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ANNALS OF HEALTH LAW
Advance Directive

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

BRINGING YOU THE LATEST DEVELOPMENTS IN HEALTH LAW

Beazley Institute for Health Law and Policy

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CONTENTS

ANNALS OF HEALTH LAW
Advance Directive

Editor's Note

The Annals of Health Law and Life Sciences is proud to present the second issue of the thirty-second volume of our online, student-written publication, *Advance Directive*. This *Spring 2023 Advance Directive* Issue focuses on innovation and evolution in the health care payment landscape.

The *Spring 2023 Advance Directive* Issue dives into a broad spectrum of issues concerning innovation and evolution in the health care payment landscape. First, it proposes solutions to physician-related payment issues, such as a shared risk bearing fiscal arrangement to incentivize physicians to shift to a value-based care model, as well as confirming the 2024 Centers for Medicare & Medicaid Services Physician Fee Schedule to lessen the financial burdens imposed upon rural healthcare providers.

Next, articles in this Issue address patient-related payment problems, specifically advancing solutions that prioritize affordable and comprehensive coverage. Regarding drug affordability, the range of topics includes implementing a single-payer prescription drug benefit program at the state level; utilizing march-in rights to ensure COVID-19 vaccinations remain affordable for all individuals, irrespective of their health insurance coverage; and amending the Inflation Reduction Act to better insulate vulnerable patients from high prescription drug costs. Further, topics that prioritize comprehensive coverage include recoding endometriosis-related procedures and demanding adequate notice for changes to Medicaid reimbursement rights concerning contraceptive coverage. In addition, this Issue develops how chronic disease prevention can reduce health care spending.

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 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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The Re-evaluation of Medicaid Reimbursement Rates for Contraceptive Drugs Based on Family Planning Classification

Divya Das, MPH

I. INTRODUCTION

How can states abide by a policy that they did not know existed? In Missouri, local government officials discovered that the Department of Health and Human Services (HHS) scrutinized reimbursement claims for contraceptive drugs in a new manner, without an announcement nor an explanation.[1] This method weighed both the indicated and off-label use of medications when determining whether to apply coverage, based on parameters set within the Social Security Act (SSA).[2] In the early 2000s, HHS applied the same methodology to five other states when evaluating reimbursements related to contraceptive drugs and family planning services.[3] Although HHS conducted audits in multiple states, the Missouri Department of Social Services was one of the few entities that challenged HHS's decision by bringing a lawsuit.[4] Ultimately, in March of 2022, the United States District Court for the District of Columbia determined that CMS's new methodology for determining Medicaid reimbursement for contraceptive drugs was improper as it departed from prior HHS policy without any acknowledgement or notification.[5]

Several states —including New Jersey, New York, Kansas, Colorado, Missouri, and North Carolina — relied on HHS's interpretation of family

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[1] Christopher Brown, *Fight Over Contraceptives Leads to Partial Win for Missouri*, BLOOMBERG LAW (Apr. 1, 2022, 5:31 PM), https://news.bloomberglaw.com/health-law-and-business/fight-over-contraceptives-leads-to-partial-win-for-missouri.
[2] *Id.*; Social Security Act 42 U.S.C. § 1905(a)(4)(C).
[3] *See generally* Missouri Dep't of Soc. Servs. v. United States Dep't of Health & Hum. Servs., No. CV 20-3611, (D.D.C. Mar. 31, 2022) (partially denying summary judgment in favor of defendant).
[4] *Id.* at 4.
[5] Brown, *supra* note 1.

planning provisions within the SSA.[6] Due to their reliance, clarification and justification for the new policy change must be provided by HHS as it significantly narrows the scope of the SSA. Moreover, despite HHS's action being deemed improper by the District Court for the District of Columbia, the agency has not addressed this new policy change in a public way nor provided further explanation for the change. Accordingly, adequate notice of this significant change in interpretation of the SSA is necessary and a grace period should be issued to all states, allowing updates to their infrastructure to comply with the new policy.

II. FAMILY PLANNING AUDITS CONDUCTED IN THE EARLY 2000'S

In the early 2000's, the HHS Office of Inspector General (OIG) took an interest in Medicaid coverage for certain medications that fall within family planning services.[7] Within this scope, the OIG became increasingly attentive towards the coverage of contraceptive drugs.[8] Accordingly, the OIG conducted numerous audits evaluating drug claims in several states including New York, New Jersey, Kansas, North Carolina, Missouri, and Colorado.[9] All audits recommended significant refunds to the federal government, amounting up to six million dollars.[10]

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[6] *Id.*; *see generally* Social Security Act 42 U.S.C. § 1905(a)(4)(C) (showing that all states that the OIG audited acted according to HHS's original interpretation of the Social Security Act).
[7] *Missouri Dep't of Soc. Servs*., No. CV 20-3611, at *3.
[8] *Id.*
[9] *Id.*
[10] Off. of Inspector Gen., Dep't of Health and Hum. Serv., Review of Pharmacy Claims Billed as Family Planning Under the New York State Medicaid Program (2007); Off. of Inspector Gen., Dep't of Health and Hum. Serv., Review of Pharmacy Claims Billed as Family Planning Under the New Jersey's Medicaid Program (2007); Off. of Inspector Gen., Dep't of Health and Hum. Serv., Review Of Prescribed Drug Costs In The Colorado Medicaid Family Planning Program (2011); Off. of Inspector Gen., Dep't of Health and Hum. Serv., North Carolina Incorrectly Claimed Enhanced Federal Reimbursement For Some Medicaid Services That Were Not Family Planning (2012); Off. of Inspector Gen., Dep't of Health and Hum. Serv., Missouri Did Not Always Correctly Claim Costs For Medicaid Family Planning Drugs For Calendar Years 2009 And 2010 (2014).

In 2007, HHS conducted its first two audits in New York and New Jersey.[11] The goal of the audits was to determine whether medications classified as contraceptive drugs had been claimed at the 90 percent reimbursement rate allowed by the SSA even though they had not been prescribed for "family planning" purposes.[12] HHS identified inconsistencies based on the National Drug Code: a universal product identifier utilized in the United States for human drugs.[13] The OIG requested that medical records be further validated for codes involving drugs not "related to family planning,"[14] as the drugs prescribed in these cases did not qualify for the 90 percent reimbursement rate.[15] Following an analysis of these records, the agency recommended implementation of a higher level of review of drug codes through the Medicaid Management Information System ("MMIS") to determine which codes applied to family planning.[16]

This new method of classifying contraceptive drugs differs from the initial approach used by all states, as it requires physicians to consider whether they are prescribing contraceptive drugs for on-label or off-label use. On-label use of a drug is defined as use of a drug according to how the Food and Drug

[11] Off. of Inspector Gen., Dep't of Health and Hum. Serv., Review of Pharmacy Claims Billed as Family Planning Under the New York State Medicaid Program (2007); Off. of Inspector Gen., Dep't of Health and Hum. Serv., Review of Pharmacy Claims Billed as Family Planning Under the New Jersey's Medicaid Program (2007).
[12] Missouri Dep't of Soc. Servs. v. United States Dep't of Health & Hum. Servs., No. CV 20-3611, at *13 (D.D.C. Mar. 31, 2022) (partially denying summary judgment in favor of defendant).
[13] Leigh A. Anderson, *National Drug Codes Explained*, DRUGS.COM (Oct. 1, 2020), https://www.drugs.com/ndc.html.
[14] *Missouri Dep't of Soc. Servs*., No. CV 20-3611, at *13.
[15] *Id.*
[16] Off. of Inspector Gen., Dep't of Health and Hum. Serv., Review of Pharmacy Claims Billed as Family Planning Under the New York State Medicaid Program (2007).; Off. of Inspector Gen., Dep't of Health and Hum. Serv., Review of Pharmacy Claims Billed as Family Planning Under the New Jersey's Medicaid Program (2007).

Administration (FDA) approved and labeled it.[17] Off-label use differs, as it reflects use of a drug that has been approved by the FDA for one purpose but is being prescribed and indicated for an alternative diagnosis that has not been approved by the FDA.[18] Some examples of common off-label medication uses are Aspirin for antithrombotic prophylaxis and magnesium sulfate for fetal neuroprotection in preterm labor.[19] The off-label use of drugs is common within the U.S. medical community.[20] Physicians at Mayo Clinic discovered that roughly 79 percent of children discharged from pediatric hospitals are administered at least one drug for off-label use, and about 37 percent of drugs administered within intensive care units are being used off-label.[21]

Following the audits conducted in New York and New Jersey, HHS performed similar audits in Kansas in 2010.[22] Here, the OIG reviewed records of 100 prescription drug claims. When conducting this review, the agency discovered that some claims were "unrelated to family planning."[23] The unrelated claims showed contraceptive drugs being prescribed for "hormone or bleeding control and for therapeutic reasons."[24] Similar to the guidance and recommendation provided in the New York and New Jersey audits, the OIG requested that "providers create a unique and unprecedented process for marking each prescription of contraceptives with the

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[17] *On-Label Use*, CLINICAL INFO HIV.GOV, https://clinicalinfo.hiv.gov/en/glossary/label-use-0.
[18] Ctr. for Medicaid & Medicare Serv., *Drugs and Biologicals, Coverage of, for Label and Off-Label Uses*, CMS.GOV (Nov. 1, 2022), https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33394.
[19] Wittich et al., *Ten Common Questions (and Their Answers) About Off-label Drug Use*, MAYO CLINIC PROC. 982, 984 (2012).
[20] *Id.* at 983.
[21] *Id.*
[22] Off. of Inspector Gen., Dep't of Health and Hum. Serv., Review Of Family Planning Pharmacy Claims Submitted By Selected Providers Under The State Of Kansas Medicaid Program (2010).
[23] *Id.*
[24] *Id.*

diagnosis."[25] Here, HHS places the burden of adjusting coding processes on the state, as state agencies are responsible for ensuring that state programs are administered in compliance with federal requirements.[26]

Furthermore, the Kansas audit resulted in the creation of new methodology for providing recommendations related to Medicaid reimbursement rates for contraceptive drugs.[27] Following the Kansas audit, HHS conducted audits in Colorado, North Carolina, and Missouri in the exact same manner.[28] For an extensive period of time, the internal controls for the classification of contraceptive drugs were automatically categorized as family planning services, regardless of the reason they were being prescribed.[29] As in the Kansas audit, the OIG required these three states to strengthen their internal controls by altering the manner in which contraceptive drugs were classified as family planning services.[30]

Following the audits, Kansas, Colorado, North Carolina, and Missouri all objected to the recommendations the OIG provided.[31] These states drafted formal response letters outlining their concerns.[32] However, these concerns were never fully evaluated until the Missouri Department of Social Services

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[25] *Id.*
[26] *Id.*
[27] Missouri Dep't of Soc. Servs. v. United States Dep't of Health & Hum. Servs., No. CV 20-3611, at *14 (D.D.C. Mar. 31, 2022) (partially denying summary judgment in favor of defendant).
[28] CMS performed audits in these final three states from 2011-2014. *Missouri Dep't of Soc. Servs*., No. CV 20-3611, at *14.
[29] *Id.*
[30] Off. of Inspector Gen., Dep't of Health and Hum. Serv., Review Of Prescribed Drug Costs In The Colorado Medicaid Family Planning Program (2011); Off. of Inspector Gen., Dep't of Health and Hum. Serv., North Carolina Incorrectly Claimed Enhanced Federal Reimbursement For Some Medicaid Services That Were Not Family Planning (2012); Off. of Inspector Gen., Dep't of Health and Hum. Serv., Missouri Did Not Always Correctly Claim Costs For Medicaid Family Planning Drugs For Calendar Years 2009 And 2010 (2014).
[31] *Missouri Dep't of Soc. Servs*., No. CV 20-3611, at *14.
[32] *Id.*

filed a suit against HHS and the Secretary of HHS regarding the audit in Missouri.[33]

III. ISSUES PRESENTED BY THE STATES

The response letters on behalf of the four states specified that making substantial edits to the MMIS to change how contraceptive drugs are classified places a considerable burden on both providers and pharmacies.[34] Reimbursements have been carried out in a consistent manner for a significant period of time. Therefore, making such a radical change to the MMIS affects all personnel using the system in relation to contraceptive drugs.[35] Further, the affected states took issue with the fact that the OIG's audits conducted from 2007 to 2014 were inconsistent with audits conducted prior.[36]

Previously, the OIG did not take issue with all claims for prescription drugs in this group assigned under the "contraceptive therapeutic classification code."[37] Moreover, response letters from North Carolina, Colorado, and Kansas noted that an audit conducted five months prior to the 2007 New Jersey audit did not include the same recommendations regarding appropriate "contraceptive therapeutic classification codes."[38] Thus, the Missouri Department of Social Services argued that the Centers for Medicare

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[33] *See id*. (showing Missouri was one of the few states that challenged its contraceptive drug audit bringing attention to the issues associated with the changes requested in the audit).
[34] Off. of Inspector Gen., Dep't of Health and Hum. Serv., Review Of Prescribed Drug Costs In The Colorado Medicaid Family Planning Program (2011); Off. of Inspector Gen., Dep't of Health and Hum. Serv., North Carolina Incorrectly Claimed Enhanced Federal Reimbursement For Some Medicaid Services That Were Not Family Planning (2012).
[35] *Id.*; *The Big Picture View of Medicaid Management Information System (MMIS)*, NETLOGX (Mar. 2014), https://netlogx.com/blog/2014/03/06/the-big-picture-view-of-medicaid-management-information-system-mmis/ (showing how involved changes to the MMIS are and how many stakeholders are affected).
[36] Missouri Dep't of Soc. Servs. v. United States Dep't of Health & Hum. Servs., No. CV 20-3611, at *14 (D.D.C. Mar. 31, 2022) (partially denying summary judgment in favor of defendant).
[37] Off. of Inspector Gen., Dep't of Health and Hum. Serv., Review Of Prescribed Drug Costs In The Colorado Medicaid Family Planning Program (2011).
[38] *Missouri Dep't of Soc. Servs*., No. CV 20-3611, at *14.

and Medicaid Services (CMS) never issued a "regulation, interpretive rule, or other guidance interpreting the statute to impose a 'family planning purpose' requirement on supplies that are expressly designed to prevent conception, such as oral contraceptives."[39] CMS announced this policy to all fifty states by imposing it, with no corresponding notice, on these six states.

