about practicability, and there may be significant consequences, both intended and unintended. *Id.* ("The law includes several provisions to lower prescription drug costs for people with Medicare.").

[9] David Blumenthal et al., *Three Essentials for Negotiating Lower Drug Prices,* COMMONWEALTH FUND (Aug. 22, 2018), https://www.commonwealthfund.org/blog/2018/three-essentials-negotiating-lower-drug-prices (explaining how other countries are able to pay lower drug prices than the United States, comparatively).

[10] *Id.*

[11] *Id.*

"pools" can use a value assessment to establish the maximum price manufacturers can receive for a drug.[12]

II. CURRENT PRICING MODELS

The big "players" involved in drug pricing include the manufacturer, the distributor, the pharmacy, the patient, and pharmacy benefit managers (PBMs).[13] The actual price that a consumer pays for a drug is determined through three different channels: from the manufacturer to the distributor, from the distributor to the pharmacy, and finally from the pharmacy to the patient.[14] Manufacturers can set the "sticker price" of a drug at whatever they believe the market will handle.[15] However, the "sticker price" of the drug is often not what the manufacturer will actually receive for the drug.[16] The average manufacturer price (AMP) is the estimate of the actual price the manufacturer will receive for the drug, after rebates or discounts, from a distributor or pharmacy.[17] Then, from the distributor, the drug is sold to the pharmacy based on individually negotiated prices.[18] The pharmacy sets their price based on a formula, usually the average wholesale price (AWP) plus a dispensing fee, which the patient either pays directly or submits to

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[12] *Id.* ("With value assessments in hand, other countries enter a negotiating process and stand behind it.").
[13] Alex Evans, *How Does Drug Pricing Work in the US?*, GOODRX HEALTH (Mar. 21, 2022), https://www.goodrx.com/hcp/providers/how-does-drug-pricing-work-in-the-us.
[14] *Id.*
[15] Thomas Waldrop, *Value-Based Pricing of Prescription Drugs Benefits Patients and Promotes Innovation*, CAP (Sept. 13, 2021), https://www.americanprogress.org/article/value-based-pricing-prescription-drugs-benefits-patients-promotes-innovation/ ("Because of the pharmaceutical industry's ability to set prices largely unchecked….").
[16] Evans, *supra* note 13.
[17] *Id*. (describing that manufacturers typically do not receive their "sticker price" of a drug due to rebates and negotiations between manufacturers, pharmacies, and distributors).
[18] *Id.* ("While some chain pharmacies negotiate on their own, most independent pharmacies and small chains join group purchasing organizations to negotiate on their behalf and secure the best pricing possible.").

insurance.[19] There are many different factors that may impact pricing at these stages, such as unequal bargaining power, high launch prices, and the interaction of market power.[20] PBMs also have a huge impact on pricing, as they are primarily responsible for processing and paying prescription drug claims.[21] PBMs negotiate upfront discounts and rebates on the prices of prescription drugs with pharmaceutical companies, but it is often hard for consumers to find this information.[22] PBMs currently negotiate on behalf of insurers with the drug manufacturers, handling negotiations and payments within the supply chain.[23]

In the United States, consumers spend nearly $334 billion annually on prescription drugs.[24] Moreover, the share of the nation's total health care spending on pharmaceutical drugs notably increased from 5.6% in 1990 to 10% in 2017.[25] Companies set the list price at whatever will reap the most profit, meaning the higher manufacturer price, the higher the amount the consumer is likely to pay.[26] Currently, patients are left in the dark about how drugs, new and old, are priced.[27] Pharmaceutical companies do not have to explain their pricing, even if high research-and-development expenses are

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[19] *Id*. ("The pharmacy buys from the distributor, usually using the average wholesale price (AWP) as a starting point for negotiations, then decides the drug's cash price.").
[20] *Factors Influencing Affordability*, NAT'L LIBR. OF MED. (NOV. 30, 2017), https://www.ncbi.nlm.nih.gov/books/NBK493090/.
[21] *Pharmacy Benefit Manager (PBM) FAQs*, ETF, https://etf.wi.gov/its-your-choice/2022/pharmacy-benefit-manager-pbm-faqs (last visited Dec. 13, 2022).
[22] *How Are Prescription Drug Prices Determined*, AM. MED. ASS'N (Apr. 9, 2019), https://www.ama-assn.org/delivering-care/public-health/how-are-prescription-drug-prices-determined.
[23] *Pharmacy Benefit Managers*, NAIC (Apr. 11, 2022), https://content.naic.org/cipr-topics/pharmacy-benefit-managers; Evans, *supra* note 13 ("Insurers often hire pharmacy benefit managers (PMBs) to handle their pharmacy claims.").
[24] *How Are Prescription Drug Prices Determined*, *supra* note 22.
[25] *Id.*
[26] *Id.* (describing how insurance companies set consumer prices based on what will maximize profits).
[27] *Id.*

not incurred.[28] Patients are ultimately kept out of discussions and agreements regarding the prices of drugs.[29] As health insurance companies often decide coverage for prescription drugs based on what maximizes company profits, the more expensive the drug is, the higher the out-of-pocket cost for the consumer.[30]

III. PROPOSED ACTIONS ON DRUG PRICING

Historically, drug reform legislation in the U.S. has been largely unsuccessful, and the increased demand for prescription drugs as a result of COVID-19 has only worsened the situation.[31] There have been many proposals and bills introduced surrounding drug reform; however, few have actually been passed, and states' actions have made little headway in reducing drug prices.[32] For example: the failed Prescription Drug Pricing Reduction Act, introduced in 2019, would have ensured that the price of drugs covered under Medicare Part D would not increase faster than inflation by penalizing the drug company if they exceeded this threshold.[33] Although this Act did not make it past introduction, the recently passed IRA aims to enact a similar remedy surrounding the pricing of drugs covered under Part

[28] *Id.*
[29] *Id.*
[30] *Id.*
[31] Jamison Chung et al., *Regulating Prescription Drug Costs*, THE REGUL. REV. (Oct. 17, 2020), https://www.theregreview.org/2020/10/17/Saturday-seminar-regulating-prescription-drug-costs/ ("U.S. drug companies set their own prices, but insurers and pharmacies determine how much patients actually pay out-of-pocket.").
[32] *2022 State Legislative Action to Lower Pharmaceutical Costs*, NAT'L ACAD. FOR STATE HEALTH POL'Y [NASHP] (Aug. 23, 2022), https://www.nashp.org/rx-legislative-tracker/ (showing the amount and status of bills that have been introduced regarding prescription drug prices).
[33] Prescription Drug Pricing Reduction Act of 2019, S.2543, 116th Cong. (2019), https://www.congress.gov/bill/116th-congress/senate-bill/2543.

D of Medicare.[34] While these bills were aimed specifically at Medicare pricing, they did not address the problem of out of control drug prices for consumers in the general population not covered by Medicare.[35]

Moreover, proposed actions specifically targeting drug pricing methods have also failed. Another act that has been introduced but not yet passed is the Affordable Drug Manufacturing Act of 2020, which aimed to address the skyrocketing price of prescription drugs.[36] The bill proposed the establishment of an Office of Drug Manufacturing ("the Office") within HHS, which would serve to lower prices and increase competition.[37] The Office would be tasked with lowering consumer prices by manufacturing select generic drugs or entering into agreements with private companies to manufacture the drug at a lower price.[38] However, one of the more promising proposals for drug pricing reform is The Lower Drug Costs Now Act introduced in 2019.[39] Under this bill, HHS would negotiate the price for certain drugs and set maximum prices for insulin products and the 125 drugs that account for the highest national spending.[40] Although these bills propose several different ways to attempt to implement drug pricing reform, few have

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[34] The IRA allows for the federal government to negotiate prices for only some high-cost drugs covered under Part D of Medicare. Cubanski et al., *supra* note 7. Medicare Part D and Part B spending is concentrated around a small share of covered drugs. *Id.*
[35] *Id.* ("[R]equires the federal government to negotiate prices for some high-cost drugs covered under Medicare.").
[36] Affordable Drug Manufacturing Act of 2020, S.3162, 116th Cong. (2020), https://www.congress.gov/bill/116th-congress/senate-bill/3162.
[37] *Schakowsky, Warren Reintroduce Affordable Drug Manufacturing Act, Legislation to Radically Reduce Drug Prices through Public Manufacturing of Prescription Drugs,* ELIZABETH WARREN (Dec. 20, 2019), https://www.warren.senate.gov/newsroom/press-releases/148chakowsky-warren-reintroduce-affordable-drug-manufacturing-act-legislation-to-radically-reduce-drug-prices-through-public-manufacturing-of-prescription-drugs.
[38] *Id.*
[39] Lower Drug Costs Now Act, H.R.3, 116th Cong. (2021), https://www.congress.gov/bill/116th-congress/house-bill/3.
[40] *Id.*

made any progress.[41] Congress has also attempted to remedy some of the problem by increasing additional generic drugs available in the market.[42] Increasing the availability of generic drugs may have an impact in some areas, but the price of prescription drugs overall has yet to decrease.[43] While there is no easy fix for the rising price of prescription drug prices, the federal government must be more proactive in the negotiation process in order to make headway toward lower drug prices for all.[44]

IV. ANALYZATION OF INTERNATIONAL METHODS OF DRUG PRICING

Even though about the same number of medications are used on average by consumers, significantly less money is spent on drugs per person in other high-income nations than in the United States.[45] Because other countries pay lower prices to drug manufacturers for prescription drugs, their residents are able to access drugs at a lower price by utilizing collective purchasing, or aggregate purchasing, to build marketing power and decrease the price of prescription drugs.[46] Countries that use this practice gain negotiating leverage with drug manufacturers, which allows for better negotiating

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[41] Juliette Cubanski et al., *What's the Latest on Medicare Drug Pricing Negotiations,* KFF (Jul. 23, 2021), https://www.kff.org/medicare/issue-brief/whats-the-latest-on-medicare-drug-price-negotiations/.
[42] Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 98th Cong. (1984), https://www.govinfo.gov/content/pkg/STATUTE-98/pdf/STATUTE-98-Pg1585.pdf.
[43] *Prescription Drug Expenditure in the United States from 1960 to 2020,* STATISTA (Jul. 27, 2022), https://www.statista.com/statistics/184914/prescription-drug-expenditures-in-the-us-since-1960/ (showing the price of prescription drugs rising since 1960).
[44] Cubanski et al., *supra* note 5 ("Allowing the federal government to negotiate drug prices, which is supported by a large majority of the public, would lower cost sharing and premiums for Medicare beneficiaries and produce significant savings for the federal government that could be used to cover the costs of other spending priorities.").
[45] Blumenthal et al., *supra* note 9.
[46] *Id.* ("Most high-income countries spend a lot less on drugs per person than the United States, even though their citizens use about the same amount of medications as Americans.").

practices.[47] In particular, by joining a purchasing "pool," the power of negotiation for drug prices is increased in the aggregate groups.[48] As a result, the ability to negotiate is shifted to one large "collective," meaning that the drug companies must negotiate a fair price or else their drug will not be purchased.[49] The United States can look to international methods of leveraging negotiating power surrounding drug pricing for reform guidance.[50]

Even in countries that maintain similar pricing models to the United States, such as the United Kingdom, drug prices are still considerably lower.[51] In particular, indirect processes are the main controller of the price of pharmaceutical products, despite drug manufacturers setting the list price of the drug and pharmaceutical companies setting the consumer price.[52] In the United Kingdom, the government functions as a single buyer under the National Health Service (NHS).[53] The United Kingdom has consolidated buying power into this one market entity, making buying power centralized in relation to prescription drugs.[54] As a result, the NHS has a large amount of leverage over drug manufacturers in setting the pricing if the NHS refuses

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[47] *Id.* ("[T]he public is willing to delegate informed purchasers the power to reach agreement on a price or, failing that, to walk away from the table. This makes it harder for drug companies to influence negotiations by appealing to elected officials or the public at large.").
[48] *Bulk Purchasing of Prescription Drugs*, NATI'L CONF. OF STATE LEGISLATURES [NCSL] (Aug. 26, 2021), https://www.ncsl.org/research/health/bulk-purchasing-of-prescription-drugs.aspx.
[49] *Id.* ("By leveraging purchasing power across states or agencies, the goal is for all parties in the pool to receive lower prices.").
[50] *Id.*
[51] *Billions Are Spent by the NHS on Drugs Every Year, But How Does It Work*, THE LOWDOWN (Mar. 31, 2021), https://lowdownnhs.info/drugs/billions-are-spent-by-the-nhs-on-drugs-every-year-but-how-does-it-work/.
[52] *Id.*
[53] *Id.* ("In the absence of direct price control mechanisms, successive UK governments have for many years relied on agreements with the pharmaceutical industry and market competition to keep drug costs from spiraling out of control for the NHS.").
[54] *Id.*

to purchase the drugs, the manufacturer will have no market share.[55] This leaves drug manufacturers with no other option and prevents them from being able to set prices too high.[56] The Netherlands is another country that has implemented collective purchasing, but, unlike the United Kingdom, the government purchaser is an alliance of private insurance companies.[57] As only some countries have a single-payer healthcare system, the aggregate "body" does not have to be a single-payer healthcare system, but can be a number of different parties that have interest in lowering the price of drugs.[58]

To determine what the aggregate or collective purchasing group is willing to pay for a drug, many other countries use value-based pricing, in which the medical effects and benefits are established, with pricing being based on that benefit.[59] Both Germany and Australia are examples of countries that have successfully decreased prices and spending on prescription drugs by implementing a value-based pricing system.[60] Germany bases the price-value of a drug on patient outcomes, which are assessed by the Federal Joint Committee.[61] Using direct clinical benefits, a single price is negotiated collectively by the nation's health insurers.[62] This approach has lowered drug prices without reducing patient access.[63]

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[55] *Id.*
[56] *Id.* ("If the NHS won't buy your products, then you have no real market share. Such centralized buying power gives the NHS the upper hand to a great extent in pricing negotiations and discounts based on volume sales.").
[57] Blumenthal et al., *supra* note 9.
[58] *Bulk Purchasing of Prescription Drugs*, *supra* note 48.
[59] Patricia Synnott et al., *A Value-Based Approach to America's Costly Prescription Drug Problem*, COMMONWEALTH FUND (May 6, 2022), https://www.commonwealthfund.org/blog/2022/value-based-approach-americas-costly-prescription-drug-problem ("Other countries take various approaches; some focus primarily on the amount of clinical benefit a therapy provides, while others are guided by cost-effectiveness analyses.").
[60] Alana Sheppard, *Value-Pricing Prescription Drugs*, THE REGUL. REV. (Nov. 24, 2021), https://www.theregreview.org/2021/11/24/sheppard-value-pricing-prescription-drugs/.
[61] Waldrop, *supra* note 15.
[62] *Id.*
[63] *Id.*

Australia's approach is similar, but more aggressive.[64] The cost effectiveness and utilization data of drugs is evaluated by the Economics Sub-Committee and the Drug Utilization Sub-Committee, who then recommend a price of the drug in question to the government.[65] Australia's federal government has the power to directly set the price of a drug.[66] If the drug manufacturer does not agree to the price that the government sets, then the drug is either not approved or faces access restrictions.[67] Both Australia and Germany, as well as other countries similar to the United States, have managed to successfully implement various ways of value-pricing drugs while also increasing access.[68]

V. LEVERAGING NEGOTIATING POWER IN THE UNITED STATES

The United States can benefit from looking at other countries' methods of drug negotiation and by adopting its own version of aggregate purchasing and value-based price controls.[69] This will prevent drug companies from having the ability to charge whatever the market will bear, as the current process allows.[70] The Netherlands and Sweden, for example, have easily been able to achieve positive drug pricing reform as they are much smaller countries than the United States.[71] A few public agencies and private group

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[64] *Id.*
[65] *Id.* ("The committees evaluate a variety of factors: whether a health condition has few or no other treatment options, the extent to which a new drug is a significant clinical advancement, the total cost to the PBS, and the economic benefit associated with the drug's impact.").
[66] *Id.*
[67] *Id.*
[68] *Id.* ("Waldrop cites the changes that Germany and Australia have made to implement value-based pricing systems and the resulting decrease in prices and spending on prescription drugs.").
[69] Blumenthal et al., *supra* note 9.
[70] Waldrop, *supra* note 15.
[71] Blumenthal et al., *supra* note 9 ("[T]hese procurement approaches to achieving lower-priced pharmaceuticals have not been replicated by enough U.S. purchasers to reap the kind of benefits that small countries like the Netherlands and Sweden realize for their residents.").

programs in the United States have attempted to create an aggregate purchasing model, but it has not been replicated enough overall to see benefits across the whole country.[72] There are currently five operational bulk purchasing pools: three that are Medicaid-focused, and two that exist for state and local governments.[73] The National Medicaid Pooling Initiative, Top Dollar Program, and the Sovereign States Drug Consortium generate savings using a preferred drug list, in which a list of specific drugs is authorized to be covered without restrictions.[74] This is used as a way for providers to encourage the prescription of certain drugs over others.[75] The other two entities are the Minnesota Multistate Contracting Alliance for Pharmacy and the Northwest Prescription Drug Consortium, which is a prescription drug discount card program for Oregon and Wisconsin residents.[76]

The United States must find a way to replicate an aggregate purchasing model on a larger scale in order to gain leverage in negotiations and have a say in drug prices.[77] The federal government can do so by implementing a plan where purchasing power is centralized through a single PBM.[78] PBMs already exist, but largely negotiate in secret, so patients do not have access to what types of discount they are provided with, if any.[79] However, if the federal government created an aggregate pharmacy benefit entity, combining HHS and the Public Health Department, heads of private insurance, Medicare, physicians, and pharmacists, it could begin to leverage its

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[72] *Id.*
[73] *Bulk Purchasing of Prescription Drugs*, *supra* note 48.
[74] *Id.*
[75] *Id.*
[76] *Id.*
[77] Blumenthal et al., *supra* note 9.
[78] *Bulk Purchasing of Prescription Drugs*, *supra* note 48 (describing how certain states have implemented programs to centralize purchasing through pharmacy benefit managers).
[79] *How Are Prescription Drug Prices Determined*, *supra* note 22.

negotiating power against drug manufacturers.[80] By leveraging the purchasing power across these agencies, the goal is for each of the parties to receive drugs at a lower price.[81] Instead of having many different buyers, aggregating them into one collective "pool" will allow for one cohesive price structure, and manufacturers will no longer be able to charge whatever they want.[82] This is due to the fact that if manufacturers refuse the price agreed upon and negotiated by the PBM, they will no longer have a buyer.[83] This is similar to the aforementioned successful negotiation structure in the United Kingdom.[84] Therefore, manufacturers would be more inclined to agree upon the set price to ensure the drugs will be purchased.[85]

The United States' prescription drug market is similar in many ways to other countries that have utilized aggregate purchasing.[86] In a study done comparing other high-income countries with the United States, it was found that while per person prescription drug utilization in the United States was at the high end among these countries, it was not an outlier.[87] Therefore, although the United States may have a larger overall population than some high-income countries, the amount of drugs consumed per person is similar

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[80] *Bulk Purchasing of Prescription Drugs*, *supra* note 48 (analyzing state aggregate programs and how they operate under single pharmacy benefit manager to generate additional savings by leveraging purchasing power).
[81] *Id.*
[82] *Id.*
[83] *Billions are Spent by the NHS on Drugs Every Year, But How Does It Work*, *supra* note 51 ("Such centralized buying power gives the NHS the upper hand to a great extent in pricing negotiations and discounts based on volume sales.").
[84] *Id.*
[85] *Id.* ("If the NHS won't buy your products, then you have no real market share.").
[86] Dana O. Sarnak et al., *Paying for Prescription Drugs Around the World: Why is the U.S. an Outlier?*, COMMONWEALTH FUND (Oct. 5, 2017), https://www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier (describing that although the United States has a high per capita drug spending, the United States' share of total national health expenditures is not out of line with that in other countries).
[87] *Id.*

to those in other countries.[88] Further, prescription drug spending in the United States as a share of total national health expenditures (NHE) is not out of line with other countries.[89] The United States prescription drug market has many similarities with other high-income countries.[90] Therefore, although some countries that utilize an aggregate purchasing model have a smaller population than the United States, there are indications that the model can be successful in the United States based on similar market features between the countries.[91]

The PBM must determine how to base price offerings. One way this can be done is by looking at an international approach of value-pricing and focusing on the benefit it provides to base the price.[92] More sophisticated approaches to value-pricing can be taken, but at the very least, the drug in question should be given an assessment and the price that the United States is willing to pay for that drug will be based on the benefit it provides.[93] This can be done through rigorous assessments to determine how much benefit the drug actually delivers, by comparing how much well-being is produced relative to the costs.[94] In this system, higher efficiency drugs are rewarded with higher prices, incentivizing drug companies to develop greater value drugs, adding another benefit for the consumer.[95] Value based pricing will

[88] *Id.*
[89] *Id.* ("[R]etail prescription drugs account for 10% of total NHE in the U.S., whereas in Norway they account for 7% and in Canada for 15%.").
[90] *Id.* (describing trends in the pharmaceutical industry between high-income countries).
[91] *Id.* ("Such reform would mark a significant shift in U.S. policy toward the more centralized pricing determinations used in other high-income countries.").
[92] Synnott et al., *supra* note 59.
[93] *Id.*
[94] *Id.*
[95] *Id.*

give the PBM an idea of what a drug is actually worth so they can have more leverage giving drug companies an informed offer based on that evaluation.[96]

There is some controversy surrounding these approaches. Pharmaceutical and manufacturing companies oppose drug pricing reform on the grounds that it will stifle innovation.[97] However, this claim is not necessarily supported by research.[98] Many countries, such as the United Kingdom and Canada, maintain profitable and innovative pharmaceutical companies while still enjoying the benefit of having lower overall drug prices.[99] In 2017, a study found that of the 46 new drugs approved by the Food and Drug Administration (FDA) that year, 20 were found to offer little to no additional benefit over existing medicines.[100] It is highly unlikely that drug pricing reform will negatively impact innovation, and therefore, it should not be an excuse for preventing drug pricing reform.[101]

Further, as drug prices continue to increase, PBM's interests are scrutinized.[102] Scholars question the extent that PBMs improve the value of United States pharmaceutical care.[103] Specifically, there has been debate that PBM business practices may not align with public policy goals to lower