IV. NECESSITY FOR EXPLANATION AND ADEQUATE NOTICE

Although CMS's lack of notice when implementing its new interpretation of the SSA affected many states, the legal proceedings conducted on behalf of the Missouri Department of Social Services had a pivotal impact on this issue. The District Court for the District of Columbia held that the new CMS policy tightening standards for when contraceptive drugs fall within the 90 percent reimbursement rate to be reasonable.[40] However, the court also determined that the impact of CMS's new interpretation of the SSA was unreasonable as it was implemented without explanation and proper notice.[41]

Based on the family planning audits facilitated, it is apparent that CMS intended to provide guidance for interpreting the SSA in the form of a rule. Unfortunately, due to inadequate notice, the agency implemented this rule in a retrospective manner as opposed to a prospective one.

Under the Administrative Procedure Act (APA), notice of proposed rulemaking is required prior to enactment.[42] Any efforts to depart from a prior policy *sub silentio* is considered arbitrary and capricious.[43] Further, it is not only necessary to announce policy changes, but an agency must also

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[39] *Id.*
[40] *Id.* at *1.
[41] *Id.*
[42] 5 U.S.C. § 553.
[43] F.C.C. v. Fox Television Stations, Inc., 556 U.S. 502, 515 (2009).

explain and provide the reason for departing from a prior policy.[44] This notice requirement exists to ensure that agencies do not frivolously change their position on policies and regulations.[45]

In *Missouri Department of Social Services v. United States Department of Health and Human Services*, it was evident that CMS did not take the necessary steps to provide notice or explanation as to why states should begin differentiating claims "for contraceptives prescribed for purely medical purposes from the vast majority that are prescribed to prevent pregnancy."[46] Therefore, the court found that OIG's actions to uphold CMS's disallowance of reimbursement for all contraceptive drugs was improper.[47] This conclusion is reinforced by the court's finding that the family planning provisions within the SSA are rather ambiguous.[48] The statute does not outline what forms of treatment fall under family planning services, resulting in greater room for interpretation by the states.[49] As a result, it is unreasonable to require states to decipher CMS's interpretation of the terminology within the statute without clear explanation and notice of those guidelines.[50]

V. PROPER PROCEDURE FOR PROVIDING NOTICE REGARDING THE NEW CMS POLICY

Ultimately, the District Court for the District of Columbia held that further explanation of CMS's new interpretation of the SSA in relation to family

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[44] Physicians for Soc. Resp. v. Wheeler, 956 F.3d 634, 645 (2020); Encino Motorcars, LLC v. Navarro, 579 U.S. 211, 221 (2016).
[45] *See generally id*. (referencing the courts holding limiting an agency's ability to change their positions without adequate explanation).
[46] Missouri Dep't of Soc. Servs. v. United States Dep't of Health & Hum. Servs., No. CV 20-3611, at *11 (D.D.C. Mar. 31, 2022) (partially denying summary judgment in favor of defendant).
[47] *Id.*
[48] *Id*. at 12.
[49] *See generally id*. (illustrating the impact that the absence of a definition "family planning services and supplies" had on the States interpretation of the statute).
[50] *See id.*

planning services is required before restrictions can be placed on states.[51] Yet, since the court established its holding, CMS has failed to publicly address the issue.[52] If CMS intends to uphold the new policy and only reimburse contraceptive drugs used for family planning services at the 90 percent rate,[53] the agency must additionally take prompt measures to explain its reasoning.

In the past, CMS adequately provided proactive notice and clarification of its intended policies and policy changes through various mechanisms.[54] The agency published yearly reports referred to as "policy and operation updates" when communicating minor policy alterations and interpretive rules.[55] Interpretive rules are documentation provided by an agency to explain a regulation or the meaning of a statute it administered.[56] CMS also issued final rules to convey new polices and technical changes to policies already

[51] *Id.* at 15.
[52] Author spoke with technical director at CMS to confirm that CMS has taken no action on this matter.
[53] *See id.* at 12 (summarizing CMS's interpretation of the types of services that should continue to fall within the 90 percent reimbursement rate).
[54] *See generally* Ctr. for Medicare & Medicaid Serv., *Plan Year 2022 Policy and Operations Updates* (Sept. 30, 2021); *See generally* Ctr. for Medicare & Medicaid Serv., *CMS Issues New Policies to Provide Greater Transparency for Medicare Advantage and Part D Plans*, CMS.GOV (Apr. 29, 2022), https://www.cms.gov/newsroom/press-releases/cms-issues-new-policies-provide-greater-transparency-medicare-advantage-and-part-d-plans; *See generally* Ctr. for Medicare & Medicaid Serv., *Contract Year 2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs Proposed Rule (CMS-4201-P)*, CMS.GOV (Dec. 14, 2022), https://www.cms.gov/newsroom/fact-sheets/contract-year-2024-policy-and-technical-changes-medicare-advantage-and-medicare-prescription-drug.
[55] Ctr. for Medicare & Medicaid Serv., *Plan Year 2022 Policy and Operations Updates*, s*upra* note 54.
[56] *Interpretive Rule*, CTR. FOR EFFECTIVE GOV. (2015), https://www.foreffectivegov.org/node/2589.

established by the agency.[57] Finally, the agency published fact sheets to revise rules and policies that it previously authorized.[58]

Although CMS utilized a myriad of methods to properly notify individuals of new policies and the alteration of existing policies, issuing a final rule or publishing a fact sheet regarding CMS's new interpretation of the SSA is most appropriate. Either approach would prove effective, as this new interpretation is not a minor policy alteration or an interpretive rule. Rather, the agency's new interpretation of the provision alters the manner in which reimbursements are processed under Title XIX of the SSA. This interpretation differs significantly from the interpretation of the provision when originally established.[59] Therefore, CMS's new interpretation requires a more formal method of providing notice.

Moreover, when enacting new policies and laws, administrative agencies have often historically chosen to apply a delayed effective date, generally known as a grace period or transition provision.[60] More recently, both CMS and the Department of Labor have afforded certain grace periods to employers, insurers, states, providers, and other stakeholders when implementing new provisions under the Affordable Care Act (ACA).[61] Under the ACA, grace periods, or transition provisions allowing for extended implementation time, have been afforded to stakeholders who have worked diligently and made a good faith effort to comply with new provisions.[62] The

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[57] Ctr. for Medicare & Medicaid Serv., *CMS Issues New Policies to Provide Greater Transparency for Medicare Advantage and Part D Plans, supra* note 54.
[58] Ctr. for Medicare & Medicaid Serv., *Contract Year 2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs Proposed Rule (CMS-4201-P)*, s*upra* note 54.
[59] Missouri Dep't of Soc. Servs. v. United States Dep't of Health & Hum. Servs., No. CV 20-3611, at *2 (D.D.C. Mar. 31, 2022) (showing that prior to the new CMS policy there was no formal definition of "family planning services and supplies" and therefore no limitation to which oral contraceptives were covered under this SSA provision).
[60] *Affordable Care Act Implementation FAQs - Set 1*, CMS.GOV, https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs.
[61] *Id.*
[62] *Id.*

length of the grace periods differed even among stakeholders, as CMS offered plans and insurers a 10 month extension[63] for implementation and provided beneficiaries 90 days to comply with insurance premiums and payments.[64] Similarly, CMS issued grace periods during the COVID-19 pandemic due to hardship in relation to health insurance for beneficiaries,[65] insurers, and health plans.[66]

Analogous with the ACA and provisions developed during the COVID-19 pandemic, the new family planning policy implemented by CMS significantly impacts health insurance procedures. The policy change will affect state governments, beneficiaries, providers, and pharmacies. In order to ensure successful implementation of the new SSA interpretation, allowance for a grace period prior to implementation is critical. Compliance with the new policy requires substantial adjustments to the MMIS and a reduction in medical coverage for several beneficiaries.[67] Therefore, implementation of a grace period of 10 months, the same timeframe allotted to plans and insurers to execute ACA provisions,[68] is reasonable to prepare for implementation and adjust the MMIS. Allowing states to facilitate

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[63] *Id.*; *Premium payments, grace periods & termination*, HEALTHCARE.GOV, https://www.healthcare.gov/apply-and-enroll/health-insurance-grace-period/.
[64] *Id.*
[65] *Payment and Grace Period Flexibilities Associated with the COVID-19 National Emergency*, CTR. FOR CONSUMER INFO. & INS. OVERSIGHT (Mar. 2020), https://www.cms.gov/files/document/faqs-payment-and-grace-period-covid-19.pdf.
[66] *See generally CMS Waivers, Flexibilities, and the Transition Forward from the COVID-19 Public Health Emergency*, CMS.GOV (Feb. 2023), https://www.cms.gov/newsroom/fact-sheets/cms-waivers-flexibilities-and-transition-forward-covid-19-public-health-emergency (discussing COVID-19 accommodations in public and private health plans).
[67] Nivin Todd, *Birth Control: Benefits Beyond Pregnancy Prevention*, WEBMD (Nov. 2022) https://www.webmd.com/sex/birth-control/other-benefits-birth-control (highlighting 14 percent of patients who use contraceptive drugs use them for non-family planning services and that this population would be at risk of reduced coverage of these drugs due to the new CMS policy).
[68] *Affordable Care Act Implementation FAQs - Set 1*, CMS.GOV, https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs.

changes and adapt to a new method of reimbursement is vital to the success of the policy as a whole.

VI. IMPLICATIONS OF CMS'S ACTIONS ON THE HEALTHCARE POLICY LANDSCAPE

Since its passing in 1946, the APA has offered necessary guidance to the administrative law field.[69] Within the APA, providing notice prior to implementing certain rules such as regulations and policies is required to ensure that industries adapt and contribute to the enactment of administrative rules.[70] Here, the altered industry is healthcare. In this instance, the policy that CMS is implementing directly affects many stakeholders within the healthcare industry including beneficiaries, providers, pharmacies, and state governments.

Specifically, potential reductions in Medicaid reimbursement rates for contraceptive drugs directly affects beneficiaries.[71] Since all uses of contraceptive drugs have been reimbursed since 1972 at a 90 percent rate as opposed to a 50 percent rate, any changes in coverage of these drugs would likely be perceived as unexpected to Medicaid recipients.[72] As a result, implementing a grace period prior to the adoption of the reimbursement policy change offers beneficiaries the opportunity to consult their provider if

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[69] *Administrative Procedure Act*, BRITANNICA, https://www.britannica.com/topic/Administrative-Procedures-Act; *see generally* Alicia Ashcraft & Jeffery F. Bar, *The Importance of the Administrative Procedure Act and the Hidden Dangers of Exemption*, ARMSTRONG TEASDALE (May 2021), https://www.armstrongteasdale.com/thought-leadership/the-importance-of-the-administrative-procedure-act-and-the-hidden-dangers-of-exemption/ (showing that all administrative agencies are required to follow procedures outlined under the APA when enacting new regulations and policies).

[70] *See id*. (illustrating the emphasis that the APA places on notice procedures to assist with successful implementation for all relevant parties).

[71] *Increased Medicaid Reimbursement Rates Expand Access to Care*, NAT'L BUREAU OF ECON. RSCH. (Oct. 2019), https://www.nber.org/bh-20193/increased-medicaid-reimbursement-rates-expand-access-care (showing that there is a correlation between Medicaid reimbursement rates and access to health care).

[72] The Henry J. Kaiser Family Foundation, *Medicaid's Role in Family Planning*, GUTTMACHER INST. 1, 2 (Oct. 2007).

they are using contraceptive drugs for non-family planning reasons. Affording beneficiaries this extra time increases the possibility that they will continue receiving the proper care they are entitled to through other treatment options or funding sources.

Furthermore, the new reimbursement policy heavily affects state agencies monitoring billing practices under Medicaid by requiring the reconfiguration of coding schemes for the "contraceptive therapeutic classification code" within the MMIS.[73] Failure to provide states with time to make these changes prior to full adoption of the policy causes a burden and hinders any potential for improvement to the billing system. HHS required state agencies to conduct this intricate coding change and facilitate compliance on the spot.[74] These conditions are not ideal for effective change within the Medicaid billing process. Therefore, allowing for a grace period prior to the adoption of the policy would increase the quality of state compliance.

Moreover, a reduced timeline for the implementation and development of planning measures directly affects successful adoption of new policies and regulations. Here, requiring the immediate adoption of the new reimbursement policy without notice reduces the ability of providers[75] and pharmacies[76] to promptly comply. Failure to properly comply with new billing and coding practices places a significant financial burden on

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[73] Off. of Inspector Gen., Dep't of Health and Hum. Serv., Review Of Family Planning Pharmacy Claims Submitted By Selected Providers Under The State Of Kansas Medicaid Program (2010).

[74] *Id.* (showing the burden of changing the coding system falls upon state agencies, and those agencies are tasked with making these changes promptly).

[75] Rachelle Wheeler, *8 Medical Billing Challenges*, TEMDEV (Oct. 2, 2021), https://www.tempdev.com/blog/2021/10/02/8-biggest-medical-billing-challenges/ (showing providers find billing changes across different payers such as Medicaid challenging when documenting patient visits).

[76] *Pharmacy Billing Challenges*, MEDISYS (Oct. 18, 2020), https://www.medisysdata.com/blog/pharmacy-billing-challenges/ (illustrating that following updates within the healthcare industry such as billing and coding changes is a challenge for pharmacies).

healthcare entities, as they lose reimbursement revenue until coding errors are rectified, and delays may be a barrier to effective healthcare delivery.[77] Including a grace period allows states to reconfigure their coding systems in an effective manner, ensuring that the quality of care is not hindered in the process of implementing the new reimbursement policy.