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[96] *Id*. ("It would provide a foundation for negotiations that is specific to the U.S. context, while avoiding the shortcomings of reference pricing and other cost-containment mechanisms.").
[97] Katherine Igoe, *Putting the Drug Debate into Context: the State of Pharmaceutical Cost Reform in the U.S.*, HARVARD SCH. OF PUB. HEALTH (Jan. 8, 2020), https://www.hsph.harvard.edu/ecpe/state-of-pharmaceutical-cost-reform-in-the-us/.
[98] Chung et al., *supra* note 31.
[99] *Id.*
[100] Richard Frank et al., *What Do High Drug Prices Buy Us*, HEALTHAFFAIRS (Apr. 29, 2020), https://www.healthaffairs.org/do/10.1377/forefront.20200424.131397/full/.
[101] *Id.*; David Blumenthal et al., *The U.S. Can Lower Drug Prices Without Sacrificing Innovation*, COMMONWEALTH FUND (Oct. 1, 2021), https://www.commonwealthfund.org/blog/2021/us-can-lower-drug-prices-without-sacrificing-innovation.
[102] Igoe, *supra* note 97.
[103] Elizabeth Seeley & Aaron Kesselheim, *Pharmacy Benefit Managers: Practices, Controversies, and What Lies Ahead*, COMMONWEALTH FUND (Mar. 26, 2019), https://www.commonwealthfund.org/publications/issue-briefs/2019/mar/pharmacy-benefit-managers-practices-controversies-what-lies-ahead.

pharmaceutical spending.[104] Currently, PBMs have an important tool to try to address the high cost of prescription drugs—the process of negotiating rebates.[105] As a result, critics contend that PBMs may have incentives to prioritize high-priced drugs over more cost-effective drugs because PBMs are partially reimbursed based on the rebates they obtain.[106] The reimbursements are calculated as a percentage of a drug's list price, so PBMs are compensated more for more expensive drugs and therefore the motivation of the PBM comes into question.[107]

There is also argument about whether the federal government should directly intervene with drug pricing.[108] For PBMs to be successful, they need size.[109] By creating a PBM with many different entities, it will be more representative of the population needs as a whole as each entity has different interests, but all are focused on lowering the cost of the drug.[110] In addition, incorporating many different entities as part of the PBM will ensure that lowering drug costs is the priority, as no one entity will be able to prioritize their own profits with the other entities keeping them in check.[111] Further, creating one PBM entity will allow for the greatest negotiating power, and actual progress can be made to lower the price of prescription drugs.[112]

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[104] *Id.*
[105] *Id.*
[106] *Id.*
[107] *Id.*
[108] *Shouldn't the U.S. Government Do More to Regulate High Drug Prices?*, DRUGCOSTFACTS.ORG, https://www.drugcostfacts.org/drug-pricing-regulations.
[109] Cole Werble, *Pharmacy Benefit Managers*, HEALTHAFFAIRS (Sept. 14, 2017), https://www.healthaffairs.org/content/briefs/pharmacy-benefit-managers.
[110] *Bulk Purchasing of Prescription Drugs, supra* note 48 ("By leveraging purchasing power across states or agencies, the goal is for all parties in the pool to receive lower prices.").
[111] Elizabeth Seeley, *The Impact of Pharmaceutical Wholesalers on U.S. Drug Spending*, COMMONWEALTH FUND (July 20, 2022), https://www.commonwealthfund.org/publications/issue-briefs/2022/jul/impact-pharmaceutical-wholesalers-drug-spending ("Consolidation in the pharmacy industry has resulted in chains being able to negotiate lower generic drug prices with wholesalers.").
[112] Werble, *supra* note 109 ("The more covered lives represented by a PBM, the more likely manufacturers will offer rebates in return for potential market share.").

The importance of the federal government acting on the issue of drug pricing is ever increasing.[113] The United States does not currently have any publicly accountable process to control the amount that pharmaceutical drugs can be sold for, compared to every other advanced society that employs the power of national government to deal with drug pricing.[114] Prices are increasing out of reach for consumers, and new treatments can be extremely expensive.[115] An estimated one in four Americans had not filled a prescription in the past year due to the cost, according to a 2015 poll.[116] This trend will only continue if nothing is changed.[117] The PBM will allow buying power to be leveraged to the group, and therefore the price of the drug can be negotiated through a value-based model.[118]

VI. CONCLUSION

The federal government needs to be more proactive and cohesive in tackling the prescription drug price problem. By creating a collective, aggregate group for purchasing, the United States will be able to leverage market power and therefore be in a better position to negotiate the price of prescription drugs with manufacturers.[119] Furthermore, by using value-based assessments, the federal government will be able to provide a foundation for

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[113] Igoe, *supra* note 97 ("Over the last two decades, patients and players have experienced frequent shocks from high and rising medication costs. As a result, pressure has increased on the federal government to control costs.").
[114] *Id.*
[115] *Id.*
[116] *A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices*, WAYS AND MEANS COMM. (Sept. 2019), https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf.
[117] *Id.*
[118] *Bulk Purchasing of Prescription Drugs*, *supra* note 48.
[119] Blumenthal et al., *supra* note 9.

negotiation, and drug companies will be forced to comply.[120] It is important to note that the prescription drug pricing problem has existed for decades, and will continue to be a problem in the future.[121] The drug pricing problem is a notoriously difficult issue to tackle as there are a large amount of moral, market, and political factors at play.[122] While there is not one solution to the drug pricing issue, changing negotiation tactics will begin to lower the extremely high price of prescription drugs, and thus increase access and efficiency overall for United States consumers and patients.

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[120] Synnott et al., *supra* note 59 ("It would provide a foundation for negotiations that is specific to a U.S. context…It would also provide drugmakers with the opportunity to justify their pricing strategies….").

[121] *Spending on Prescription Drugs Has Been Growing Exponentially Over the Past Few Decades*, PETER G. PETERSON FOUND. (June 16, 2022), https://www.pgpf.org/infographic/spending-on-prescription-drugs-has-been-growing-exponentially-over-the-past-few-decades ("U.S. spending on prescription drugs has risen substantially in the past 20 years, climbing from $122 billion in 2000 to $348 billion in 2020.").

[122] Michelle Mello, *What Makes Ensuring Access to Affordable Prescription Drugs the Hardest Problem in Health Policy?*, 102 Minn. L. Rev. 2273 (2018) ("[T]here are a number of things about the prescription drug affordability problem that make it distinctively tricky. These problems can be grouped under three rubrics: (1) moral factors; (2) market factors; and (3) political factors.").

"What's Wrong with Having a Lot of Patents?": The AbbVie Antitrust Decision & Why Impeding Pharmaceutical Patenting Practices is Crucial for Affordable Medicines

Amal Mir

I. INTRODUCTION

It is no secret that as the cost of medication in the United States has skyrocketed over the past decade, Americans have been forced to pay more for prescription drugs than any other country in the world.[1] The overlap between flimsy patent laws, originator drug monopolies, and the lobbying power of pharmaceutical companies is central to accessibility issues resulting from high drug pricing.[2] Although regulating drug prices and increasing financial transparency of drug development stand as just two of many proposals for legislators to help lower drug costs for Americans,[3] another solution calls for limitations on the U.S. Patent and Trademark Office's (USPTO) ability to issue continuation applications that encourage evergreening practices.[4] Patent evergreening, also known as "life-cycle management," refers to a marketing strategy that pharmaceutical companies employ to protect the profitability of their products.[5] When a pharmaceutical company reformulates an aspect of their drug, they can ultimately "extend"

[1] Cynthia Cox et al., *How Do Prescription Drug Costs in the United States Compare to Other Countries?* PETERSON-KFF HEALTH SYS. TRACKER (Feb. 8, 2022), https://www.healthsystemtracker.org/chart-collection/how-do-prescription-drug-costs-in-the-united-states-compare-to-other-countries/.
[2] Diane Archer, *Pharma's Monopolies Are the Reason for High Drug Prices*, JUSTCARE (May 30, 2018), https://justcareusa.org/ pharmas-monopolies-are-the-reason-for-high-drug-prices/.
[3] *Id.*
[4] JOHN R. THOMAS, CONG. RSCH. SERV., R40917, PATENT "EVERGREENING": ISSUES IN INNOVATION AND COMPETITION, at 5 (2009), https://ipmall.law.unh.edu/sites/default/files/hosted_resources/crs/R40917_091113.pdf.
[5] Robert Collier, *Drug Patents: The Evergreening Problem*, CMAJ, (June 11, 2013), https://www.ncbi.nlm.nih.gov/ pmc/articles/PMC3680578/.

the life of their patent and maintain the monopoly protection of their product.[6] Evergreening, compounded with "patent thicketing," is only one of many contributing factors to unreasonable drug prices. Accordingly, there are calls for new approaches to patent regulations in the United States.[7]

This article will first provide an overview of the corporate practice of evergreening, patent thicketing, and its impact on drug prices. It will then discuss the Court's decision in *Mayor & City of Baltimore v. AbbVie Inc.* to illustrate how using antitrust as a vehicle to remedy the harms of pharmaceutical patenting practices is inefficient. Lastly, this article will argue that Congress and the USPTO should adopt specific regulations to curtail the impact of patent misuse to promote public health and well-being.

II. BACKGROUND

Article I, Section 8, Clause 8 of the United States Constitution grants Congress the authority "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."[8] Under this provision, Congress is afforded broad power to legislate national copyright and intellectual property laws.[9] The ratification of the Constitution also promulgated federal patent law legislation: specifically, the Patent Act of 1952 codified in Title 35 of the United States Code.[10]

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[6] KEVIN T. RICHARDS ET AL., CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES, at 3 (Feb. 11, 2020), https://sgp.fas.org/crs/misc/R46221.pdf.
[7] *Id.*
[8] U.S. CONST. art. I, § 8, cl. 8.
[9] *See Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980) (holding that engineered micro-organisms could be patented as it was an invention that fell within the scope of patentability).
[10] Patent Act of 1952, 35 U.S.C. §§ 1-293 (1952).

A patent is an exclusive property right that allows its grantee to exclude others from using, making, importing, and selling their patented invention for a designated amount of time.[11] Among other requirements, an invention must be useful, novel, and nonobvious for it to receive federal patent protection.[12] Once an inventor files an application with the USPTO, an examiner will determine whether their invention fulfills all the patent requirements.[13] If the patent is granted, the inventor has exclusive rights over their invention for twenty years from the application's filing date.[14]

A patent grant does not automatically allow a product to enter the market for sale.[15] Instead, pharmaceutical drugs must also obtain approval by the U.S. Food and Drug Administration (FDA) by demonstrating that the drug is safe and effective.[16] Once the patent is granted by the USPTO, approved by the FDA, and the exclusivity period has elapsed, only then will the patent protection expire and others may freely use the previously patented invention.[17] This means that generic forms of an originator drug—or the first model of a drug authorized for marketing— can finally enter the market.[18] The increased competition consequently drives down the market price of a pioneer drug, making the drug more accessible to consumers.[19] Evergreening practices can prolong a patent holder's right to exclude, lengthening their

[11] *Id.*
[12] *Id.*
[13] *Guide to Intellectual Property: What is the Patent Process?*, NAT'L INVENTORS HALL OF FAME, https://www.invent.org/blog/intellectual-property/how-to-patent-idea-product (last visited Dec. 16, 2022).
[14] Megan Van Etten, *IP Explained: How Does the U.S. Patent Process Work?* PHRMA FOUND. (Jun. 24, 2021), https://catalyst.phrma.org/ip-explained-how-does-the-u.s.-patent-process-work.
[15] *Id.*
[16] *Id.*
[17] Thomas, *supra* note 4, at 3.
[18] *Id.*
[19] *Id.*

monopoly period by preventing generic competitors from flooding the market.[20]