It is also noteworthy that the new reimbursement policy allows CMS to alter reimbursement rates based on whether a drug is being utilized for on-label or off-label purposes.[78] As a result, this decision has the capacity to influence the coverage of other non-family planning related drugs that are used off-label. As previously discussed, the utilization of drugs off-label is considered common practice within the medical industry.[79] Therefore, applying the reasoning behind this new policy to the off-label use of drugs in other areas of medicine could potentially be a barrier to access to care. CMS's new policy could result in a reduced reimbursement rate for other drugs with prevalent off-label uses.

Ultimately, there are many key factors and considerations that states need to iron out before effectively adopting the new reimbursement policy. Offering a grace period before adoption affords states the opportunity to analyze the impact of the policy on beneficiaries, providers, pharmacies, and the government. Furthermore, extending states extra time to comply will provide them with the opportunity to reduce the burden this policy may pose and mitigate any potential barriers to implementation.

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[77] *Consequences of Medical Coding & Billing Errors & How to Avoid Them*, DUVA SAWKO, https://www.duvasawko.com/medical-coding-errors/.
[78] Christopher Brown, *Fight Over Contraceptives Leads to Partial Win for Missouri*, BLOOMBERG LAW (Apr. 1, 2022, 5:31 PM), https://news.bloomberglaw.com/health-law-and-business/fight-over-contraceptives-leads-to-partial-win-for-missouri.
[79] Wittich, *supra* note 19, at 984.

VII. CONCLUSION

Requiring states to comply with an unknown policy without reasoning is improper. *Missouri Department of Social Services* correctly required that CMS explain the reasoning behind its new interpretation of "family planning services and supplies" under the SSA.[80] If CMS intends to move forward with the new interpretation of the statute, additional clarification must be provided to states in a timely manner. Further clarification must be supplied through a final rule or CMS fact sheet to ensure the most comprehensive understanding of the policy is achieved. Additionally, states should be afforded a grace period to facilitate the necessary changes required to effectuate compliance with the new reimbursement policy and to reduce the negative implications this policy may impose upon those affected.

[80] Missouri Dep't of Soc. Servs. v. United States Dep't of Health & Hum. Servs., No. CV 20-3611, at *15 (D.D.C. Mar. 31, 2022) (partially denying summary judgment in favor of defendant).

A State Level Proposal Introducing a Prescription Drug Benefit Program

Juhi Desai

I. INTRODUCTION

For decades, outrageous drug prices in the United States have been the topic of a national conversation.[1] Notably, nearly "66 percent of all U.S. adults take prescription drugs," and more than "12 percent of the country's healthcare spending goes towards it."[2] When compared against other industrialized nations, Americans pay a significantly higher price for branded drugs.[3] This forces consumers to choose between life-saving prescription drugs and forgoing treatment based on affordability.[4] Unfortunately, this is the current landscape of the American healthcare system.

American drug pricing operates on a highly commercialized model.[5] This means private pharmaceutical companies negotiate drug prices based on what would be most beneficial to them and what the current market can bear, not considering affordability to the average consumer.[6] While there are some benefits—like active competition in the healthcare industry as explained below—there are also several fundamental issues, including excessive drug prices for necessary, life-saving drugs.

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[1] Sydney Lupkin, *A Decade Marked By Outrage Over Drug Prices*, NPR (Dec. 31, 2019), https://www.npr.org/sections/health-shots/2019/12/31/792617538/a-decade-marked-by-outrage-over-drug-prices.

[2] Anne Jacobson, *Prescription drug statistics 2023*, SINGLECARE (Feb. 3, 2023), https://www.singlecare.com/blog/news/prescription-drug-statistics/ (citing Health Policy Institute, 2021); *Prescription Drug Spending*, U.S. GOV'T ACCOUNTABILITY OFF., https://www.gao.gov/prescription-drug-spending.

[3] Paul B. Ginsburg & Steven M. Lieberman, *Government regulated or negotiated drug prices: Key design considerations*, BROOKINGS (Aug. 30, 2021), https://www.brookings.edu/essay/government-regulated-or-negotiated-drug-prices-key-design-considerations/.

[4] Lupkin, *supra* note 1.

[5] Joey Mattingly, *Understanding Drug Pricing*, U.S. PHARMACIST (June 20, 2012), https://www.uspharmacist.com/article/understanding-drug-pricing.

[6] 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/.

In contrast to the American model, there are several countries like Germany and Australia that utilize a value-based pricing system for prescription drugs.[7] Canada has also implemented a single-payer-like drug model.[8] These systems have several benefits that exceed those resulting from the current U.S. model. Namely, authorities in Canada created a federal agency that determined the maximum price for drug sales, which must then be deemed not excessive by the agency.[9]

Although there have been several single-payer proposals for healthcare, few have been focused on prescription drugs, especially at the state level. Implementing a prescription drug benefit program on a state level in the U.S., rather than at the federal level, would likely benefit individuals who need access to affordable drugs. By doing so, each state would have "more leverage to negotiate better prices."[10] By "using money collected via the tax system," a prescription drug benefit program would have all payments come from the state government.[11] The most known proposal for a single-payer healthcare system is "Medicare for All," which would "eliminate private insurance" companies and instead opt for universal health insurance.[12] Currently, the closest thing to a single-payer system that the United States utilizes is through "Medicare and Veteran Health System Administration,"

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[7] *Id.*
[8] Alison Drinkwater, *The drug reimbursement environment in Canada: An overview*, AMERISOURCEBERGEN (Feb. 17, 2022), https://www.xcenda.com/insights/htaq-spring-2022-drug-reimbursement-in-canada.
[9] *Id.*
[10] Zachary Brennan, *How Would a Single-Payer Health System Pay for Drugs? CBO Explains*, REGULATORY FOCUS (May 1, 2019), https://www.raps.org/news-and-articles/news-articles/2019/5/how-would-a-single-payer-health-system-pay-for-dru.
[11] Kelly Montgomery, *Single-Payer Healthcare v. Universal Coverage*, VERYWELL HEALTH (June 10, 2022), https://www.verywellhealth.com/difference-between-universal-coverage-and-single-payer-system-1738546.
[12] Shannon M. Rotolo et al., *An Introduction to Single Payer for Pharmacists and Pharmacy Technicians*, PNHP (May 1, 2020), https://pnhp.org/news/an-introduction-to-single-payer-for-pharmacists-and-pharmacy-technicians/; Alice Ollstein, *Harris dives into 'Medicare for all' minefield*, POLITICO (Jan. 31, 2019), https://www.politico.com/story/2019/01/31/kamala-harris-medicare-for-all-1130970.

though the government sources its finances from multiple entities.[13] However, both of these programs are implemented on a federal level and place more focus on access to health care rather than paying for prescription drugs.

Maintaining higher drug prices and not advocating for a change fuels the inequities that face our healthcare system. Therefore, this article advocates to implement a state program that would combat the increasing costs of prescription drugs. The prescription drug benefit program calls for a separate insurance card that would provide state citizens with prescription drugs that are on a formulary after being negotiated by a Committee. This would allow for individuals to not only gain access to more affordable drugs, but the entirety of the prescription drug system would change.

II. BACKGROUND ON OUR CURRENT PRESCRIPTION DRUG SYSTEM

United States spends more of its healthcare budget on prescription drugs per capita than any other country in the world.[14] Currently, in this game of setting prescription prices in the United States, there are three valuable players, including but not limited to: drug manufacturers, pharmacy benefit managers (PBMs), and private insurers.[15] These players all set prices they believe the drug should cost, and then negotiate amongst themselves.[16] The negotiation process occurs without almost any government or other subsidiary intervention.[17] Other counties often delegate a "body [which] negotiate[s] drug prices or rejects coverage of products if the price demanded

[13] Montgomery, *supra* note 11.
[14] Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States*, 316 JAMA 858 (2016).
[15] Laura Entis, *Why Does Medicine Cost So Much?*, TIME (Apr. 9, 2019, 10:00 AM), https://time.com/5564547/drug-prices-medicine/.
[16] *Id.*
[17] *Id.*

by the manufacturer is excessive in light of the benefit provided."[18] This is not the case in the United States, where manufacturers are allowed to set prices at whatever standard they feel is best.[19] In addition, PBMs are a key player in this setup, because they are the ones who can "negotiate with the manufacturers and insurers to get drugs listed [in formularies] and to establish prices."[20] After doing so, PBMs take a share of the profits by either collecting a fee from insurance companies or a rebate from the manufacturing company.[21]

PBMs are an integral part of this game because it is after they negotiate prices that are financially advantageous for themselves and their beneficiaries that patients can find cheaper drugs for their ailments. PBMs utilize their services to "determine where on the formulary hierarchy any drug will be."[22] This results in drugs that are higher up on the formulary being more affordable for patients; however, if that is not the case, or a drug is not listed on the formulary, beneficiaries will be "on the hook for the full list price."[23] Because they have so much discretion in their work, PBMs interfere with patients and their ability to receive medications needed for survival.

Although there have been proposed changes to how drug prices are set, patients have yet to see a difference in the amount they pay for prescription drugs.[24] The Inflation Reduction Act of 2022 (IRA) was signed into law by

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[18] Kesselheim, *supra* note 14, at 3.
[19] *Id.*
[20] Entis, *supra* note 15.
[21] *Id.*
[22] *Id.*
[23] *Id.*
[24] Juliette Cubanski et al., *Explaining the Prescription Drug Provisions in the Inflation Reduction Act*, KFF (Jan. 24, 2023), https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/.

President Biden on August 16, 2022.[25] The goal of the IRA is to reduce overall government spending on prescription drugs and, ultimately, the amount patients pay out of pocket.[26] The IRA requires the federal government to negotiate prices for an increased number of drugs typically not covered under Medicare Part D or B.[27] Medicare Part D typically covers retail prescription drugs, while Part B covers prescription drugs administered by physicians.[28] Though the IRA is a step in the right direction, it does not solve the fundamental issue of providing cheaper drugs to the U.S. population. The IRA is focused on federal government intervention and narrows in on only the population of people who are on Medicare insurance plans.[29] Implementing a system that includes the uninsured and non-Medicare users alike at the state level will give Americans broader access to life-saving drugs and will allow each state to focus on the needs of its population.

III. PROPOSED ACTIONS FOR A SINGLE-PAYER PRESCRIPTION DRUG SYSTEM

In an effort to create a more equitable pricing system for prescription drugs, a prescription drug benefit program should be established in every state. Presently, research only shows what a similar program would look like if it were implemented on a federal level.[30] A proposal has been made in the Senate to grant the U.S. Department of Health and Human Services (HHS)

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[25] Juliette Cubanski et al., *How Will the Prescription Drug Provisions in the Inflation Reduction Act Affect Medicare Beneficiaries?*, KFF (Jan. 24, 2023), https://www.kff.org/medicare/issue-brief/how-will-the-prescription-drug-provisions-in-the-inflation-reduction-act-affect-medicare-beneficiaries/.
[26] *Id.*
[27] *Id.*
[28] *Id.*
[29] *Id.*
[30] Katie Cudmore, *How Would Single Payer Healthcare in the US Impact pharma? A pricing perspective*, PHARMAPHORUM (Mar. 5, 2020), https://pharmaphorum.com/views-analysis-market-access/how-would-single-payer-healthcare-in-the-us-impact-pharma-a-pricing-perspective/.

the power to negotiate drug prices across the country, specifically for the Medicare program.[31] HHS is traditionally in charge of enhancing the well-being and health of Americans by advancing the current healthcare system.[32] This federal-level intervention would be a step towards equalizing drug pricing across the country, but it has also been met with political backlash.[33]

The option that this article proposes is for individual states to establish a single entity, similar to Medicare Part D, to provide an independent negotiated price structure that only focuses on drug prices and not health insurance. This model entity would be responsible for bargaining manufacturer drug prices and ensuring that patients of that state can receive medications they deserve without paying increasing out-of-pocket costs. Currently, federal law prohibits public insurers, such as those governed by CMS (i.e., Medicare), from negotiating prices of drugs directly with manufacturers.[34] By creating a single entity like CMS' Part D in each state, the state's autonomy to choose whether they would like to offer their citizens a uniform formulary with lower-priced prescription drugs increases significantly. This program would be available with populations of any type of insurance as well the uninsured. The program would also extend to medical tourists and citizens of other states.

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[31] Julia Cusick, *Congress Can Act Now To Lower Drug Costs by Allowing Medicare To Negotiate Prices*, AM. PROGRESS (Feb. 1, 2022), https://www.americanprogress.org/article/congress-can-act-now-to-lower-drug-costs-by-allowing-medicare-to-negotiate-prices/.

[32] *Introduction: About HHS*, U.S. DEPT. OF HEALTH AND HUM. SERVICES, https://www.hhs.gov/about/strategic-plan/2022-2026/introduction/index.html.

[33] Emily Cochrane and Catie Edmondson, *Manchin Pulls Support From Biden's Social Policy Bill, Imperiling Its Passage*, N.Y. TIMES (Dec. 19, 2021), https://www.nytimes.com/2021/12/19/us/politics/manchin-build-back-better.html.

[34] Nicole Rapfogel and Thomas Waldrop, *Congress to Act Now To Lower Drug Costs by Allowing Medicare To Negotiate Prices*, AM. PROGRESS (Feb. 1, 2022), https://www.americanprogress.org/article/congress-can-act-now-to-lower-drug-costs-by-allowing-medicare-to-negotiate-prices/.