Pharmaceutical companies are currently "recycling and repurposing" old drugs, with almost 80% of new patents being linked to existing medicines.[21] Evergreening allows a company to pile on new patents to old inventions either by patenting an aspect of the drug, such as its coating, or by patenting an improvement of the drug, such as its dosage.[22] Defenders of evergreening argue that regulation can stifle innovation by disincentivizing inventors to create new products that would benefit the public.[23] These pharmaceutical companies also argue that the impact of evergreening is heavily exaggerated, and purport that without the advantageous pricing model accompanying their monopoly, the development of new drugs would diminish due to their inability to fund clinical trials necessary for such drug research.[24] However, studies have shown that pharmaceutical companies spend far more on advertisements than on research and development.[25] In 2020 alone, AbbVie spent nearly "$11 billion on sales and marketing, compared to $8 billion on research and development."[26] Moreover, the argument that evergreening regulation can curb innovation is even less compelling considering that since the 1990s, "about 85-90% of all new drugs provide few or no clinical

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[20] *Id.* at 4.
[21] Robin Feldman, *May Your Drug Price Be Evergreen,* U.C. HASTINGS J.L. & BIOSCI., 590, 617 (2018), https://academic.oup.com/jlb/article/5/3/590/5232981.
[22] *Id.*
[23] Kelley Chandler, *Patents, and the Pharmaceutical Industry: Curbing the Abusive Practices Employed by Blockbuster Drug Companies to Prolong Market Exclusivity*, CORNELL J.L. & PUB. POL'Y. 487, 488 (2019).
[24] *Id.*
[25] *New Study: In the Midst of COVID-19 Crisis, 7 out of 10 Big Pharma Companies Spent More on Sales and Marketing than R&D,* AHIP (Oct. 27, 2021), https://www.ahip.org/news/articles/new-study-in-the-midst-of-covid-19-crisis-7-out-of-10-big-pharma-companies-spent-more-on-sales-and-marketing-than-r-d.
[26] *Id.*

advantages for patients"—namely, "the real innovation crisis."[27] Rewarding companies for repackaging old inventions at the expense of patients and the healthcare system is simply unjustifiable as evergreening can disrupt generic drug availability and leave the public with no lower-cost alternatives to life-saving brand-name medication.[28]

However, evergreening is not the only tactic that pharmaceutical companies utilize to protect their monopoly in the pharmaceutical sector. The use of patent thickets, or a group of overlapping patents for a particular product, also falls under the umbrella of patent misuse.[29] Specifically, patent thickets are a "dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology."[30] This essentially keeps generic competitors from entering the market due to the risk of patent infringement of any of the several filed patents on the same originator drug.[31]

Notably, one of the most infamous examples of a company employing evergreening tactics coupled with patent thicketing is the case of AbbVie and its blockbuster rheumatoid arthritis drug, Humira.[32] Although the original patent on Humira expired in 2016, the company obtained over 132 additional patents on the drug's formulation and manufacturing process.[33] While the FDA subsequently approved generic biologic competitor drugs of Humira,

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[27] Donald W Light & Joel Lexchin, *Pharmaceutical Research and Development: What Do We Get For All That Money?* BMJ (Aug. 7, 2012), https://www.bmj.com/content/345/bmj.e4348.
[28] *Id.*
[29] Uri Y. Hacohen, *Evergreening at Risk*, 33 HARV. J.L. TECH. 479, 484 (2020).
[30] Carl Shapiro, *Navigating the Patent Thicket: Cross Licensing, Patent Pools, and Standard Setting*, INNOVATION POL'Y & ECON. 119, 120 (2001).
[31] Gina Campanelli, Feeling Evergreen: A Case Study of Humira's Patent Extension Strategies and Retroactive Assessment of Second-Line Patent Validity (Apr. 20, 2022) (unpublished M.A. thesis, Harvard University) (on file with Harvard Library).
[32] *Id.* at 1.
[33] *Id.* at 32.

the price of the drug itself increased by 144% and continues to rise.[34] This price spike can be attributed to generic manufacturers' risk of marketing their drugs at the expense of being sued for patent infringement by AbbVie.[35] The practice of "launching at risk" has proven to be costly for generic manufacturers, and companies comparable to AbbVie are generally successful in scaring off competitors.[36] The impenetrable patent wall that AbbVie built around Humira allows it to maintain monopoly pricing, resulting in higher prices for consumers across the country.[37] The rising prices of drugs such as Humira can be fatal, with about a quarter of Americans skipping their doses of medication due to its cost.[38] This calls for serious reform measures to curb the over-pricing and over-patenting of life-saving medications.

III. THE ABBVIE DECISION AND THE ROLE OF COURTS

When the principal patent on Humira expired in 2016, AbbVie obtained an additional 132 patents relating to aspects of the drug—including its form and administration— in order to extend its patent protections to 2034.[39] Under the Biologics Price Competition & Innovation Act (BPCIA), biologics such as Humira have twelve years of exclusivity before generic biosimilars

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[34] Eric Sagonowsky, *AbbVie, Already Famous for its Humira Strategy, Forms Another 'Patent Wall' Around Imbruvica: Report,* FIERCE PHARMA (Jul. 21, 2020), https://www.fiercepharma.com/pharma/abbvie-already-famous-for-its-humira-strategy-forms-another-patent-wall-for-imbruvica-report.
[35] Jeff Bank et al., *Seventh Circuit Affirms Denial of Claims Brought Against AbbVie*, JD SUPRA (Aug. 9, 2022), https://www.jdsupra.com/legalnews/seventh-circuit-affirms-denial-of-4963877/.
[36] *Id.*
[37] *Id.*
[38] Alex Montero et al., *Americans' Challenges with Health Care Costs,* KFF (Jul. 14, 2022), https://www.kff.org/health-costs/issue-brief/americans-challenges-with-health-care-costs/.
[39] Jonathan Rubin, *AbbVie's Humira Patent Settlement Not a Violation of Sherman Antitrust Act, Seventh Circuit Affirms*, NAT'L L. REV. 215 (Aug. 3, 2022), https://www.natlawreview.com/article/abbvie-s-humira-patent-settlement-not-violation-sherman-antitrust-act-seventh.

can compete.[40] However, in 2019, indirect payers for Humira filed a class action complaint against AbbVie, alleging its patent procurement process and "pay-for-delay" settlements with biosimilar competitive drug companies violated Sections 1 and 2 of the Sherman Antitrust Act.[41] The Sherman Antitrust Act—promulgated in 1890— constituted the first iteration of federal legislation targeting unfair monopolies that restricted the public's access to goods.[42] To litigate based on an illegal monopoly under the Sherman Act, a party must show a company's "specific intent to monopolize" and "a dangerous probability of achieving monopoly power."[43]

Accordingly, the complaint stated that "AbbVie successfully prevented all biosimilars from launching in the U.S. market through widespread anticompetitive conduct that has allowed it to maintain its monopoly and supracompetitive prices."[44] The plaintiffs further claimed that AbbVie's "evergreened" patent thicket forced generic biosimilar companies into settlements.[45] Rather than litigating in court, a "pay-for-day" settlement is an agreement for a generic drug manufacturer to abstain from marketing its generic drug for some period of time.[46] These settlements blocked generic biosimilar drugs from entering the U.S. market, but allowed them to enter European markets.[47] The district court dismissed the class action complaint

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[40] Kasey E. Koballa, *The Biologics Price Competition and Innovation Act: Is a Generic Market for Biologics Attainable?*, WILLIAM & MARY BUS. L. REV. 479, 483 (2018).
[41] *See In re Humira (Adalimumab) Antitr. Litig*., 465 F. Supp. 3d 811, at 1 (N.D. Ill. 2020) (alleging that AbbVie applied for, obtained, and asserted patents to gain power it needed to get rid of its competitors).
[42] 15 U.S.C. § 2 (2000).
[43] *Id.*
[44] Complaint at 22, *In re Humira*, 465 F. Supp. 3d 811, at 3 (N.D. Ill. 2019).
[45] *In re Humira*, 465 F. Supp. 3d at 819.
[46] Chelsea Olivera, *Is the End Near for Pharmaceutical Pay-for-Delay Deals?*, UMLR (Nov. 1, 2021), https://lawreview.law. miami.edu/pharmaceutical-pay-for-delay-deals/.
[47] *In re Humira*, 465 F. Supp. 3d at 825.

against AbbVie, bolstering its ability to aggregate patents to protect Humira from biosimilar competitors at the consumers' expense.[48]

The district court's decision predicated on the broad scope of the *Noerr-Pennington* doctrine outlined in two distinct Supreme Court cases: *Eastern Railway President's Conference v. Noerr Motor Freight, Inc* and *United Mine Workers v. Pennington*.[49] The *Noerr-Pennington* doctrine gives private entities First Amendment freedom to petition the government.[50] These cases invoke antitrust immunity for patent applications with the logic that a granted patent is "objectively reasonable."[51] However, the sham exception could apply if a petition is determined "to be both objectively baseless and the petitioner intends to use the process to interfere with a competitor's business."[52] This doctrine further legitimizes patent thickets by allowing them to evade antitrust complaints.[53] Because AbbVie did not use the patent procurement process for the purpose of harming market rivals, the district court ruled that amassing a large portfolio of patents did not trigger the sham exception under *Noerr-Pennington*.[54]

In August of 2022, the issue that the indirect buyers raised on appeal concerned whether the "pay-for-delay" settlements were anti-competitive.[55] Specifically, the Appellant stated that AbbVie "sought exclusion not through recognition of legitimate patent rights but through raising its rivals' costs by forcing them to invest time and money rebutting allegedly worthless

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[48] *In re* Humira (Adalimumab) Antitr. Litig., 465 F. Supp. 3d 811, 819 (N.D. Ill. 2020).
[49] Lisa Orucevic, *A Machete for the Patent Thicket: Using Noerr-Pennington Doctrine's Sham Exception to Challenge Abusive Patent Tactics by Pharmaceutical Companies*, 75 VAND. L. REV. 277, 296-7 (2022) https://vanderbiltlawreview.org/ lawreview/wp-content/uploads/sites/278/2022/01/A-Machete-for-the-Patent-Thicket.pdf [hereinafter *Machete Patent Thicket*].
[50] *Id*. at 281.
[51] *Id*. at 300.
[52] *Mayor and City Council of Baltimore v. AbbVie Inc.*, 42 F.4th 709, 713 (7th Cir. 2022).
[53] Orucevic, *Machete Patent Thicket, supra* note 48, at 277.
[54] *In re Humira*, 465 F. Supp. 3d at 830.
[55] *Mayor and City Council of Baltimore v. AbbVie Inc*., 42 F.4th at 709.

arguments."[56] The Seventh Circuit Court of Appeals affirmed the district court's decision to dismiss the complaint.[57] The Seventh Circuit reasoned that AbbVie's patents had a legitimate basis because they were granted by the USPTO and are presumed to be valid per 35 U.S.C. §282(a).[58] It asserted that there was nothing inherently monopolistic about amassing a large portfolio of patents.[59] Notably, presiding Judge Frank Easterbrook remarked, "[w]hat's wrong with having lots of patents? The patent laws do not set a cap on the number of patents any one person can hold."[60]

Judge Easterbrook's decision has several potential implications. First, it is significant because it indicates how "patent thicket" lawsuits based on antitrust theory are unlikely to succeed in the future. It also demonstrates the relative failure of using antitrust doctrine to mitigate the effects of anti-competitive practices within the patenting industry.[61] Moreover, it emphasizes the pressing need for Congress and administrative agencies to push for reform of the current patent system.[62] Lastly, it illustrates the exorbitant nature of challenging pioneer drugs' patents, and how it deters competitors from seeking legal action. [63]

This stark power imbalance confirms that relying on the courts to scrutinize the validity of patents may be futile and costly for both consumers and generic manufacturers. Judge Manish S. Shah for the Northern District

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[56] Brief of Petitioner-Appellant at 20, *UFCW Local 1500 Welfare Fund, et al., v. AbbVie Inc.*, No. 20-2402 (7th Cir. 2020).
[57] *Id.* at 715.
[58] *Id.* at 713.
[59] *Id.* at 712.
[60] *Id.*
[61] *See, e.g.*, Robin C. Feldman, *The Insufficiency of Antitrust Analysis for Patent Misuse*, 55 HASTINGS L.J. 399, 406-7 (2003) (discussing that the history and conceptual overlap of patent law and antitrust law have left the doctrine of misuse hopelessly entangled with antitrust doctrines).
[62] *Id*. at 401.
[63] *Id*. at 493.

of Illinois stated that patent infringement lawsuits would not "revamp the FDA's biologics application process or the USPTO's drug patenting process" and that although patent system reform may be necessary, "antitrust laws were not designed to repair other government regulatory processes."[64]

IV. ATTEMPTS TO REGULATE & NEW PROPOSALS

In *Diamond v. Chakrabarty*, the Supreme Court stated that Congress is responsible for defining the limits of patentability.[65] As previously discussed, combatting evergreening and patent-thicketing practices through antitrust litigation seems far from fruitful. Antitrust doctrines have historically upheld the value of innovation, and *City of Baltimore v. AbbVie* illustrates how current antitrust enforcement tends to reward innovators.[66] Moreover, the specific-intent language of the Sherman Act is particularly restrictive, as it overlooks the material consequences of concentrated monopoly power.[67] Rather than relying on judicial intervention to resolve patent disputes, which can be costly and complex, it may be more practicable for the legislature and appropriate administrative bodies to elucidate the bounds of patent laws and procedures.[68] Therefore, to alleviate the costs of high-priced drugs, legislators and administrators should work towards

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[64] *In re Humira*, 465 F. Supp. 3d 811, 834 (N.D. Ill. 2020).
[65] *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).
[66] Shun Iwamitsu, *Antitrust Reform, Big Tech, and Innovation: A Word of Caution*, COLUM. BUS. L. REV., (Feb. 25, 2022), https://journals.library.columbia.edu/index.php/CBLR/announcement/view/502; *See also Mayor & City Council of Baltimore v. AbbVie Inc*., 42 F.4th at 709 (7th Cir. 2022) (describing how antitrust reform must consider its impact on innovation).
[67] 15 U.S.C. § 2 (2000).
[68] *See generally, In re Humira (Adalimumab) Antitr. Litig*., 465 F. Supp. 3d 811, at 114 (N.D. Ill. 2020) https://storage.courtlistener.com/recap/gov.uscourts.ilnd.362729/gov.uscourts.ilnd.362729.109.0.pdf (alleging that AbbVie's conduct surrounding the patenting of its drug Humira was anticompetitive).

redefining the scope of patentable subject-matter and restructuring the USPTO internal examination process.

A. *Restricting Subject Matter Patentability*

A direct approach to preserve the generic market would be to amend the Patent Act.[69] Proposals to heighten patenting standards are not unique as there have been long-standing concerns recognizing the overly permissive nature of patent grants.[70] On August 2nd, 2022, Senator Thomas Tillis introduced the Patent Eligibility Restoration Act of 2022, which would amend 35 U.S.C. § 101 to include eligibility exclusions and define "useful" as "specific and practical utility from the perspective of a person of ordinary skill in the art to which the invention of discovery pertains."[71] If passed, this amendment could restrict the scope of patentability by barring incremental innovation.

Accordingly, Congress should amend the Patent Act to invoke additional scrutiny for patent applications. India is an example of a country whose patent scheme inhibits a manufacturer's ability to evergreen their products.[72] India's current patent law explicitly defines standards of non-patentable subject matter:

> [T]he mere discovery of a new form of a known substance, which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine, or apparatus unless such

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[69] Julian W. Marrs, *Forever Green? An Examination of Pharmaceutical Patent Extensions,* 18 OR. REV. INT'L L. 81, 96-7 (2016).
[70] *Id.* at 96.
[71] S.4734, 117th Cong. (2022).
[72] Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and The Rise of Indian Pharmaceutical Innovation,* 68 U. PITT. L. REV. 491, 503 (2006).

> known process results in a new product or employs at least one new reactant.[73]

The statutory language of Section 3(d) of the Patent Act instructs applicants to show enhanced efficacy of their original products.[74] Unlike India's restrictive statute, Section 101 of the U.S. Patent Act is broad.[75] It states that an invention is patentable if it is a "new and useful process, the machine, manufacture, or composition of matter; or any new and useful improvement thereof."[76] The Act's lack of definitions is over-inclusive and creates a low threshold for patent eligibility.[77] Amendments to existing patent law could heighten patentability standards by defining what it means for an invention to be "new" or "useful" or by expanding on what an "improvement" encompasses.[78] The U.S. could also adopt an enhanced therapeutic efficacy standard for secondary patents, requiring a showing of improved patient outcomes.[79] Altering patent law through the addition of amendments similar to India's Section 3(d) could help eliminate evergreening practices and introduce affordable generic drugs to the market.[80]

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[73] The Patent Act, No. 39 of 1970, §3(d) (Universal 2005).
[74] Mueller, *supra* note 69, at 553.
[75] *Id.* at 557.
[76] *See* 35 U.S.C. §101 (2000) (discussing subject matter requirements for patentability).
[77] Kelley Chandler, *Patents, and the Pharmaceutical Industry: Curbing the Abusive Practices Employed by Blockbuster Drug Companies to Prolong Market Exclusivity*, CORNELL J.L. & PUB. POL'Y. at 483 (2019), https://ww3.lawschool.cornell.edu/research/JLPP/upload/Chandler-note-final.pdf.
[78] Office of Patent Legal Administration United States Patent and Trademark Office, *35 U.S.C. §101: Statutory Requirements and Four Categories of Invention* (Aug. 2015), https://www.uspto.gov/sites/default/files/101step1refresher.pdf.
[79] Dorothy Du, *Novartis AG v. Union of India: 'Evergreening,' TRIPs, and 'Enhanced Efficacy' Under Section 3(d)*, 21 J. INTELL. PROP. L. 223, 252 (2014), https://digitalcommons.law.uga.edu/jipl/vol21/iss2/2.
[80] Julian W. Marrs, *Forever Green? An Examination of Pharmaceutical Patent Extensions*, 18 OR. REV. INT'L L. 81, 97 (2016).

B. *USPTO Patent Examination Reform*

Another bill introduced by Senator Tillis was the "Patent Examination and Quality Improvement Act of 2022," a bipartisan measure to ameliorate the patent examination process at the USPTO.[81] Amongst other measures, the bill calls on the USPTO for reports on the patent examination process as a way for Congress to "evaluate the need for greater clarity in terms of what constitutes patent quality, the setting of patent quality metrics, and how the quality of work performed by patent examiners is measured within the office."[82] While this bill is commendable in that it calls for transparency of the patent process, it may not be enough of a definite intervention to curb patent thickets and evergreening practices.[83] Accordingly, to supplement this proposal, Congress should require the USPTO to revamp its current internal procedures surrounding the allocation of patent examination time.

Studies have shown that roughly one-third of patents litigated to final judgment are invalid.[84] With the increasing number of patent applications and patent grants, Congress should specifically focus on the impact of understaffed patent offices and its correlation with errors in patent prosecution.[85] In particular, the USPTO is authorized to establish self-regulatory rules governing its procedures.[86] The role of a patent examiner is to assess patent applications and to determine the patentability of a claimed

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[81] S.4704, 117th Cong. (2022).
[82] *See* Press Release, Thom Tillis, Senator, Tillis and Leahy Introduce Bipartisan Legislation to Improve Patent Quality (Aug. 2, 2022), https://www.tillis.senate.gov/2022/8/tillis-and-leahy-introduce-bipartisan-legislation-to-improve-patent-quality (proposing legislation to improve patent examination processes).
[83] *Id.*
[84] Shine Tu, *Invalidated Patents and Associated Patent Examiners*, 18 VAND. J. ENT. & TECH. L. 135, 135 (2015), https://researchrepository.wvu.edu/cgi/viewcontent.cgi?article=1028&context=law_faculty.
[85] *Id.* at 137.
[86] United States Patent and Trademark Office, *General information concerning patents* (Mar. 14, 2018), https://www.uspto.gov/ patents/basics/general-information-patents.

invention.[87] The majority of invalidated patents were based on "prior art" and were not found by either the USPTO, the applicant, or the examiner.[88] Prior art is evidence of what is publicly known about an invention before the date that a patent application is filed, and describes how the novelty of a claimed invention is assessed.[89] The search for prior art is time-consuming, especially when considering that the average time a patent examiner spends on an application is nineteen hours.[90] Given the amount of time spent on each patent application, it is unsurprising that invalid applications slip through the cracks.[91] The decrease in examination time results in an increase in patent grants, ultimately keeping generic medicines out of the market and maintaining high drug prices for consumers.[92] Therefore, it is crucial for the USPTO to focus on restructuring how its examiners search for prior art.[93] This administrative level of reform would likely reduce errors in patent prosecution along with the expense of potential patent litigation that may arise with attacking a patent thicket.

The competing interests of innovators, generic manufacturers, and consumers make it difficult to create unanimously satisfactory solutions. Moreover, the pharmaceutical industry would likely oppose any measures that restrict patent protection of their products. The industry alone spent approximately $390 million on lobbying and campaign contributions in

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[87] *Id.*
[88] Tu, *supra* note 81, at 165.
[89] Cynthia Ho, *Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies*, 39 U. MICH J.L. REFORM 433,445-6 (2006).
[90] Josh Landau, *Granted in 19 Hours*, PATENT PROGRESS (Mar. 6, 2018), https://www.patentprogress.org/2018/03/06/granted-19-hours/.
[91] *Id.*
[92] *Id.*; *see also* Alison Kodjak, *Tighter Patent Rules Could Help Lower Drug Prices, Study Shows*, NPR (Aug. 23, 2016), https://www.npr.org/sections/health-shots/2016/08/23/491053523/tighter-patent-rules-could-help-lower-drug-prices-study-shows (describing how evergreening can keep drug prices high).
[93] *Id.*

2021, which is another barrier in the uphill battle for patent law reform.[94] However, this framework to curb evergreening practices will likely garner Congressional support in several respects. First, it may improve patent quality, giving the U.S. a competitive edge and driving economic growth.[95] Additionally, reforms aimed at limiting patent thickets would inevitably deter monopolies that hamper the development of new inventions.[96] Lastly, legislators are interested in promoting public health and likely support ways to protect access to lifesaving drugs.[97]

Bipartisan efforts have long recognized that the regulatory scheme of the current U.S. patent system is susceptible to exploitative practices by the pharmaceutical industry.[98] Restructuring USPTO evaluation practices coupled with amending existing patent laws to impede an inventor's ability to engage in evergreening strategies will allow for more affordable medicines to enter the market while simultaneously driving down the costs of originator drugs.