Though this may seem like a foreign concept, the State of Illinois proposed a plan that would resemble a prescription drug benefit program, akin to the proposal that each state develop a CMS-like program.[35] The House committee in Illinois proposed establishing a similar single-payer system health care plan for its residents.[36] Though its primary purpose would be to provide health insurance covering all of its residents, part of the proposal includes the coverage of prescription drugs.[37] In its proposal, the House committee suggests setting up a Pharmaceutical and Durable Medical Goods Committee (Committee) that would negotiate prices of pharmaceuticals and durable medical goods with suppliers or manufacturers on an "open bid competitive basis."[38] The committee would be made up of health care professionals as well as other highly-qualified professionals who are able to understand the U.S. health care market. The Committee would serve as the single entity that would negotiate the prices rather than PBMs.[39] Where one entity would be responsible for negotiating prices in the state, this proposal provides a beneficial alternative to the current system for setting prices of drugs in the U.S. This single Committee would eliminate the need for multiple privatized profit-driven companies to negotiate prices for personal instead of societal benefit.

Further, this proposal calls for each resident of the State to receive a unique insurance card to receive health service benefits specific to prescription drugs.[40] The separate insurance card would be attained by filling

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[35] Mike Miletich, *House committee approves Illinois universal health care plan*, WSILTV (Mar. 16, 2021), https://www.wsiltv.com/news/illinois-capitol-news/house-committee-approves-illinois-universal-health-care-plan/article_b76cb261-b9b8-5b55-a999-f07b2e873bf2.html.
[36] *Id.*
[37] H.R. 62, 102nd Gen. Assemb., Reg. Sess. (Il. 2021), https://ilga.gov/legislation/102/HB/PDF/10200HB0062lv.pdf.
[38] *Id.* at 1.
[39] *Id.*
[40] *Id.* at 3.

out an application which includes the individual's demographic information, medical history, household annual income, and current insurance plan. Once the application is reviewed, accepted, and the insurance card is assigned, the Committee would pay for the "covered prescription drugs" according to a "fee schedule" established between the Committee and the manufacturers on an annual basis.[41] The Illinois Health Services Governing Board (Board) would establish a "single prescription drug formulary" that may be reviewed alongside health professionals on a quarterly basis.[42] During these quarterly meetings, the health professionals would make recommendations to the Board and the Board would update the formulary "according to sound medical practice."[43] The prices that are established by the Board and the Committee would be reviewed and negotiated on an annual basis to adhere to economic and industry changes. In addition, an opportunity would be given to the public to participate in an open forum to petition their grievances.[44]

Though this proposal is expansive, there are a few changes that should be made. First, for the medications that are not listed on the formulary, the Committee should establish a relationship with private companies to establish an open marketplace where residents are still able to access prescriptions at a discounted rate. The scope of these Committee relationships would vary by each state considering the difference in each state population. The discounted rates would be provided based on the individual's medical history and income that was provided on the insurance card application. Due to states negotiating the drug prices, individual insurance companies would no longer have to negotiate drug prices with

[41] *Id.* at 6.
[42] *Id.* at 10.
[43] *Id.*
[44] *Id.* at 11.

manufacturers. Acquiring this information prohibits individuals from misusing the discounted rate for medications they would otherwise be able to afford or covered by secondary insurance. For this to be successful, the Committee would have to contract with manufacturers and cap the amount of money they could charge for uncovered prescriptions. This would be very similar to the single-payer system in Canada that was mentioned previously.[45] Though drug manufacturers would be less inclined to participate in this program, statutory provisions or legislation can require manufacturers to negotiate up to a certain quantity of medications every year.

Additionally, the proposal should have a separate addendum that would cover the prescription of individuals who are otherwise uninsured or under-insured, medical tourists, or who are not Illinois residents. It is essential for the proposal to offer solutions to those who are traveling within the state who require prescription coverage. By allowing individuals who are not residents of the State of Illinois to have access to affordable prescription drugs, the state would thereby foster inclusivity and the overall well-being of society. Though the plan does not list the details of how long a person must be in the state, it is necessary for the proposal to include an umbrella for individuals who are not permanent residents of the state. For medical tourists or individuals who require medications in emergency situations, the benefit program would offer the drug price that is listed on the state's formulary in real-time.[46] After the required treatment is administered, however, care providers can then bill the appropriate state and receive a reimbursement for the treatment. This would allow for the system to remain uniform regardless

[45] Drinkwater, *supra* note 8.
[46] Defining medical tourists (There are varying degrees of medical tourism, and some 'tourists' are simply coming to the US facilities for a second opinion and would not therefore be seeking therapies in the same way.).

of an individual's resident status in the state while also building inter-state relationships and maintaining the cost-effectiveness for each state.

A state level single-payer prescription system offers a plethora of benefits to state residents as well. First, it is speculated that a single-payer pharmaceutical company would have increased power in negotiating with pharmaceutical companies while providing these same companies with the incentive of a larger consumer reach.[47] Second, patients would no longer have to go through a complicated process of filling their prescriptions at various pharmacies which would mean "simplified billing and predictable reimbursement."[48] Therefore, the complicated billing process which would ordinarily deter low-income or non-English speaking patients would no longer be an issue. Third, a single-payer system will not only give millions of Americans access to medications they previously could not afford, but the system would also provide increased legal benefits by reducing "the cost of the current malpractice system."[49] Since the state government would finance the prescription formularies, the basis of noncompliance claims can shift from "who will pay for mistakes" to "how can we learn from mistakes and prevent them."[50] Currently, most compliance violations catered to pharmaceutical companies stem from the tension between the inclination to price fix versus a desire to provide quality drugs.[51] By shifting the focus from legal concerns to a solution building model, a higher level of accountability will be placed on healthcare providers, prescribers, and power

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[47] Rotolo, *supra* note 12.
[48] *Id.*
[49] H.R. 62, 102nd Gen. Assemb., Reg. Sess. (Il. 2021), https://ilga.gov/legislation/102/HB/PDF/10200HB0062lv.pdf.
[50] *Id.* at 9.
[51] *Pharmaceutical Companies Pay Over $400 Million to Resolve Alleged False Claims Act Liability for Price-Fixing of Genetic Drugs*, U.S. DEP'T OF JUST. (Oct. 1, 2021), https://www.justice.gov/opa/pr/pharmaceutical-companies-pay-over-400-million-resolve-alleged-false-claims-act-liability. (Explaining that there are lawsuits regarding price-fixing).

players in the industry.[52] The single-payer model would also continue to shift to adhere to the solutions developed through past compliance violations.

Though this plan has been proposed by Democratic officials, no official changes have been brought to the state's agenda.[53] One of the concerns posed is that the Republican party fears the burden states may face in covering the costs of discounted drugs.[54] Specifically, they question whether the state would be able to afford to cover the cost without facing financial repercussions from funding existing healthcare plans. [55] However, Democrats argue the plan would be appropriately funded via "budget apportions, grants, the federal government" and by setting up a health services trust.[56] In addition to utilizing state grants, the state of Illinois could also utilize the income coming from resident taxes to support this nuanced proposal. In order to do so, a tax allocation meeting must be governed to allocate a reasonable proportion of state taxes to a single entity. If Illinois is able to properly execute this single-payer system for prescription drugs, it may serve as a leading model for other states to follow suit. At that point, each state can address how they would want to fund the program according to their best practice.

IV. DISADVANTAGES

A prescription drug benefit program has many benefits, such as providing affordable care for individuals, but a major concern that exists is the lack of competition in the healthcare market. Antitrust plays a critical role in the healthcare field because it promotes innovation and competition while also "facilitating the development of efficient methods of healthcare

[52] Miletich, *supra* note 35.
[53] *Id.*
[54] *Id.*
[55] *Id.*
[56] *Id.*

delivery."[57] Creating a system where only a single entity exists to negotiate prices would eliminate private insurers and PBMs from the drug price market.[58] There's a fear that "the loss of competition will, over time, lead to higher prices and a reduced incentive to innovate."[59] The solution to this, however, would be for states to compete with the pharmaceutical markets across the nation.

Another concern that state residents may have is that, in an effort to obtain coverage for their prescriptions, states may have to increase state taxes.[60] However, increasing taxes as a whole to obtain state-wide coverage for prescriptions may not be a dealbreaker if individuals no longer have to pay out-of-pocket costs for overpriced prescriptions. Additionally, if state taxes are increased for only certain income levels, low-income taxpayers may not even be impacted.

VI. CONCLUSION

A single-payer system for prescription drugs should be implemented in the United States on a state level. In every state, a public entity should exist that sets standard prices for each prescription. This would eliminate the need for prices to be negotiated between numerous insurance and pharma companies. If such a system is implemented in every state, consumers would have access to cost-effective solutions to improve their health. Additionally, legislation that would allow residents of each state to have access to drugs with set prices would significantly limit the need for insurance companies to

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[57] Mark Whitener, *Antitrust, Medicare Reform and Health Care Competition*, FED. TRADE COMM'N (Dec. 1995), https://www.ftc.gov/news-events/news/speeches/antitrust-medicare-reform-health-care-competition.
[58] Phillip Longman, *Why Universal Health Care Needs Antitrust*, DEMOCRACY (Jan. 2, 2018), https://democracyjournal.org/arguments/why-universal-health-care-needs-antitrust/.
[59] *Id.*
[60] Leila Abbas, *Breaking down the Single-Payer healthcare system*, OAK ST. HEALTH (Oct. 18, 2021), https://www.oakstreethealth.com/breaking-down-the-single-payer-healthcare-system-625587.

get involved and negotiate prices with pharmaceuticals. It would eliminate the business-like structure that currently exists in our healthcare system. Though antitrust concerns may rise, the benefit of the system being cost-effective and eliminating healthcare inequities outweighs the cost.

Excessive drug prices are a blight on our nation's consciousness. In contemporary times where transparency has become the key to success for several industries and business models, the world of healthcare, insurance, and pharmaceutical companies remains a mystery to the average person. A state level single-payer model for prescriptions may be the key to changing that.

The Inflation Reduction Act of 2022: Addressing Prescription Drug Coverage

Jay-Donavin Ved

I. INTRODUCTION

High prescription drug prices disproportionately impact low-income individuals, uninsured individuals, and people of color.[1] Importantly, the Inflation Reduction Act of 2022 includes several provisions pertaining to lowering prescription drug costs for Medicare recipients and reducing drug spending by the federal government.[2] In particular, this Act was signed into law as a result of strong bipartisan support for the government to lower prescription drug costs and spending.[3] The prescription drug provisions in the Act specifically include: limiting the costs of insulin products to $35 per month for Medicare beneficiaries, requiring the federal government to negotiate prices for certain drugs covered under Part B and Part D of Medicare, and capping out-of-pocket spending for Medicare Part D enrollees.[4] These provisions are supportive, yet ineffective regarding the battle against the high and continuously rising drug prices in America. Although a step in the right direction, the government should amend the Inflation Reduction Act to insulate vulnerable populations from further harm.

This article begins by discussing the history of prescription drug coverage through Medicare. Next, this article examines some of the problems associated with legislation related to prescription drug coverage. Finally, this

[1] *States Curb Racial Inequities in Rx Drug Affordability with Targeted Legislation*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Oct. 26, 2020), https://nashp.org/states-curb-racial-inequities-in-rx-drug-affordability-with-targeted-legislation/.
[2] Juliette Cubanski et al., *Explaining the Prescription Drug Provisions in the Inflation Reduction Act*, KAISER FAM. FOUND. (Jan. 24, 2023), https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/.
[3] *Id.*
[4] *The Inflation Reduction Act Lowers Health Care Costs for Millions of Americans*, CTRS. FOR MEDICARE & MEDICAID SERVS.: NEWSROOM (Oct. 5, 2022), https://www.cms.gov/newsroom/fact-sheets/inflation-reduction-act-lowers-health-care-costs-millions-americans.

article provides three recommendations to amend the Inflation Reduction Act. First, the Inflation Reduction Act should be amended to address the increasing cost of insulin by including provisions to protect uninsured patients who tend to pay full price for the lifesaving drug. Second, the Act should be amended to increase the number of drugs subject to price negotiation under Part D and Part B beginning in 2026. Lastly, the Inflation Reduction Act should be amended to incentivize Medicare Part D plans to exercise control of costs below the spending cap.

II. HISTORY OF PRESCRIPTION DRUG COVERAGE IN MEDICARE

Medicare beneficiaries can obtain prescription drug coverage through either Original Medicare plus added coverage or Medicare Advantage, depending on which plan they pursue.[5] Original Medicare includes Part A and Part B, which covers hospital insurance and medical insurance.[6] At an additional cost, there is an option to obtain Part D, which covers the cost of prescription drugs.[7] Medicare Advantage, or Part C, provides another option for beneficiaries to gain prescription drug coverage where beneficiaries can choose a Medicare-approved plan from a private company offering an alternative to Original Medicare, which largely includes Part A, Part B, and typically Part D.[8] Medigap plans are available to Original Medicare beneficiaries to assist with extra out of pocket costs; however, they are not

[5] *Parts of Medicare*, MEDICARE.GOV, https://www.medicare.gov/basics/get-started-with-medicare/medicare-basics/parts-of-medicare (last visited: Apr. 25, 2023).
[6] *Id.*
[7] *Id.*
[8] *Id.*

available for Medicare Advantage beneficiaries, so they still have to pay copays, deductibles, and premiums when applicable.[9]

The Social Security Amendments of 1980 implemented the previously mentioned Medigap plans, which aimed to lower out-of-pocket expenses, including coverage gaps, copayments, deductibles, and coinsurance for Medicare enrollees.[10] Although these sources of coverage funded by the federal government may support Medicare beneficiaries' out-of-pocket prescription drug costs, the omission of outpatient prescription drug coverage in the Original Medicare was a missed opportunity as this article will discuss below.[11] The Medicare Catastrophic Coverage Act of 1988 expanded Medicare benefits to include outpatient drugs and cap enrollees' copayment costs for certain covered services.[12] Congress repealed the prescription drug provisions one year later, resulting in health problems worsening and costs rising.[13] Later, the prescription drug coverage in the Health Security Act of 1993 was a failed opportunity to add an outpatient prescription drug benefit after losing public support.[14] On December 8, 2003, President George W.