V. CONCLUSION

Revamping the current patent system against the backdrop of antitrust litigation appears to be an improbable feat. As the *City of Baltimore* decision

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[94] Brooke Fox, *Healthcare Companies Spent More on Lobbying Than Any Other Industry Last Year*, PROMARKET (Jun. 29, 2022), https://www.promarket.org/2022/06/29/healthcare-companies-spent-more-on-lobbying-than-any-other-industry-last-year/.
[95] Wayne Brough, *Improving patent quality improves innovation*, R STREET (Jun. 9, 2022), https://www.rstreet.org/ 2022/06/09/improving-patent-quality-improves-innovation/.
[96] *Id.*
[97] Kristi Martin, *Policymakers' Attention Turns to Drug Patents in the Debate on Prices*, THE COMMONWEALTH FUND BLOG (Oct. 7, 2021), https://www.commonwealthfund.org/blog/2021/policymakers-attention-turns-drug-patents-debate-prices.
[98] Press Release, *Tillis and Leahy Introduce Bipartisan Legislation to Improve Patent Quality* (Aug. 2, 2022), https://www.tillis.senate.gov/2022/8/tillis-and-leahy-introduce-bipartisan-legislation-to-improve-patent-quality.

demonstrates, pushing for policies that stymie a pharmaceutical company's ability to engage in life-cycle management practices may be a more practical way of addressing the root of systemic patenting issues.[99] Policies that address regulatory loopholes will inevitably allow for increased market entry of generic drugs, driving prices of drugs down for consumers. By no means would reform intended to curb patent misuse foreclose all opportunities for pharmaceutical companies to game the system, but it is a start.[100] Until Congress and the USPTO address the dire need for regulatory mechanisms that hinder a company's ability to evergreen their products, makers will continue to hold powerful monopolies that obstruct a patient's access to affordable medicines.[101]

[99] *Mayor and City Council of Baltimore v. AbbVie Inc*., 42 F.4th at 710.
[100] Michael Bluhm, *The Role of Monopoly in America's Prescription Drug Crisis,* OPEN MARKETS INSTITUTE (Dec. 9, 2019) https://static1.squarespace.com/static/5e449c8c3ef68d752f3e70dc/t/5ea4d29f9bc8f31a1117feec/1587860128096/WhitePaper_DrugPrices_Bluhm.pdf.
[101] *Id.*

CMS Hospital Price Transparency Rule: Enforcement Challenges and Recommendations for Improvement

Nina Ordinario

I. INTRODUCTION

In January 2021, the Centers for Medicare and Medicaid Services ("CMS") began enforcing the Hospital Price Transparency Rule ("HPTR") as an effort to help patients understand the cost of healthcare services and their financial responsibilities.[1] Under this rule, CMS now requires hospitals to provide prospective patients with the cost of medical treatments before the hospital renders services.[2] CMS began auditing hospitals for compliance with the HPTR provisions once it took effect, and in June 2022, CMS issued the first civil monetary penalty ("CMP") notices to two hospitals.[3] Although only two hospitals have been penalized so far, the most recent research shows that only sixteen percent of hospitals comply with the HPTR requirements.[4] As the second anniversary of the HPTR approaches in January 2023, many hospitals could face penalties for noncompliance if the current trends continue.[5] Accordingly, CMS should take the following actions to help hospitals improve compliance before penalties arise. First, CMS should encourage widespread consumer education on the new price transparency regulations. Second, CMS should provide increased guidance on price estimator methods and tools, which many hospitals rely on. Finally, CMS

[1] Hospital Price Transparency, 45 C.F.R. § 180 (2019).
[2] *Id.*
[3] *See infra* pp. 6-7 (describing how CMS issued CMP notices to Northside Hospital Cherokee and Northside Hospital Atlanta, both located in Georgia, for noncompliance with the HPTR requirements).
[4] *See infra* pp. 7-8 (describing a research study conducted by Patient Rights Advocate in August 2022 revealing low compliance rates with the HPTR).
[5] *Almost 95% of Hospitals Fell Short of Price Transparency. Now, the Fines are Starting.*, ADVISORY BD. (June 10, 2022), https://www.advisory.com/daily-briefing/2022/06/10/price-transparency [hereinafter ADVISORY BD.].

should enforce both the Transparency in Coverage Rule ("TICR") and the HPTR in equal measure.[6]

II. PRICE TRANSPARENCY IN RECENT HISTORY

Price transparency occurs when sellers openly provide consumers with the prices for products or services.[7] When consumers have full access to prices, they are empowered to "price shop" and negotiate better prices for services.[8] As a result, sellers are encouraged to compete with one another by lowering their prices and improving the quality of their services to attract consumers.[9] Price transparency thus enables consumers to access services that are more affordable and of higher quality.[10] In addition, sellers can benefit from price transparency as well.[11] Because sellers can view how much their competitors charge for services, sellers can use this data to analyze the market and alter their business models by lowering prices to remain competitive.[12]

Although the concept of price transparency can be applied in various industries and markets, in the past few years, price transparency has mainly been associated with healthcare reform.[13] There is much ambiguity surrounding the pricing for treatments, procedures, and prescriptions.[14] For example, many patients do not know how much services will cost before they

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[6] Transparency in Coverage, 45 C.F.R. § 147 (2020).
[7] Hospital Price Transparency Rule, 84 Fed. Reg. 65524, 65525-27 (Nov. 27, 2019) (to be codified at 45 C.F.R. § 180); D. ANDREW AUSTIN & JANE G. GRAVELLE, CONG. RSH. SERV., RL34101, DOES PRICE TRANSPARENCY IMPROVE MARKET EFFICIENCY? IMPLICATIONS OF EMPIRICAL EVIDENCE IN OTHER MARKETS FOR THE HEALTHCARE SECTOR 1 (2007).
[8] Hospital Price Transparency Rule, 84 Fed. Reg. at 65525-27.
[9] *Id.*
[10] *Id.*
[11] *Id.*
[12] *Id.*; *see also* AUSTIN & GRAVELLE, *supra* note 7, at 3 (describing how price transparency "may alter the strategic
incentives of sellers, inducing them to become tougher bargainers").
[13] AUSTIN & GRAVELLE, supra note 7, at 34-46 (describing the impacts of price transparency on various industries such as airlines, gas, stocks, and other commercial goods); Hospital Price Transparency Rule, 84 Fed. Reg. 65524, 65525-27 (Nov. 27, 2019) (to be codified at 45 C.F.R. § 180).
[14] Hospital Price Transparency Rule, 84 Fed. Reg. at 65525-27.

receive treatment, and similarly, many patients are shocked when they receive "surprise bills."[15] In these situations, patients lack the opportunity to discuss the cost with their insurance carrier and plan for their financial responsibilities.[16]

The push for price transparency dates back as early as 2006 when President George W. Bush expressed support for "infus[ing] transparency about price and quality into the healthcare system."[17] Although this goal did not come to complete fruition, the Bush administration stimulated discussion and research on price transparency and motivated future administrations to implement price transparency actions.[18] The most pivotal executive action occurred in 2019 when the Trump administration refocused on the goal of price transparency in the President's Executive Order on "Improving Price and Quality Transparency in American Healthcare to Put Patients First."[19] The executive order ultimately required the Secretary of Health and Human Services ("HHS") to propose and implement a regulation requiring hospitals to "publicly post standard charge information, including charges and information based on negotiated rates and for common or shoppable items

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[15] *Id.* at 65530; Karen Pollitz, *Surprise Medical Bills*, KAISER FAMILY FOUNDATION (2016), https://www.kff.org/private-insurance/issue-brief/surprise-medical-bill ("'Surprise medical bill' is a term commonly used to describe charges arising when an insured individual inadvertently receives care from an out-of-network provider.").

[16] *See* Hospital Price Transparency Rule, 84 Fed. Reg. at 65578 (stating that insured patients need to know the total charge for items and services in addition to their insurance plan benefits "in order to determine their personal out-of-pocket obligations").

[17] *President Bush Strengthened America's Health Care System*, GEORGE W. BUSH WHITE HOUSE ARCHIVES, https://georgewbush-whitehouse.archives.gov/infocus/bushrecord/factsheets/healthcare.html (last visited Sept. 2, 2022).

[18] *See generally* Affordable Care Act (ACA), 42 U.S.C. § 18001 (2010) (amending the Public Health Service Act, 42 U.S.C. § 300gg-18(e), by adding a provision requiring that "[e]ach hospital operating within the United States shall for each year establish . . . and make public . . . a list of the hospital's standard charges for items and services provided by the hospital"); *see also* FY 2019 IPPS/LTCH PPS Final Rule, 83 Fed. Reg. 41144, 41686 (Aug. 17, 2018) (requiring hospitals to "make available a list of their current standard charges via the Internet in a machine-readable format and to update this information at least annually, or more often as appropriate").

[19] Proclamation No. 13877, 84 Fed. Reg. 30849, 30850 (June 24, 2019).

and services, in an easy-to-understand, consumer-friendly, and machine-readable format using consensus-based data standards that will meaningfully inform patients' decision making and allow patients to compare prices across hospitals."[20] As a result, CMS proposed and finalized the HPTR, which requires hospitals to "provide clear, accessible pricing information online about the items and services they provide."[21]

In July 2021, President Joe Biden further supported implementation by directing the Secretary of HHS to "support existing price transparency initiatives for hospitals, other providers, and insurers along with any new price transparency initiatives or changes made necessary by . . . statut[e]."[22] History shows that price transparency has been a bi-partisan effort for many years, and President Biden's July 2021 executive order expresses that his administration is committed to seeing the HPTR succeed as well.[23]

III. HOSPITAL PRICE TRANSPARENCY RULE REQUIREMENTS

Under the HPTR, CMS requires hospitals to provide patients with all available and applicable standard charges for items and services before rendering treatment in two formats: a "machine-readable" file and a display of "shoppable services."[24] According to CMS, standard charges include gross charges, payer-specific negotiated charges, discounted cash prices, de-

[20] *Id.*
[21] Hospital Price Transparency, 45 C.F.R. § 180 (2019); Hospital Price Transparency Rule, 84 Fed. Reg. 65524, 65524 (Nov. 27, 2019) (to be codified at 45 C.F.R. § 180).
[22] Proclamation No. 14036, 86 Fed. Reg. 36987, 36996 (July 9, 2021); *see also* No Surprises Act, Pub. L. No. 116-260, 134 Stat. 1182 (2020) (establishing federal regulations to protect patients and consumers from surprise billing).
[23] Alexandra Ellerbeck, *The Health 202: Biden Says He'll Enforce Trump-Era Rules Requiring Hospitals to Post Their Prices*, WASH. POST (July 12, 2021), https://www.washingtonpost.com/politics/2021/07/12/health-202-biden-says-he-enforce-trump-era-rules-requiring-hospitals-post-their-prices/.
[24] 45 C.F.R. § 180.

identified minimum negotiated charges, and de-identified maximum negotiated charges.[25]

CMS defines "machine-readable format" as "a digital representation of data or information in a file that can be imported or read into a computer system for further processing."[26] Examples of machine-readable files may include XML, JSON, and CSV formats.[27] Under the HPTR, the machine-readable file should be a comprehensive file listing all standard charges for all items and services for which a hospital has established a charge.[28] At a minimum, the machine-readable file must include a description of each item or service, all standard charges, and any codes used by the hospital for accounting or billing purposes.[29]