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[9] *Medigap and Medicare Advantage Plans*, MEDICARE.GOV, https://www.medicare.gov/supplements-other-insurance/whats-medicare-supplement-insurance-medigap/medigap-medicare-advantage-plans (last visited: Apr. 25, 2023).
[10] Rachael Zimlich, *Understanding Medicare Out-of-Pocket Maximums*, HEALTHLINE (July 20, 2021), https://www.healthline.com/health/medicare/medicare-out-of-pocket-maximum#takeaway.
[11] Thomas R. Oliver et al., *A Political History of Medicare and Prescription Drug Coverage*, 82 THE MILLBANK Q. 283, 285 (2004).
[12] Aditi P. Sen et al., *Catastrophic Coverage in the Medicare Part D Drug Benefit: Which Beneficiaries Need It and How Much Are They Spending*, THE COMMONWEALTH FUND (Sept. 17, 2020), https://www.commonwealthfund.org/publications/issue-briefs/2020/sep/catastrophic-coverage-medicare-part-d-drug-benefit; Sandra Christensen, *The Medicare Catastrophic Coverage Act of 1988*, CONG. BUDGET OFF. (Oct. 1988), https://www.cbo.gov/sites/default/files/100th-congress-1987-1988/reports/88doc140.pdf.
[13] Thomas R. Oliver et al., *A Political History of Medicare and Prescription Drug Coverage*, 82 THE MILLBANK QUARTERLY 283, 283-354 (2004); Dan Diamond, *When Health Repeal Was 'Catastrophic'*, CAL. HEALTHLINE (February 2, 2011), https://californiahealthline.org/news/when-health-repeal-was-catastrophic/.
[14] *Id.*

Bush pushed for expanded prescription drugs by signing the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), which provided outpatient prescription drug coverage for Medicare beneficiaries.[15] This MMA demonstrated a significant shift in Medicare coverage; 38 years after Medicare was initially signed into law, this Act provided outpatient prescription drug coverage that was omitted in the initial package.[16]

In addition, the MMA stated that "the Secretary may not interfere with the negotiations between drug manufacturers and pharmacies and prescription drug program sponsors; and may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs."[17] This allows insurers to negotiate with drug manufacturers to add certain prescription drugs to their formularies.[18] Consequently, the federal government paid more for Medicare brand-name prescription drugs than other federal programs.[19] For example, the average net price for the top-selling brand name drugs ranged from $118 in Medicaid to $343 under Medicare Part D.[20] Accordingly, the Inflation Reduction Act of 2022 was signed into law to address concerns about the increasingly expensive prescription drug costs for Medicare beneficiaries and reduce drug spending by the federal government.[21]

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[15] *Id.*
[16] *Id.*
[17] Medicare Prescription Drug, Improvement and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2195 (2003).
[18] Rachel Christian, *Medicare Modernization Act*, RETIREGUIDE (Jan. 17, 2003), https://www.retireguide.com/medicare/basics/history/medicare-modernizationact.
[19] U.S. GOV'T ACCOUNTABILITY OFF., GAO-14-578, PRESCRIPTION DRUGS: COMPARISON OF DOD, MEDICAID, AND MEDICARE PART D RETAIL REIMBURSEMENT PRICES 1 (2014).
[20] *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs*, CONG. BUDGET OFF. (Feb. 2021), https://www.cbo.gov/publication/57007.
[21] Cubanski, *supra* note 2.

III. MISSED OPPORTUNITIES

A. Uninsured Patients

In the Inflation Reduction Act of 2022, there is a specific provision pertaining to insulin products.[22] This provision caps sharing for Medicare beneficiaries to $35 per month, including insulin covered under Part B and Part D.[23] Along with Medicare Part D plans, stand-alone drug plans and Medicare Advantage Plans will be required to limit insulin costs to $35 per month as well.[24] None of these plans are required to cover all insulin products.[25] To fully address the increasing cost of insulin for patients, the Inflation Reduction Act should be amended to include provisions to protect nearly 30 million uninsured patients.[26]

Typically, drug pricing begins when manufacturers sell insulin to pharmacy benefit managers (PBM) after finalizing a negotiated list price.[27] Manufacturers typically include rebates in the list price for the PBMs, who then pass these rebates onto insurers for placement on their insurance formulary plans.[28] The net price for insulin that manufacturers collect is "equal to the list price minus any rebates paid to PBMs, other fees paid to wholesalers, and discounts paid to pharmacies."[29] Accordingly, manufacturers have a financial motive to negotiate an increasing list price

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[22] *Id.*
[23] Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1819 (2022).
[24] Cubanski, *supra* note 2.
[25] *Id.*
[26] Patrick Drake & Jennifer Tolbert, *Key Facts about the Uninsured Population*, KAISER FAM. FOUND. (Dec. 19, 2022), https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/.
[27] Sherry Glied & Benjamin Zhu, *Not So Sweet: Insulin Affordability Over Time*, THE COMMONWEALTH FUND (Sept. 2020), https://www.commonwealthfund.org/sites/default/files/2020-09/Glied_not_so_sweet_insulin_affordability_ib.pdf.
[28] *Id.*
[29] *Id.*

because they collect their profits only after the rebates, discounts, and fees are dispersed.[30] As a result of this redundant cycle of rising costs, vulnerable populations are detrimentally impacted by the pharmaceutical industry's financial greed.[31]

Managing diabetes can be costly and unsustainable in America.[32] Out-of-pocket insulin costs alone have doubled in the last decade.[33] For example, "[o]ne vial of Humalog (insulin lispro), which used to cost $21 in 1999, costs $332 in 2019, reflecting a price increase of more than 1000 percent."[34] The dramatic increase in insulin costs can be attributed to more complex insulin supply chains, in which new entities enter the supply chain collecting profits, leading to higher insulin costs for patients.[35] As a result of the increasing cost of insulin, one in four diabetic patients has reported underusing or skipping their insulin doses.[36] "A study of the National Hospital Discharge Survey from 2004 of 370,785 inpatient records found that the hospital cost of uncontrolled diabetes without complications was $552 million ($52,294 per admission), but this skyrocketed to $1821 billion ($124,510 per

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[30] *Id.*
[31] *See* Walid F. Gellad et al., *How The New Medicare Drug Benefit Could Affect Vulnerable Populations*, NAT'L LIBRARY OF MED. (Mar. 2006), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1403812/ (explaining that "[B]lacks, people with lower incomes, and people with more chronic health conditions are more likely to have this high level of (drug) spending than are whites and Hispanics, people with higher incomes, and people without chronic health conditions").
[32] *Insulin and Drug Affordability*, AM. DIABETES ASS'N, https://diabetes.org/advocacy/insulin-and-drug-affordability (last visited Apr. 4, 2023).
[33] Kendall Teare, *One in four patients say they've skimped on insulin because of high cost*, YALENEWS (Dec. 3, 2018), https://news.yale.edu/2018/12/03/one-four-patients-say-theyve-skimped-insulin-because-high-cost.
[34] S. Vincent Rajkumar, *The High Cost of Insulin in the United States: An Urgent Call to Action*, MAYO CLINIC PROCEEDINGS (Jan. 2020), https://www.mayoclinicproceedings.org/article/S0025-6196(19)31008-0/fulltext.
[35] Mallory Locklear, *Insulin is an extreme financial burden for over 14% of Americans who use it*, YALENEWS (July 5, 2022), https://news.yale.edu/2022/07/05/insulin-extreme-financial-burden-over-14-americans-who-use-it.
[36] Teare, *supra* note 33.

admission) for patients with a diagnosis of uncontrolled diabetes with ketoacidosis."[37] Diabetic patients who struggle with affording insulin, a lifesaving drug, should not be forced to choose between their medications, housing, food, and the many other necessities.[38] Uninsured diabetic patients pay almost double for out-of-pocket insulin costs in comparison to Medicaid beneficiaries and the privately insured.[39] Moreover, almost three-quarters of uninsured patients pay over $100 out-of-pocket per prescription of insulin.[40] The Inflation Reduction Act of 2022 missed the opportunity to include provisions protecting uninsured patients who struggle to pay for insulin. 41.1 percent of patients who take insulin were Medicare beneficiaries, and the Inflation Reduction Act did address those individuals.[41] 2.2 percent of uninsured patients took insulin, yet the Inflation Reduction Act failed to include these individuals who spend the most on the medication.[42] Although a few House lawmakers lobbied to add such protections for uninsured patients, the unfortunate outcome is that uninsured patients will continue to pay the list price for insulin unless the Inflation Reduction Act is amended.[43] There are about two million uninsured diabetic patients aged 18-64 in the

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[37] Sunny Kim, *Burden of Hospitalizations Primarily Due to Uncontrolled Diabetes: Implications of inadequate primary health care in the United States*, AM. DIABETES ASS'N (May 2007), https://diabetesjournals.org/care/article/30/5/1281/29879/Burden-of-Hospitalizations-Primarily-Due-to.
[38] *Insulin and Drug Affordability*, *supra* note 32.
[39] Glied *supra* note 27, at 1.
[40] *Id.*
[41] Locklear, *supra* note 35.
[42] *Id.*
[43] Rachel Pannett & Rachell Roubein, *The GOP blocked an insulin price cap: What it means for diabetics*, THE WASH. POST (Aug. 9, 2022), https://www.washingtonpost.com/health/2022/08/08/insulin-price-cap-diabetes-senate-republicans/.

United States, some of which pay upwards of $1,000 per month for insulin.[44,] The impact could have been more significant if the Inflation Reduction Act was amended to specifically include provisions protecting the most financially vulnerable uninsured individuals paying full price for the medication.

B. Number of Drugs Subject to Price Negotiation

The MMA established the Medicare Part D benefit that covers prescription drugs.[45] The "non-interference clause" stipulates that the United States Department of Health and Human Services "may not interfere with the negotiations between drug manufacturers and pharmacies and prescription drug plan sponsors; and may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs."[46] Because of the "non-inference clause," Medicare reimburses providers based on 106 percent of the Average Sales Price (ASP), which is "the revenue from a manufacturer's sales of a drug to all purchasers divided by the total number of units of the drug sold by the manufacturer in the same quarter... The ASP is net of any discounts."[47] Policymakers have targeted the Part D "non-interference clause" for an extended period, and the Inflation Reduction Act

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[44] Sarah Stark Casagrande & Catherine C. Cowie, *Health Insurance and Diabetes*, NAT'L LIBR. OF MED. (Aug. 2018), https://www.ncbi.nlm.nih.gov/books/NBK567967; Berkeley Lovelace Jr., *Nearly 1 in 5 U.S. adults with diabetes ration insulin to save money, study finds*, NBCNEWS (Oct. 17, 2022), https://www.nbcnews.com/health/health-news/insulin-prices-many-adults-diabetes-ration-insulin-study-finds-rcna52287.
[45] Medicare Prescription Drug, Improvement and Modernization Act, *supra* note 17.
[46] *Id.*
[47] *Average Sale Price (ASP) payment system*, ALL. FOR HEALTH POL'Y, https://www.allhealthpolicy.org/glossary/average-sales-price (last visited: Apr. 5, 2023); Juliette Cubanski, *What's the Latest on Medicare Drug Price Negotiations*, KAISER FAM. FOUND. (July 23, 2021), https://www.kff.org/medicare/issue-brief/whats-the-latest-on-medicare-drug-price-negotiations/.

of 2022 afforded the federal government the ability to negotiate with drug manufacturers in a controlled manner.[48]

The Inflation Reduction Act of 2022 amended the "non-interference clause" to establish a Drug Price Negotiation Program that affords the Secretary of HHS the ability to "enter into agreements with manufacturers of selected drugs" and "negotiate and, if applicable, renegotiate maximum fair prices for such selected drugs."[49] Under the Drug Price Negotiation Program, the Secretary of HHS will select ten Part D drugs in 2026, another fifteen Part D drugs in 2027, another fifteen Part D and Part B drugs in 2028, and another twenty Part D and Part B drugs in 2029 and later years.[50] Only the drugs with the highest spending in Part D and Part B will be available for selection to negotiate.[51]

The impacts of this provision will be detrimental to Medicare beneficiaries that rely on these prescription drugs.[52] One of the primary concerns with this provision is that the process of selecting these drugs and negotiating their price points in a few years will result in the continuing issue of high out-of-pocket expenses for Medicare beneficiaries. These individuals will recognize lower out-of-pocket drug expenses depending on whether their prescription drug was selected for that given year for negotiation. If one of their prescription drugs is selected, then it will be negotiated for a maximum fair price between the Secretary of HHS and drug manufacturers.[53] If more Medicare Part D and Part B drugs could be chosen in the initial year of

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[48] Cubanski, *supra* note 2.
[49] Inflation Reduction Act of 2022, *supra* note 23.
[50] *Id.*
[51] Cubanski, *supra* note 2.
[52] *The Inflation Reduction Act Lowers Health Care Costs for Millions of Americans*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Oct. 5, 2022), https://www.cms.gov/newsroom/fact-sheets/inflation-reduction-act-lowers-health-care-costs-millions-americans.
[53] Inflation Reduction Act of 2022, *supra* note 23.

negotiation, then more Medicare beneficiaries can be impacted by the lower out-of-pocket costs. Another concern with the provision is the lengthy timeline. The first ten Medicare Part D drugs are selected for negotiation beginning on September 1, 2023, and the negotiated maximum fair prices will be finalized and published for the public on September 1, 2024.[54] Implementing the negotiated price should not take over one year, especially when the primary concern is assisting and supporting the most vulnerable populations in America. Although the Inflation Reduction Act's provisions about lowering drug costs and spending are a revolutionary achievement in health care, the Act still lacks urgency for the individuals deciding whether to pay rent, buy groceries, or purchase prescriptions.[55]

Negotiating a discounted price for Medicare beneficiaries can lead to adverse effects.[56] First, the discounted price for Medicare beneficiaries may cause pharmaceutical manufacturers to increase the cost of drugs that Medicare does not cover.[57] Because Medicare targets the elderly population aged 65 and older, individuals below that threshold are at risk of this increase in drug pricing.[58] Second, the federal government's role in drug pricing may impact innovation through research and development.[59] If drug prices are lowered and pharmaceutical returns from investment are diminished,

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[54] *Inflation Reduction Act: CMS Implementation Timeline*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/files/document/10522-inflation-reduction-act-timeline.pdf (last visited: Apr. 5, 2023).
[55] *The Inflation Reduction Act is a Milestone Achievement in Lowering Americans' Health Care Costs*, THE COMMONWEALTH FUND (Aug. 15, 2022), https://www.commonwealthfund.org/blog/2022/inflation-reduction-act-milestone-achievement-lowering-americans-health-care-costs; Sunny Kim, *supra* note 37.
[56] *See* Jim Han et al., LIBR. OF CONG. RSCH. SERV., *The Pros and Cons of Allowing the Federal Government to Negotiate Prescription Drug Prices* (Feb. 18, 2005).
[57] *Id.*
[58] *Id.*
[59] *Id.*

research and development will suffer as a result.[60] Finally, there is a possibility that the price negotiations may not be significant enough to see a positive impact on Medicare beneficiaries. The Secretary of HHS is required to consider the pharmaceutical manufacturer's research and development costs in negotiating the maximum fair market price.[61] If this was not a required criterion for the Secretary of HHS, the negotiated price point might be significantly reduced considering that research and development are expensive costs for pharmaceutical manufacturers. Because the Secretary of HHS is required to consider the research and development costs, there is a likelihood that the drug price reductions may be minuscule. Alternatively, the federal government's role in negotiating specific drug prices may result in more consistent pricing for beneficiaries.[62]

Regardless of the potential disadvantages of negotiating a discounted price for Medicare beneficiaries, the Inflation Reduction Act should be amended to increase the number of drugs subject to negotiation under Part D and Part B beginning in 2026 to increase access to vulnerable populations because the benefits outweigh the potential costs.[63] The drug selection process is lengthy; that being the case, it would be in the best interest of vulnerable populations to increase the number of drugs selected to mitigate the increasingly high out-of-pocket expenses. Specifically, the Inflation Reduction Act should be amended to select drugs that impact the highest number of Medicare beneficiaries.