In addition, each hospital must provide patients with a display of shoppable services.[30] This display must be in a consumer-friendly format that allows patients to access clear pricing information that they can use for financial planning.[31] CMS defines "shoppable service" as "a service that can be scheduled by a healthcare consumer in advance."[32] Some examples of shoppable services may include laboratory services, such as blood panels or urinalysis tests, or radiology services, such as CT, MRI, and X-Ray scans.[33] Other shoppable services include psychotherapy visits, consultations, diagnostic procedures, and vaginal or cesarean deliveries.[34] The HPTR further requires each hospital to provide at least 300 shoppable services on

[25] Hospital Price Transparency Rule, 84 Fed. Reg. at 65536.
[26] 45 C.F.R. § 180.20.
[27] Hospital Price Transparency Rule, 84 Fed. Reg. 65524, 65561 (Nov. 27, 2019) (to be codified at 45 C.F.R. § 180).
[28] *Id.* at 65555.
[29] Hospital Price Transparency, 45 C.F.R. § 180.50 (2019).
[30] *Id.* § 180.60.
[31] Hospital Price Transparency Rule, 84 Fed. Reg. at 65564, 65576.
[32] 45 C.F.R. § 180.20.
[33] Hospital Price Transparency Rule, 84 Fed. Reg. 65524, 65571-72 (Nov. 27, 2019) (to be codified at 45 C.F.R. § 180).
[34] *Id.*

its display, including as many CMS-specified shoppable services as available.[35] However, if a hospital offers less than 300 shoppable services, then it should display as many services as possible.[36] Like the machine-readable file requirement, the HPTR also specifies what types of information the shoppable services display should include.[37] At a minimum, the shoppable services display must include a plain-language description of each shoppable service, all standard charges available, any primary code used by the hospital for accounting or billing purposes, and whether the hospital provides the shoppable service in an inpatient or outpatient setting.[38] In addition, hospitals must also indicate when it does not offer one or more CMS-specified shoppable services.[39]

CMS has also provided requirements for how the machine-readable file and shoppable services display should be made available to the public.[40] First, both formats must be digitally searchable by service description, billing code, and payer.[41] The ability to search the file helps consumers easily locate the specific item or service they seek.[42] Additionally, the hospital should prominently display its machine-readable file and shoppable services display on its public website and make it accessible to the public free of charge and without barriers, such as creating an account or entering personal identifying information.[43]

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[35] Hospital Price Transparency, 45 C.F.R. § 180.60(a)(1) (2019). There are 70 "CMS-specified shoppable services" which are the most frequently billed procedures for which CMS covers. *Id.* CMS created this list for the purposes of the Hospital Transparency Final Rule. *Id.*
[36] *Id.* § 180.60(a)(1)(ii).
[37] *Id.* § 180.60((b)(1)-(8).
[38] *Id.*
[39] *Id.* § 180.60(b)(2).
[40] *Id.* § 180.50-60.
[41] Hospital Price Transparency, 45 C.F.R. §§ 180.50(d)(4), 180.60(d)(3)(iv) (2019).
[42] Hospital Price Transparency Rule, 84 Fed. Reg. 65524, 65561 (Nov. 27, 2019) (to be codified at 45 C.F.R. § 180).
[43] 45 C.F.R. §§ 18.50(d)(1)-(5), 180.60(d)(1)-(3)(iv).

IV. COMPLIANCE CHALLENGES

CMS monitors compliance by evaluating complaints from the public submitted to CMS, reviewing noncompliance analyses, and auditing hospital websites.[44] According to CMS, a hospital may be found noncompliant if it violates any requirement of the HPTR as stated in 45 CFR § 180.[45] If a hospital is found noncompliant, CMS will provide written notice of the specific violations, request a Corrective Action Plan ("CAP"), or impose civil monetary penalties ("CMPs").[46]

As of June 2022, CMS has issued 352 warning notices and 157 CAPs to hospitals.[47] In addition, as of November 2022, CMS has issued CMPs to two hospitals.[48] On June 7, 2022, CMS cited Northside Hospital Cherokee for noncompliance with the HPTR and issued a CMP of $214,320.[49] On this date, CMS also cited Northside Hospital Atlanta and issued it a CMP of $883,180.[50] Both hospitals failed to respond to CMS warning notices, submit requested CAPs, or take other corrective actions, leading CMS to impose the CMPs.[51] Although CMS has only issued CMPs to these two hospitals,

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[44] *Id.* § 180.70.
[45] Hospital Price Transparency Rule, 84 Fed. Reg. at 65590.
[46] *Special Edition - Monitoring for Hospital Price Transparency*, MLN CONNECTS NEWSL. (CMS, Baltimore, M.D.), Dec. 18, 2020, https://www.cms.gov/outreach-and-educationoutreachffsprovpartprogprovider-partnership-email-archive/2020-12-18-mlnc-se.
[47] Maanasa Kona & Sabrina Corlette, *Hospital And Insurer Price Transparency Rules Now In Effect But Compliance Is Still Far Away*, HEALTH AFFAIRS (Sept. 12, 2022), https://www.healthaffairs.org/content/forefront/hospital-and-insurer-price-transparency-rules-now-effect-but-compliance-still-far-away.
[48] *Enforcement Actions*, CMS (June 8, 2022, 2:18 PM), https://www.cms.gov/hospital-price-transparency/enforcement-actions.
[49] Letter from John Pilotte, Performance-Based Policy Group Director, CMS, to Robert Quattrocchi, President and Chief Executive Officer, Northside Hospital Atlanta (June 7, 2022), https://www.cms.gov/files/document/notice-imposition-cmp-northside-hospital-atlanta-6-7-22finalredacted.pdf [hereinafter Northside Hospital Atlanta Notice].
[50] Letter from John Pilotte, Performance-Based Policy Group Director, CMS, to William Hayes, Chief Executive Officer, Northside Hospital Cherokee (June 7, 2022), https://www.cms.gov/files/document/notice-imposition-cmp-northside-hospital-cherokee-6-7-22finalredacted.pdf [hereinafter Northside Hospital Cherokee Notice].
[51] Northside Hospital Atlanta Notice, *supra* note 49; Northside Hospital Cherokee Notice, *supra* note 50.

research studies have revealed that compliance with the HPTR started low and remains low.[52] For example, the Johns Hopkins Bloomberg School of Public Health published one of the first studies after the HPTR took effect on January 1, 2021.[53] In this study, researchers found that as of June 1, 2021, 55 percent of 3,558 Medicare-certified acute-care hospitals did not comply with the machine-readable file requirements.[54]

The Journal of American Medical Association ("JAMA") published a similar study examining early hospital compliance rates.[55] In the JAMA study, researchers surveyed 5,239 hospital websites between July 1 and September 30, 2021, and discovered that only 5.7 percent of surveyed hospitals had both an adherent machine-readable file and an adherent shoppable display.[56] In contrast, 43.3 percent of hospitals had either an adherent machine-readable file or an adherent shoppable display, and 50.9 percent of hospitals had neither an adherent machine-readable file nor an adherent shoppable display.[57]

Since the JAMA study, compliance rates appear to have improved minimally.[58] The most recent study was conducted by Patient Rights Advocate, a nonprofit organization focused on promoting healthcare price transparency and representing the interests of patients and consumers in the

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[52] *See infra* p. 7 (describing research studies reporting low compliance rates with HTPR in 2021 and 2022).
[53] John Xuefeng Jiang et al., *Factors Associated with Compliance to the Hospital Price Transparency Final Rule: A National Landscape Study*, 37 J. GEN. INTERNAL MED. 3577, 3577 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8667537/.
[54] *Id.* at 3579.
[55] Waqas Haque et al., *Adherence to a Federal Hospital Price Transparency Rule and Associated Financial and Marketplace Factors*, JAMA NETWORK OPEN (2022), https://jamanetwork.com/journals/jama/fullarticle/2792987?resultclick=1.
[56] *Id.*
[57] *Id.*
[58] PATIENT RIGHTS ADVOCATE, SEMI-ANNUAL HOSPITAL PRICE TRANSPARENCY COMPLIANCE REPORT 2 (Aug. 2022 ed., 2022), https://www.patientrightsadvocate.org/august-semi-annual-compliance-report-2022 [hereinafter COMPLIANCE REPORT].

healthcare marketplace.[59] In its August 2022 report, Patient Rights Advocate claims only sixteen percent of surveyed hospitals fully complied with all the HPTR requirements outlined in 45 CFR § 180.[60] Moreover, the study revealed that 5.1 percent of hospitals did not publish any standard charges files on their websites.[61] Additionally, most hospitals that published pricing information had missing or incomplete data and were thus deemed noncompliant by Patient Rights Advocate.[62]

Recently, there has been greater speculation as to why compliance rates are low.[63] Some researchers argue that the COVID-19 pandemic delayed hospitals from implementing the HPTR requirements.[64] Although the HPTR was not effective until January 2021, the COVID-19 pandemic may have prevented hospitals from dedicating resources to creating and publishing machine-readable files and shoppable services displays as required.[65] Other sources have argued that hospitals face a financial barrier because implementation is too expensive.[66] Studies have also shown that hospitals with weak "IT preparedness" or limited investment in health IT may face more obstacles in implementing the HPTR requirements.[67] In addition, critics have argued that obtaining accurate price estimates is complex and

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[59] *Our Mission*, PATIENT RIGHTS ADVOCATE, https://www.patientrightsadvocate.org/our-mission (last visited Aug. 25, 2022).
[60] COMPLIANCE REPORT, *supra* note 58, at 2.
[61] *Id.*
[62] *Id.*
[63] *See infra* pp. 8-9 (describing various opinions by researchers and journalists speculating why compliance rates are low).
[64] Amitai S. Miller et al., *Hospital Noncompliance with U.S. Price Transparency Regulations*, LANCET (2022), https://www.thelancet.com/journals/lanam/article/PIIS2667-193X(22)00092-8/fulltext.
[65] Ariel Levin, *Hospitals and Health Systems Are Working to Implement Price Transparency Policies and Help Patients Understand Costs*, ACA: BLOG (June 16, 2022, 12:44 PM), https://www.aha.org/news/blog/2022-06-16-hospitals-and-health-systems-are-working-implement-price-transparency-policies.
[66] Jiang et al., *supra* note 53, at 3580.
[67] *Id.*

burdensome for hospitals.[68] For instance, prices for services may vary from patient to patient depending on their insurance policy, and hospitals may have varying negotiated rates with different payers.[69] In summary, these barriers prevent hospitals from implementing and complying with the HPTR requirements.

V. RECOMMENDATIONS FOR IMPROVEMENT

Despite these challenges, there is still hope for hospital compliance rates to improve. Although hospitals are running out of time to become compliant with the HPTR before CMS imposes penalties, CMS could implement initiatives to encourage adherence, provide guidance, and facilitate interoperability.

First, CMS should encourage widespread consumer education on the new price transparency regulations, which may encourage hospitals to promptly publish compliant machine-readable files and displays of shoppable services. In June 2021, nearly six months after the HPTR became effective, a study by Peterson-KFF found that only nine percent of adults knew that hospitals are required to disclose pricing information publicly.[70] Of the other ninety-one percent of adults, sixty-eight percent were unsure whether such requirements exist, and twenty-two percent did not believe such requirements exist.[71] This data suggests that although there is bi-partisan and public approval of price transparency goals, the average consumer is unaware that they should be able

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[68] Katie Adams, *Flawed Design is Why Hospitals are Not Complying with Price Transparency Rules*, MEDCITY NEWS (June 27, 2022, 12:53 AM), https://medcitynews.com/2022/06/flawed-design-is-why-hospitals-are-not-complying-with-price-transparency-rules/.
[69] *Id.*
[70] Nisha Kurani et al., *Few Adults are Aware of Hospital Price Transparency Requirements*, PETERSON-KFF HEALTH SYSTEM TRACKER (June 28, 2021), https://www.healthsystemtracker.org/brief/few-adults-are-aware-of-hospital-price-transparency-requirements/.
[71] *Id.*

to research prices for treatment and services on the Internet.[72] Consequently, because not enough patients are requesting or asking about the hospitals' pricing information, not enough hospitals are prioritizing creating and publishing machine-readable files and shoppable displays as required by the HPTR.