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[60] *Id.*
[61] Cubanski, *supra* note 2.
[62] Han, *supra* note 56.
[63] Cubanski, *supra* note 2.

C. Financial Incentives

The Inflation Reduction Act of 2022 amended the Medicare Part D design.[64] Before the Act's passing, Medicare Part D beneficiaries would spend a limitless amount of out-of-pocket dollars on prescription drugs.[65] If Medicare enrollees exceeded the catastrophic threshold, they were required to pay five percent of their total drug costs, or a small copay, whichever is greater.[66] Many Medicare enrollees do not reach the catastrophic coverage phase, but for the individuals that do reach it, the five percent coinsurance can add up if they need expensive medications.[67] For example, Medicare Part D enrollees who take high-priced prescription drugs for conditions related to cancer treatment will save exponentially once the cap is enforced.[68] The average annual cost of the cancer drug Revlimid was $6,200; $5,700 for the cancer drug Imbruvica; and $4,100 for the Multiple Sclerosis drug Avonex.[69]

The Inflation Reduction Act eliminated the five percent Medicare beneficiary coinsurance requirement, resulting in a $3,250 cap beginning in 2024 and lowered to $2,000 in 2025.[70] Medicare Part D plans will likely face financial incentives to mitigate the possible premium increases due to the

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[64] *Inflation Reduction Act and Medicare*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Jan. 10, 2023), https://www.cms.gov/inflation-reduction-act-and-medicare.
[65] Cubanski, *supra* note 2.
[66] *Catastrophic Coverage (Part D)*, MEDICARERESOURCES.ORG, https://www.medicareresources.org/glossary/catastrophic-coverage/ (last visited: Feb. 13, 2023).
[67] *Id.*
[68] Juliette Cubanski et al., *How Will the Prescription Drug Provisions in the Inflation Reduction Act Affect Medicare Beneficiaries*, KAISER FAM. FOUND. (Jan. 24, 2023), https://www.kff.org/medicare/issue-brief/how-will-the-prescription-drug-provisions-in-the-inflation-reduction-act-affect-medicare-beneficiaries/.
[69] *Id.*
[70] Cubanski, *supra* note 2.

spending cap.[71] To further address the increasing cost of prescription drugs, the federal government can encourage utilization management, a collection of treatment reviews, and cost reduction techniques used by health insurers and health plans, particularly for high-cost specialty medications.[72] A typical utilization management technique is step therapy which requires patients to try a lower-cost medication substitute before gaining coverage for a higher-cost medication.[73] This technique is typically utilized for pain medications, but this concept can also be applied to high-cost cancer medications.[74] The federal government can also encourage generic drug utilization, if applicable.[75] Medicare could save up to $1 billion annually if they required the use of generic drugs.[76] Generic drugs do not have a positive perception with the general public, but if the federal government encouraged generic drug usage, the perception could be transformed.[77] The Inflation Reduction Act should be amended to include financial incentives for recommending generic drugs and encouraging utilization management techniques like step therapy.

Amending the Inflation Reduction Act to promote generic drugs would also reduce costs for patients. Generic drugs have the same active ingredients as the brand-name drugs and cost twenty to seventy percent less and are just

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[71] *Id.*
[72] *Just the Facts: Prescription Drug Utilization Management*, AMER. CANCER SOC'Y: CANCER ACTION NETWORK, https://www.fightcancer.org/sites/default/files/Prescription-Drug-Utilization-Management-factsheet.pdf (last visited Apr. 5, 2023).
[73] *Id.*
[74] *Id.*
[75] Cubanski, *supra* note 2.
[76] Jennifer Howard et al., *Influencers of General Drug Utilization: A Systematic Review*, 14 RES. SOCIAL ADM. PHARM. 1, 8 (July 1, 2019).
[77] *Id.* (explaining that "…[w]hile the majority of patients have positive perceptions of generic drugs, lingering negative perceptions among some may still exist…").

as effective.[78] And finally, overall savings to Medicare create positive results in the healthcare system.

IV. CONCLUSION

The drug cost provisions in the Inflation Reduction Act of 2022 have become one of the most impactful healthcare legislations in the last twenty years. As a result of public outcry to lower prescription drug prices, the Inflation Reduction Act included provisions that focused on the patient instead of the pharmaceutical industry.[79] Although revolutionary, through amendments, the Act can continue further to address the increasing drug prices for uninsured diabetic patients. The federal government made a grand first step of affording the Secretary of Health and Human Services the ability to negotiate the price of certain prescription drugs. Subsequently, the lengthy timeline and minimal prescription drug selection may not efficiently reduce drug prices. The federal government should encourage utilization management and generic drug prescription substitutions to reduce and exercise control of drug spending.

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[78] *Generic Drugs and Low-Cost Prescriptions*, FED. TRADE COMM'N (July 2012), https://consumer.ftc.gov/articles/generic-drugs-low-cost-prescriptions.
[79] Cubanski, *supra* note 2.

Changes to Stark Exceptions that Will Facilitate Outcome-Based Reimbursement and Drive Innovation in Healthcare

Natasha Ganesh

I. BACKGROUND ON THE CURRENT REIMBURSEMENT MODEL

The United States healthcare system has historically operated as a fee-for-service model that results in little to no reward for delivering holistic, value-based care.[1] In particular, this model utilizes an itemized billing scheme, which requires the physician to bill for each health care product or service separately rather than reimburse based on treatment outcomes.[2] Every product or service on a bill is allocated a code that is entered into a medical billing system, which in turn generates a price for the particular service provided.[3] The price calculation of the service provided differs; however, based on whether the patient holds Medicare or commercial insurance.[4] For example, Medicare uses a "fee schedule"—updated by the Centers for Medicare and Medicaid Services (CMS)—which provides the maximum payment amount a physician can receive for a service provided to a Medicare patient.[5] Although geography, skill set, and physician experience are some of the specific factors that CMS considers when determining the physician's reimbursement amount, the fee-for-service model ultimately encourages a physician to increase the volume of patients in order to increase their payout amount without consideration for the patient's outcome.[6] Based on the AMA Journal of Ethics, the "current reimbursement model incentivizes physicians

[1] Kaitlin Hunter et al., *The Case Against Fee-for-Service Health Care*, THIRD WAY (Sept. 9, 2021), https://www.thirdway.org/report/the-case-against-fee-for-service-health-care (highlighting that "fundamentally, fee-for-service rewards volume and high prices over quality").
[2] *Id.*
[3] *See id.* (highlighting that one provider has "over 70,000 different ICD-10 codes, from an acute post-traumatic headache (G44.311) to being struck by a falling object (W20.8xxA)").
[4] *Id.*
[5] *Id.*
[6] Hunter et al., *supra* note 1.

to engage in behaviors designed to 'game the system' based on expectations for productivity that can compete with physicians' presumed obligations to provide patients with high-quality care."[7]

Notably, with the fee-for-service—the current majority model— cost and quality of service performance incentives make up only 8.3% of the total primacy care providers (PCP) compensation.[8] Volume-based compensation, however, contributed to 83.9% of the PCP compensation amount.[9] Thus, there is a potential for fraud and abuse because fee-for-service models financially incentivize physicians to increase volume without corresponding quality outcomes.[10] Strikingly, in 2016, CMS spent $95 billion on payments that were improper and connected to physician fraud and abuse.[11] Adverse events, or undesirable health outcomes, also cost Medicare beneficiaries over $4 billion dollars in one year.[12]

First, the article will explain the current exceptions under the Stark Law that allow for leniency under a value-based/outcome-based reimbursement model. Next, the article will analyze those exceptions, evaluating the advantages and disadvantages. Finally, this article will discuss the necessary changes that need to be made to the exceptions to allow for more physicians

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[7] Katherine Drabiak et al., *What Should Health Care Organizations Do to Reduce Billing Fraud and Abuse?*, AMA J. ETHICS: POL'Y F. (Mar. 2020), https://journalofethics.ama-assn.org/article/what-should-health-care-organizations-do-reduce-billing-fraud-and-abuse/2020-03.

[8] Joe Aguilar, *New Stark Rule and Anti-Kickback Statute Pave the Way for Physicians and Value-based Arrangements*, MED. GRP. MGMT. ASS'N. (Mar. 15, 2022), https://www.mgma.com/resources/financial-management/new-stark-rule-and-anti-kickback-statute-pave-the.

[9] *Id.*

[10] *See* Drabiak et al, *supra* note 7 (noting that a cycle of bad behaviors are induced in part by financial incentives).

[11] *Id.*

[12] *Management Challenge 2: Transitioning to Value-Based Payments for Health Care*, U.S. DEP'T OF HEALTH & HUM. SERV.: OFF. OF INSPECTOR GEN., https://oig.hhs.gov/reports-and-publications/top-challenges/2013/challenge02.asp (last visited: Feb.7, 2023).

to voluntarily implement a value-based/outcome-based reimbursement model while bearing less risk and receiving more reward for doing so.

II. INTRODUCTION TO A VALUE-BASED CARE MODEL (VBC)

A fee-for service model does little to account for and monitor a patient's social determinants of health, which has proven to be crucial in delivering quality care.[13] Social determinants of health include factors such as living environment, socioeconomic status, and food deserts.[14] Moreover, it is well known that because a fee-for-service model prioritizes billing over patient outcome, it is near impossible to address a patient's social determinants of health under this model.[15] Accordingly, to rectify this, hospitals should implement a value-based/outcome-based reimbursement model (VBC).[16] A VBC model is a reimbursement model that connects the payments of services delivered to the quality of care provided to the patient.[17] Under the VBC model, providers are compensated and reimbursed according to the effectiveness and efficiency of the health care service.[18] Thus, VBC models provide a wide array of benefits, including reducing costs; increasing transparency; maintaining less hospital debts; increasing patient trust and

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[13] *See 5 Things You Should Know About Full-Risk Value Based Care*, CHENMED (Aug. 3, 2021), https://www.chenmed.com/blog/5-things-you-should-know-about-full-risk-value-based-care (highlighting the importance of social determinants to health by reporting that research has shown that social determinants of health can account for more than one-third of deaths in the United States each year).
[14] *Id.*
[15] *Id.*
[16] *See id*. (proposing that a full-risk value-based care system would naturally leverage the motivators intrinsic in physicians).
[17] *What Is Value-Based Care, What It Means for Providers*, REVCYCLEINTELLIGENCE: FEATURES (Mar. 2, 2022), https://revcycleintelligence.com/features/what-is-value-based-care-what-it-means-for-providers.
[18] *Id.*

provide focus on patient specific care; and providing less opportunity for overbilling and fraudulent reimbursements.[19]

Accordingly, we want to move towards a VBC model, and away from the current fee-for-service model that both encourages providers to run more tests and procedures.[20] In an effort to transform the reimbursement model for providers, CMS has introduced a handful of demo VBC models, like the Medicare Shared Savings Program and Pioneer Accountable Care Organizations Model.[21] Enacted to reward physicians for the quality of care patients receive,[22] there are numerous benefits associated with the VBC model. Under the VBC model, evidence-based medicine is prioritized and physicians are required to use and report data to payers on metrics that demonstrate the improvement and wellbeing of patients.[23] However, VBC models presently pose one of the greatest financial challenges to the healthcare system because they are an unpopular, burdensome, and often inaccessible option for most healthcare providers.[24] In addition, a VBC model is significantly more subjective than a fee-for-service model since there is no single way to measure quality and improvement in care.[25]

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[19] *See* CHENMED, *supra* note 13 (describing that physicians' job satisfaction is strongly correlated to their ability to provide high-quality of care).
[20] Duncan Ghallager, *From Volume to Value: 10 Essential Strategies for Navigating the Healthcare Shift*, HEALTH CATALYST (June 8, 2021), https://www.healthcatalyst.com/insights/fee-service-value-based-care-making-shift.
[21] REVCYCLEINTELLIGENCE: FEATURES, *supra* note 17.
[22] *Id.*
[23] *See* Rupert Dunbar-Rees, *Paying for What Matters Most: The Future of Outcomes-Based Payments in Healthcare*, 5 FUTURE HEALTHCARE J. 98, 99 (2018) (clarifying that "the terms 'value-based payment' and 'outcomes- based payment' are often used interchangeably and generally mean payment to providers for achieving better outcomes").
[24] *See* Wendy Gerhardt et al., *The road to value-based care: Your mileage may vary*, DELOITEE CENTER FOR HEALTH SOLUTIONS, https://www2.deloitte.com/content/dam/insights/us/articles/value-based-care-market-shift/DUP-1063_Value-based-care_vFINAL_5.11.15.pdf (highlighting "the market shift towards value-based care (VBC) presents unprecedented opportunities and challeneges for the US health care system") (last visited: May 1, 2023).
[25] *See id.* (highlighting how "the choice of model (or combination of models) will depend on each stakeholders capabilities, market position, financial situation, and VBC goals").

Currently, the VBC model is voluntary for physicians and health systems more generally.[26] Historically, in healthcare system, innovative models like the VBC model are often introduced as demo projects.[27] Despite the lack of receptivity, however, the desire to improve the healthcare system is present.[28] Elizabeth Fowler, the director of the CMS Innovation Center (CMMI Center) stated that the "commitment to value-based care has never been stronger."[29]

III. CURRENT STARK LAW EXCEPTIONS FOR VALUE-BASED ARRANGEMENT

Since physicians do not presently receive adequate fiscal reimbursement to make it worthwhile to transfer to a VBC model,[30] they need to be incentivized to focus on patient outcomes over volume.[31] Accordingly, to encourage such change, new exceptions under the Stark Law and new safe harbors under the Anti-Kickback Statute have been implemented by CMS, the OIG, and the United States Department of Health and Human Services (HHS) for certain value-based arrangements.[32] For example: the Stark Law

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[26] *See What are the value-based programs?*, CTR. MEDICARE & MEDICAID SERV. (MAR. 31, 2022), https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Value-Based-Programs (highlighting the requirements for the VBC model and explaining the requirements for a provider to transition into the VBC model if they elect to).

[27] *Innovation in Healthcare: Importance and Explosive* Examples, ACCEPT MISSION (Nov. 1, 2020), https://www.acceptmission.com/blog/innovation-in-healthcare-importance-and-explosive-examples/.

[28] Robert King, *New CMMI Director Says Value-Based Care Models at 'Crossroads'*, FIERCE HEALTHCARE: PAYERS (Apr. 20, 2021, 3:10 PM), https://www.fiercehealthcare.com/payer/new-cmmi-director-says-value-based-care-models-at-crossroads.

[29] *Id.*

[30] Molly Bogan, *Who Benefits from Moving Health Care from Volume to Value?*, INST. HEALTHCARE IMPROVEMENT (Jul. 24, 2019), https://www.ihi.org/communities/blogs/who-benefits-from-moving-health-care-from-volume-to-value.

[31] *Id.*

[32] Lisa G. Han et al., *New Stark Law, Anti-Kickback Statute Exceptions and Safe Harbors for Value-Based Arrangements*, JONES DAY: COMMENTARY (Dec. 2020), https://www.jonesday.com/en/insights/2020/12/new-stark-law-antikickback-statute-exceptions-and-safe-harbors-for-valuebased-payments.

(also known as the Physician Self-Referral Law) was enacted to prohibit any physician from making referrals for "designated health services" to any person or entity payable by Medicare that financially benefitted the physician or any of the physician's family members has a financial relationship with.[33] However, many VBC models could involve these types of referrals, so Stark Law exceptions were adopted to carve out situations where remuneration may be paid under a value-based arrangement.[34] If any of these exceptions apply to the physician, the indirect compensation—in this case, the renumeration— would still be allowed under the Stark Law.[35] Specifically, these exceptions protect remuneration paid to the physician under a value based arrangement where the physician is at (1) a "meaningful downside financial risk," which results in the physician being responsible to "repay or forgo at least 10% of the total value of remuneration the physician receives under value based arrangement;" (2) where a physician is at full financial risk; or (3) where a physician bears no risk with minimum financial reward and extensive monitoring.[36] The protection provided by this exception means that some physicians can refer a patient that would ordinarily not be allowed because it would provide better care for the patient.[37]

These exceptions also protect value-based enterprises (VBE), which are at full financial risk of the total cost of care.[38] These exceptions require the VBE to be fully financially responsible for the payer-covered cost of all items

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[33] *Id.*
[34] *Id.*
[35] *See* Gretchen Heinze Townshend et al., *Fraud and Abuse Rules Part III: New Value-Based Arrangement* Protections, MCGUIREWOODS (Jan. 20, 2021), https://www.mcguirewoods.com/client-resources/Alerts/2021/1/fraud-abuse-rules-part-iii-new-value-based-arrangement-protections (suggesting that "under the Stark Law value-based arrangement exception, a VBE could compensate physicians for providing post-discharge services to patients in a target patient population and have the compensation be dependent on readmission rates").
[36] Han et al., *supra* note 32.
[37] *Id.*
[38] *Id.*

and services rendered to the patient for the target population for one year.[39] In order to be identified as a VBE, the entity could be a health care provider, digital health company, or an accountable body that is responsible for operational and financial oversight.[40] VBE participants must include two or more entities that are collaborating to achieve a value-based purpose, which is meant to improve the quality of care for the target population while reducing costs without reducing the quality of care.[41] The financial risk can affect a physician's compensation; however, the exception allows them more latitude to innovate solutions to improve patient care, the ultimate value-based purpose.[42]

IV. PROPOSAL FOR INCREASING IMPLEMENTATION OF VALUE-BASED CARE

Although these current exceptions allow for greater flexibility in value-based reimbursement, the narrow eligibility under the exceptions coupled with increased requirements for eligibility disincentivizes providers to move towards a VBC model.[43] Moreover, the amount of regulatory constraints are inversely related to the amount of financial risk a physician is willing to carry.[44] Therefore, under the current exception model, there is a high risk-

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[39] *See* Townshend, *supra* note 35.
[40] *See* Carrie Nixon, *What is a Value-Based Enterprise? New Opportunities for Digital Health and Healthcare Innovation*, NIXON GWILT LAW (Jan. 24, 2021), https://nixongwiltlaw.com/nlg-blog/2021/1/24/what-is-a-value-based-enterprise-new-opportunities-for-digital-health-and-healthcare-innovation (describing the various types of entities that could quality as a value-based enterprise).
[41] *Id.*
[42] *Id.*
[43] *See* King, *supra* note 28 (quoting the CMMI director's statement that "the landscape of value-based care models has gotten more complex with some overlapping and providers having to compete over benchmarks and savings," which indicates that the current landscape causes financial confusion and stress for providers).
[44] Chad N. Eckhardt & Darren S. Skyles, *The Three Stark Law Exceptions for Value-Based Care Offer Advantages for Providers*, FROST BROWN TODD ATT'Y: HEALTH L. MATTERS (Oct. 31, 2022), https://frostbrowntodd.com/the-three-stark-law-exceptions-for-value-based-care-offer-advantages-for-providers/.

high reward situation; consequently, physicians are too averse to adopt a VBC model.[45]

A VBC model prioritizes the creation of greater care coordination.[46] Currently, physicians are concerned about being evaluated based on such outcomes due to the lack of clarity that is associated with the relationship between financial incentives and performance.[47] However, physicians are also bearing a large initial financial risk at the time of treating the patient under the Stark exception.[48] There is a need, therefore, to strike a balance between the standardization of care received in a fee-for-service model, and the personalization of care attained through a VBC model. Accordingly, developing a new model to help adhere to the Stark exceptions will pave the way for this balance and lead physicians to prefer a VBC model over a fee-for-service model.

The narrow rules that presently exist under Stark are hair-raising for physicians due to their restrictive nature.[49] Notably, the liability a physician

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[45] *Id.*

[46] *See* Kyle Gibler et al., *How Providers Can Best Confront the Reality of Value-Based Care*, MCKINSEY & CO.: HEALTHCARE (Apr. 17, 2019), https://www.mckinsey.com/industries/healthcare/our-insights/how-providers-can-best-confront-the-reality-of-value-based-care (describing that VBC arrangements can "increase physician alignment" and help a health care system deliver greater value of care at a lower total cost).

[47] *Id*. (describing that reducing the complexity of VBC arrangements specifically by aligning "the financial incentives being offered…and clarify how those incentives are linked to performance" can increase a transition).

[48] *Id*. (describing that "reducing the complexity of VBC arrangements increases the likelihood that providers will succeed" and choose a VBC model).

[49] *See Whistleblowers Can Report Violations of the Anti-Kickback Statute and Stark Law Using the False Claims Act*, CONSTANTINE CANNON: PRAC., https://constantinecannon.com/practice/whistleblower/whistleblower-types/healthcare-fraud/anti-kickback-stark/ (stating that the "Anti-Kickback Statute and Stark Law prohibit medical providers from paying or receiving kickbacks, remuneration, or anything of value in exchange for referrals of patients who will receive treatment paid for by government healthcare programs such as Medicare and Medicaid, and from entering into certain kinds of financial relationships").

currently carries to treat a patient is extremely high.[50] Even with the current Stark risk-bearing arrangement, physicians carry a higher financial risk than with a fee for service model.[51] Specifically, because physicians can test for everything and be rewarded for it under the fee-for-service model (the idea of defensive medicine), but must take on some fiscal liability depending on the outcome under a VBC model, the latter carries more risk.[52] However, this typically ends up costing the patients more for unnecessary procedures.[53] Thus, redefining the risk bearing arrangement by creating a shared risk bearing arrangement for physicians would give more room to expand VBC activity. This arrangement would further allow for more physicians to get just compensation, ensure increased quality of care, and lessen the opportunity for fraud. Therefore, the key would be to focus on creating a value-based arrangement where the physician would share the risk with CMS from any renumeration attained from other value-based entities.

Specifically, this paper proposes that CMS should serve as the value-based enterprise participant per the Stark exception in order to share the risk that physician's face in 42 C.F.R. § 411.352(i):

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[50] *Physician Burnout*, AGENCY FOR HEALTHCARE RSCH. & QUALITY: PREVENTION, https://www.ahrq.gov/prevention/clinician/ahrq-works/burnout/index.html (reporting an increase in burned-out physicians, which can "threaten patient safety and care quality" as well as "lead to poor interactions with patients").
[51] *See* Gibler et al., *supra* note 46 (describing how "providers may be hesitant to enter VBC arrangements because they can lead to a near-term decline in inpatient volume").
[52] *Id.*
[53] Hunter et al., *supra* note 1.

> Proposed Exception. A physician who practices care under a VBC model, as described in the Stark exceptions delivered by CMS, shall receive the opportunity to share the risk with CMS as long as the physician continues to drive its practice to a value-based purpose that improves the management of patients care. Risk percentage will be calculated similar to the current fee-for-service model using geography, skill set, and physician experience. Yearly audits will be conducted to ensure the physician's compliance with the necessary regulations per CMS. *If this exception were to be violated, physicians will be required to pay back CMS for the percentage of risk bared under the arrangement and bare full financial risk of all patient care for future services.*

A shared risk bearing arrangement would assign CMS as the value-based entity that partners with physicians to create a VBE. Currently, CMS has no power to negotiate risk percentages, thus one solution could be to adopt legislation that would allow Medicare to directly negotiate risk management percentages with physicians to help bear the risk a physician takes per each service.[54] The negotiated percentage of risk can utilize many of the same factors that are used to determine reimbursement in a fee-for-service model like success rate of the physician, years in service, and target population.[55] For example, if the physician has a history of providing more than adequate care, the risk bearing percentage will decrease. However, this would be a challenging policy to promulgate. Enacting legislation takes time, and the government has yet to crack the code on the right mix of laws needed to ensure affordable and high-quality healthcare, while utilizing key players in

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[54] *See* Theodore T. Lee et al., *The Politics of Medicare and Drug-Price Negotiation*, HEALTH AFF.: DRUGS & MED. INNOVATION (Sept. 19, 2016), https://www.healthaffairs.org/do/10.1377/forefront.20160919.056632/ (highlighting that Medicare, which is administered by CMS, cannot negotiate drug prices currently but could enter risk-sharing agreements with drug manufacturers under a VBC model).

[55] *See Provider Payment Under Fee for Service*, MEDICAID & CHIP PAYMENT & ACCESS COMM'N, https://www.macpac.gov/subtopic/provider-payment/ (last visited Apr. 14, 2023) (describing the factors considered when calculating reimbursement rates in current physician payment models).

the government.[56] Thus, this solution may work better as a long-term solution.

Alternatively, if CMS acted as a VBE participant and shared the risk assigned to the physicians, there would be an inclination for physicians to transition to a VBC model since they would take on less risk. In order to fall within the definition of CMS's value-based arrangement, the parties to the arrangement must include a physician and an entity focused on a value-based activity.[57] There are several value-based activities that CMS and the partnered physician could work towards. These activities include: (1) providing health technology to track patient data in order to assess quality of care, and/or (2) coordinating and managing the care of a target population.[58] As a result, there is a creation of a VBE consisting of the physician and CMS working on a value-based activity. In order to comply with CMS's goal to push physicians to transfer to a VBC model and away from fee-for-service model, a shared risk-based arrangement between CMS and the physician can be created to achieve the value-based activity.[59] In this instance, the renumeration will be a shared risk arrangement, where CMS shares the financial burden a physician typically carries by providing a fund that covers the prospective cost basis of all patient care and services covered at the time of treatment. The risk arrangement could be proposed and governed by the

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[56] Roslyn Murray et al., *The State of State Legislation Addressing Health Care Costs and Quality*, HEALTH AFF. (Aug. 22, 2019), https://www.healthaffairs.org/do/10.1377/forefront.20190820.483741/full/.