To address this challenge, CMS should promote the HPTR and educate consumers on what they can expect under the new regulations. For example, CMS could launch a media campaign to reach more consumers and inform them that they can now find out the cost of hospital treatment before scheduling an appointment or procedure. If CMS could help inform more patients about the HPTR, more patients might seek the information from their hospital providers. In turn, this may encourage hospitals to meet their patients' expectations by providing the pricing information in the consumer-friendly formats prescribed by the HPTR. With this influence, hospitals may also begin to prioritize implementing the HPTR requirements sooner, thus improving compliance rates.

Additionally, CMS could better inform the public of its ability to submit complaints directly to CMS.[73] Under the HPTR, CMS has developed monitoring and enforcement methods, which include reporting mechanisms allowing consumers to submit complaints of hospital noncompliance on its website.[74] CMS relies on these complaints to notify it of noncompliance risks and incidents so that it may initiate audits.[75] Through these audits, CMS can

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[72] *Id.*
[73] Hospital Price Transparency Rule, 84 Fed. Reg. 65524, 65582-83 (Nov. 27, 2019) (to be codified at 45 C.F.R. § 180).
[74] Hospital Price Transparency, 45 C.F.R. § 180.70 (2019); Hospital Price Transparency Rule, 84 Fed. Reg. at 65582-83; *see generally Contact Us*, CMS, https://www.cms.gov/hospital-price-transparency/contact-us (Dec. 1, 2021, 8:00 PM) (inviting patients to submit complaints to CMS on its website via electronic form).
[75] Hospital Price Transparency Rule, 84 Fed. Reg. at 65582-83.

notify hospitals of their noncompliance and provide hospitals with an opportunity to correct their mistakes or implement operational changes.[76]

Second, CMS should provide more guidance on price estimator tools and methods, which many hospitals rely on. As revealed in the August 2022 Patient Rights Advocate study, eighty-two percent of the 2,000 surveyed hospitals published a price estimator tool, but 81.3 percent were still deemed noncompliant due to incomplete pricing information.[77] Patient Rights Advocate claims that most hospitals were noncompliant due to missing specific standard charges and price estimator tools that provide estimates or price ranges, which are insufficient under the HPTR.[78] In addition, Patient Rights Advocate noted that many of the websites it audited had barriers, such as requesting users to input personal or insurance information or create an account before they can view pricing information or estimates, which also violates the HPTR.[79] Although most hospitals use price estimator tools, most still fail to meet the HPTR requirements. [80] This data may suggest that hospitals are relying on the capabilities of their current price estimator tools without implementing the additional HPTR requirements.[81]

Similarly, hospitals might be dependent on their current price estimation methods rather than implementing the HPTR requirements. For example, Northside Hospital Atlanta responded to CMS' request for a CAP by presenting their price estimate quote procedure in which potential patients could request price estimate quotes via call or email.[82] This communication,

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[76] *Id.* (stating that CMS may self-initiate an audit of a hospital's website and, if it determines that a hospital is noncompliant, then it may provide a written warning notice to the hospital of the specific violations or request a CAP).
[77] COMPLIANCE REPORT, *supra* note 58, at 4.
[78] *Id.* ("We estimate that . . . 82.0% of the hospitals (1,640/2,000) published a price estimator tool, but 81.3% of them
(1,333/1,640) were still noncompliant due to incomplete standard charges file.").
[79] *Id.*
[80] *Id.*
[81] *Id.*
[82] Northside Hospital Atlanta Notice, *supra* note 49.

as described by CMS, may imply that Northside Hospital Atlanta believed its price estimate quote procedure was sufficient to comply with the HPTR, and for this reason, it did not implement the Rule requirements.

As described in the HPTR, CMS is not opposed to the use of price estimation tools and methods.[83] Specifically, under the HPTR, if a hospital chooses to use a price estimator tool in place of a shoppable services display, then it must adhere to additional requirements as stated in 45 CFR § 180.60(a)(2), the HPTR section regulating price estimator tools.[84] According to this section, the price estimator tool must provide estimates for all CMS-specified shoppable services and at least 300 shoppable services.[85] In addition, the price estimator tool must be Internet-based, prominently displayed on the hospital's website, and freely accessible to the public without barriers such as requiring users to create an account.[86]

Considering the Patients Rights Advocate August 2022 Compliance Report and the recent CMPs that were issued, there appears to be some misunderstanding on what the HPTR requires and whether price estimator methods and tools are allowable. To address this concern, CMS should provide clearer guidance for hospitals on what qualities and functions it allows for price estimator tools under 45 CFR § 180.60(a)(2).[87] For example, under this section, if a hospital uses an price estimator tool, then the tool must "[p]rovide estimates for as many of the 70 CMS-specified shoppable services that are provided by the hospital, and as many additional hospital-selected shoppable services as is necessary for a combined total of at least 300

[83] Hospital Price Transparency Rule, 84 Fed. Reg. 65524, 65577-78 (Nov. 27, 2019) (to be codified at 45 C.F.R. § 180) ("[W]e [CMS] believe it is possible that hospitals with price estimator tools could be considered as having accomplished the goals we intended to achieve by requiring hospitals to repackage and display their standard charge information for common shoppable services in a consumer-friendly manner.").
[84] Hospital Price Transparency, 45 C.F.R. § 180.60(a)(2) (2019).
[85] *Id.* § 180.60(a)(2)(i).
[86] *Id.* § 180.60(a)(2)(iii).
[87] *Id.* § 180.60(a)(2).

shoppable services."[88] The word "estimate" as it is used in this section of the regulation is not defined, which creates a burden for hospitals to interpret the language. Accordingly, CMS should provide clearer guidance on what standard charge information the price estimator tool must contain to alleviate misinterpretation of this provision.

In addition, CMS should emphasize that if a hospital uses a price estimator tool in compliance with 45 CFR § 180.60(a)(2), it will only be deemed compliant with the requirements of 45 CFR § 180.60 regarding the shoppable services display.[89] Hospitals using price estimator tools are still required to implement and adhere to all other HPTR requirements, including the provisions set forth in 45 CFR § 180.50 regarding machine-readable files.[90]

Moreover, CMS should also reiterate that consumers should be able to access price estimator tools without the barriers of creating an account or providing personal or insurance information. Further, CMS should make clear that solely relying on price estimation methods, like Northside Hospital Atlanta, is insufficient under the HPTR requirements. In summary, as the agency responsible for enforcing the HPTR, CMS should clarify the HPTR language and further emphasize requirements and expectations regarding price estimation methods.

Finally, CMS should enforce the TICR, effective July 1, 2022, and the HPTR with equal force.[91] The TICR, which CMS designed to complement the HPTR, applies to health plans and insurance issuers and further

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[88] *Id.* § 180.60(a)(2)(i).
[89] *Id.* §180.60(a)(2) (stating that "[a] hospital is deemed by CMS to meet the requirements of [45 C.F.R. § 180.60] if the hospital maintains an internet-based price estimator tool which meets the following requirements [in § 180.60(a)(2)]").
[90] Hospital Price Transparency Rule, 84 Fed. Reg. 65524, 65578 (Nov. 27, 2019) (to be codified at 45 C.F.R. § 180) (stating that hospitals that use price estimator tools in compliance with 45 C.F.R. 180.60(a)(2), "would still be required to publish all standard charges in a machine-readable file consistent with the requirements we finalize in section II.E [45 C.F.R. § 180.50] of this final rule").
[91] Transparency in Coverage, 45 C.F.R. § 147 (2020).

encourages price transparency on the payer side.[92] The TICR has two requirements which will be introduced and implemented in three stages.[93] Per the first requirement, starting July 1, 2022, payers must provide machine-readable files, which include in-network rates for all covered items and services and the "allowed amounts" the payer will reimburse for out-of-network charges.[94] Per the second requirement, by January 1, 2023, payers must provide an Internet-based price comparison tool for at least 500 items or services, and by January 1, 2024, the tool must include all items or services.[95]

Now that the TICR is in effect, hospitals will likely be able to access standard charge information from payers with greater convenience and ease since payers are required to publish their rates for items and services. For example, hospitals can leverage the published payer information and incorporate the information into their own database. Moreover, if payers and hospitals adhere to the machine-readable format requirement, then this would make the data highly interoperable and easier to integrate.[96] Payers and hospitals can equally benefit from the price transparency rules so long as the entities implement their respective rule requirements. Since the price transparency rules complement one another, CMS has an interest in enforcing both rules equally and consistently to encourage compliance rates.

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[92] *Id.*; *see also Private Practice Toolkit: Payor Contracting 101*, AMA, (2021), https://www.ama-assn.org/system/files/payor-contracting-toolkit.pdf ("[A] 'payor' is the entity that pays for services rendered by a healthcare provider. The payor may be a commercial insurance company, government program, employer, or patient.").

[93] 45 C.F.R. § 147; *Transparency in Coverage Final Rule Fact Sheet (CMS-9915-F)*, CMS (Oct. 29, 2020), https://www.cms.gov/newsroom/fact-sheets/transparency-coverage-final-rule-fact-sheet-cms-9915-f.

[94] 45 C.F.R. § 147.

[95] *Id.*

[96] *See generally Interoperability in Healthcare*, HIMSS, https://www.himss.org/resources/interoperability-healthcare (last visited Dec. 2, 2022) ("[Interoperability] is the ability of different information systems, devices and applications (systems) to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organizational, regional and national boundaries.").

To do so, CMS should adhere to the monitoring methods set out in the regulations by performing audits, issuing warnings, requesting CAPs, and imposing penalties. In addition, these monitoring and enforcement mechanisms are not burdensome to CMS. CMS can audit hospital and payer websites without sending personnel on-site. Further, these websites should be free and open to the public thus allowing CMS to access and audit the websites without barriers. Moreover, CMS can easily identify which hospital and payer websites require auditing by reviewing submitted complaints by consumers.

VI. CONCLUSION

The HPTR became effective on January 1, 2021, however, studies have shown that most hospitals have failed to implement all the machine-readable file and shoppable services display requirements.[97] The issuance of two CMPs in June 2022 and the implementation of the TICR in July 2022 suggest that CMS is focused on prioritizing price transparency goals, initiatives, and regulations.[98] As the HPTR approaches its second anniversary on January 1, 2023, there are several solutions CMS could implement to strengthen hospital compliance rates, such as encouraging widespread consumer education, providing hospitals with guidance on price estimator methods and tools, and enforcing all price transparency regulations with equal force. Through implementing these strategies, the intended goals of the HPTR may start taking effect. Additionally, over time the entire healthcare industry may start experiencing the benefits of price transparency, including increased competition, lowered prices for services and treatment, and improved quality of care.

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[97] Jiang et al., *supra* note 53, at 3580; Haque et al., *supra* note 55; COMPLIANCE REPORT, *supra* note 58, at 2-5.
[98] *Enforcement Actions*, *supra* note 48; 45 C.F.R. § 147 (2020).