[57] Allison M. Cohen et al., *Regulatory Sprint: Understanding the Impact on the Stark Law, Anti-kickback Statute, and Value-based Arrangement*, BAKER DONELSON: PUBL'N (Dec. 18, 2020), https://www.bakerdonelson.com/regulatory-sprint-understanding-the-impact-on-the-stark-law-anti-kickback-statute-and-value-based-arrangements.

[58] It is important to note that CMS also manages the Health Insurance Portability and Accountability Act (HIPAA). By creating a partnership between CMS and physicians, CMS will be able to ensure compliance with HIPAA
A as society continues to evolve towards a technology-based health care landscape.

[59] *See* King, *supra* note 28 (quoting CMS Elizabeth Fowler's statement that "our commitment to value-based care has never been stronger").

physician's variable compensation contract.[60] Thus, the VBE will bear the burden of the financial risk which then will alleviate the burden on the physicians. By having the VBE bear the financial burden, the physician is free to make medical decisions without taking into account the financial risk.

In addition to the financial risk associated with VBC models, it also increases the administrative burden that weighs heavily on healthcare providers and health systems.[61] There is a two-prong benefit to implementing an exception like the one mentioned above that allows CMS to act as a partner in a VBE. First, it increases the efficiency of delivering quality of care by creating a partnership between physicians and a regulating body.[62] Second, by creating this fixed enterprise partnership with CMS and physicians, CMS's goal can be achieved, which includes motivating physicians to voluntarily transition to a VBC model with less risk.[63] The reason being, a VBC model operates with varying risk levels, and, per the Stark exceptions, physicians carry the burden of a significant percentage of risk based on the services provided to the patient in the target population.[64] However, if the physician is successful in achieving the goal of serving in the best interest of the patients, then the physician succeeds financially.[65] CMS is the best entity to monitor and provide the necessary VBC partnership, to

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[60] *See Understanding Physician Employment Contracts*, AM. MED. ASS'N (Dec. 29, 2022), https://www.ama-assn.org/medical-residents/transition-resident-attending/understanding-physician-employment-contracts (describing the various types of compensation models that are typically in a physician employment contract).

[61] Emily Gee & Topher Spiro, *Excess Administrative Costs Burden the U.S.Health Care System*, CAP: Rep. (Apr. 8, 2019), https://www.americanprogress.org/article/excess-administrative-costs-burden-u-s-health-care-system/.

[62] The goal is achieved through the formation of a network of participants consisting of physicians, providers, and suppliers encouraged to collaborate to increase efficiencies in delivering and improving the quality of care for a target population.

[63] *See* CTR. MEDICARE & MEDICAID SERV, *supra* note 26 (describing that "value-based programs are important because they're helping us move toward paying providers based on the quality, rather than the quantity of care they give patients").

[64] CHENMED, *supra* note 13.

[65] *Id.*

help physicians stay on track to meet the outcome-based goals while offering risk-sharing support. Monitoring and providing the necessary VBC partnership through CMS is the most appropriate method to help physicians stay on track to meet outcome-based goals while offering risk-sharing support.

That being said, the steps that would need to be taken in order to lessen the risk of fraud and encourage physicians to move towards a VBC model also create disadvantages. First, the OIG would have to conduct more audits on shared risk-bearing arrangements. Increased audits would ensure compliance with both Stark and Anti-Kickback provisions, but it would be costly and time-consuming. However, Medicare has already announced plans for increased audits under the VBC model.[66] Second, CMS would have to allocate funds and manpower to run a separate physician value-based enterprise partnership. This would require CMS to reevaluate its budget and create a sample physician population to test a partnership model like the one recommended above. Lastly, there is also the concern about the rising healthcare costs. CMS projects that between 2019 and 2028, healthcare spending will rise to 5.4%.[67] However, the benefits outweigh the drawbacks, as in a full-risk VBC model, a physician has the financial freedom to provide the right care at the right time to the target population.[68] Moreover, with CMS's partnership, the physician has an agency that will help the physician

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[66] Jennifer W. Lazio, *NOTE TO: Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties*, CTR. MEDICARE & MEDICAID SERV. (Apr. 4, 2012), https://www.cms.gov/files/document/2023-announcement.pdf (explaining "the potential development of a measure to capture the value-based care arrangements MA organizations have with providers based on health outcomes and quality of services provided to their patients, including how plans are aligning incentives with their providers so they are rewarding better value and outcomes rather than the volume of services").

[67] *National Health Expenditure Projections 2019-2028*, CTR. MEDICARE & MEDICAID SERV., https://www.cms.gov/files/document/nhe-projections-2019-2028-forecast-summary.pdf (last visited Apr. 14, 2023).

[68] CHENMED, *supra* note 13.

stay within the compliance regulations while sharing the overall risk the physician faces when treating a patient.

V. CONCLUSION

Although the new Stark exceptions provide for more flexibility for physicians to move towards a VBC reimbursement model, the exceptions are still narrow and consequently require physicians to be extremely cautious and detailed in order to comply. Therefore, in order broaden such exception and incentivize the transition to the VBC model, Congress should adopt the proposed exception, and CMS should further create a team of agency experts that would be in charge of monitoring and creating the partnerships with physician entities to create a VBE. Accordingly, by allowing a shared risk bearing arrangement, physicians will be more inclined to shift to a VBC model, ultimately leading to improved patient outcomes.

Re-Coding Endometriosis: Recognizing Excision Surgery as the Golden Standard Specialty for Treatment

Farisa Khan

I. INTRODUCTION

Women make up half the population of the country.[1] They also represent seventy percent of the healthcare workforce.[2] Their social and biological roles contribute the most to furthering generations and human development.[3] Taken together, women play a central role in overall population health.[4] However, very little is invested in their health care.[5]

Most women in the United States are responsible for both paid and unpaid work.[6] Unpaid work consists of rearing children, caring for family members, and completing household chores.[7] A majority of all domestic work, about 76 percent, is done by women globally.[8] By taking care of individual households, the welfare of the community as a whole is also benefitted.[9]

Furthermore, a large majority of healthcare professionals are women.[10] An increase of unhealthy women would directly impact society as fewer medical professionals would be available to provide treatment and care to those who are sick. As women continue to increase their presence and

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[1] Geri Stengel, *Female Founders Are Energizing Investment In Women's Healthcare: Expect More In 2023*, FORBES (Jan. 4. 2023), https://www.forbes.com/sites/geristengel/2023/01/04/female-founders-are-energizing-investment-in-womens-healthcare-expect-more-in-2023/?sh=495266903add.
[2] Michelle Remme et al., *Investing in the Health of Girls and Women: a Best Buy for Sustainable Development*, THE BRITISH MED. J. (June 2, 2020), https://www.bmj.com/content/369/bmj.m1175#.
[3] *Id.*
[4] *Id.*
[5] Stengel, *supra* note 1.
[6] Remme et al., *supra* note 2.
[7] *Id.*
[8] *Id.*
[9] *Id.*
[10] *Id.*

representation in the workforce, increased productivity by a healthy woman also contributes to societal and economic wellbeing.[11]

Economic wellbeing is also promoted by nurturing and environment.[12] Statistically, a woman's health during birth, childhood, and pregnancy influences the health of her children at each of those stages and into adulthood.[13] The health and development issues often result in literacy and income rate deficiencies as the child grows.[14]

Despite this reality, very little is invested in women's health care.[15] Notably, only one percent of research and innovation is dedicated to female-specific conditions.[16] Endometriosis, for example, is a female-specific condition that affects up to ten percent of American women and young girls.[17] Endometriosis is a chronic condition where tissue that is similar to the uterine lining grows outside the uterus, causing scar tissue to form within the abdominal cavity.[18] While there is significant conversation surrounding endometriosis, the topics largely focus on fertility issues resulting from the disease rather than the pain that women with this condition suffer from.

Endometriosis causes severe and unbearable pain during bowel movements, urination, periods, and intercourse, consequently disrupting the daily life of a woman.[19] Symptoms contributing to the pain also may include headaches, nausea, fatigue, and mental health struggles.[20] To manage their

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[11] *Id.*
[12] *Id.*
[13] *Id.*
[14] *Id*. (For example, Nigerian and Chinese studies found that maternal malnutrition had negative impacts on literacy and income of the fetus as he grew into adulthood.)
[15] Stengel, *supra* note 1.
[16] *Id.*
[17] *Endometriosis*, JOHNS HOPKINS MED., https://www.hopkinsmedicine.org/health/conditions-and-diseases/endometriosis.
[18] *Endometriosis*, WORLD HEALTH ORG. (Mar. 31, 2021), https://www.who.int/news-room/fact-sheets/detail/endometriosis.
[19] *Id.*
[20] *Id.*

symptoms, women often resort to different forms of treatments depending on the severity of their disease.[21] In its most advanced form, or when pain is unresolved, endometriosis usually requires a laparoscopic excision, a surgical procedure, to remove or destroy extrauterine tissues.[22] Most women who undergo such excision surgery find that their pain significantly decreases over a period of time.[23] Many endometriosis patients find other treatment options, such as medication and hormonal therapies, to be palliative at best.[24]

The problem regarding accessibility is that the billing code for laparoscopic endometriosis is "one size fits all," meaning that whether the procedure is a long and intensive surgery or a short non-invasive method, the same code is used for billing purposes.[25] This means that the reimbursable amount a physician or surgeon receives is the same, irrespective of the work they put in.[26] As a result, many surgeons choose to become out-of-network providers, making both cost and access a large barrier for endometriosis treatment.[27]

Endometriosis affects a large population of women, so insurance payers need to provide quality coverage for essential and proven treatments like laparoscopic excision surgery. Changing the coding method for laparoscopic

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[21] JOHNS HOPKINS MED., *supra* note 17.
[22] *Id.*
[23] Jillian Gilchrest, *Endometriosis and the Barriers to Care*, CONN. NEWS PROJECT (Dec. 7, 2022), https://ctmirror.org/2022/12/07/endometriosis-and-the-barriers-to-care/.
[24] Meghan Cleary, *Insurance 101: A Guide on How to Get Your Surgery Covered*, ENDOMETRIOSIS FOUND. AM. (Jan. 16, 2018), https://www.endofound.org/insurance-101-a-guide-on-how-to-get-your-surgery-covered.
[25] Jon Hathaway, *Decoding Coding: What is the Best Way to Code for Endometriosis?*, AMER. ASSOC. OF GYNECOLOGIC LAPAROSCOPISTS NEWSSCOPE (Apr. 19, 2019), https://newsscope.aagl.org/volume-33-issue-2/decoding-coding-what-is-the-best-way-to-code-for-endometriosis/.
[26] *Id.*
[27] Paul MacKoul, *Why You Don't Need to Pay Out of Pocket for Endometriosis Care*, CTR. FOR INNOVATIVE GYN CARE (Oct. 22, 2020), https://innovativegyn.com/blog/out-of-pocket-endometriosis-care/.

procedures will alleviate a significant portion of these burdens. This article will discuss the current coding method and its impacts on endometriosis patients. It will then describe how the coding method should be amended to achieve the desired results. Finally, the article will illustrate what impact such an amendment and the overall investment in women's health can have in the larger community.

II. CURRENT CODING METHODS

Endometriosis patients usually fall in the "care gap," namely, where insurers do not pay the extra costs to the surgeon for excision surgery.[28] The Current Procedural Terminology (CPT) code is a set of medical codes maintained by the American Medical Association (AMA) and used by healthcare professionals to describe the procedures they perform.[29] These codes are then used for reimbursement from federal and private insurance companies.[30] Currently, laparoscopic procedures for endometriosis tissue removal are coded as 58662: "Laparoscopy, surgical; with fulguration or excision of lesions of the ovary, pelvic viscera, or peritoneal surface by any method."[31] Essentially, the removal of endometriosis, regardless of the method used, is coded the same, which is the result of a 1992 Medicare Part B ruling.[32] This means that a surgeon who performs extensive excision surgery on a deeply invasive and aggressive prognosis is paid the same as a general OB-GYN physician that uses a different method, such as ablation, for stage 1 treatment.[33] In this case, although the surgeon is usually more experienced and spends several hours performing the procedure compared to

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[28] Cleary, *supra* note 24.
[29] *What is CPT?*, AM. ACAD. PROF. CODERS (Dec. 15, 2021), https://www.aapc.com/resources/medical-coding/cpt.aspx.
[30] *Id.*
[31] Hathaway, *supra* note 25.
[32] Gilchrest, *supra* note 23.
[33] *Id.*

the much shorter procedure by the generalist, they are paid exactly the same.[34]

Most surgeons can financially afford to be in-network, meaning that they have pre-negotiated rates as part of their contract with insurance companies.[35] This makes the surgeon more affordable and accessible for patients that have a plan with the specific insurance company.[36] However, in response to the unfair billing practice, many surgeons who can afford to be in-network choose to sever those ties.[37] Accordingly, they work as out-of-network providers and set their own prices for the surgeries performed [38] a model referred to as "cash-only."[39] Under this model, surgeons have the ability to charge tens of thousands of dollars for the tissue removal procedural and leave their patients on their own to contact their insurance providers for reimbursement.[40] Unfortunately, insurance providers rarely cover these procedures.[41]

There are several reasons for this care gap.[42] First, the aforementioned 1992 Medicare ruling grouped the various endometriosis removal procedures all within the same code, so there is no separate code for the excision surgery.[43] This is an issue because insurance providers base their own reimbursable rate on Medicare.[44] Additionally, excision surgery is not recognized as a specialty by either the AMA or the American Congress of

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[34] MacKoul, *supra* note 27.
[35] Paula Sunshine, *In-Network vs Out-of-Network: What Does It Mean?* INDEPENDENCE BLUE CROSS (Nov. 9, 2020), https://insights.ibx.com/understanding-the-difference-between-in-network-and-out-of-network/.
[36] *Id.*
[37] MacKoul, *supra* note 27.
[38] *Id.*
[39] *Id.*
[40] *Id.*
[41] *Id.*
[42] Cleary, *supra* note 24.
[43] *Id.*
[44] *Id.*

OB-GYNs (ACOG). [45] This procedure is not taught in medical schools, not used to identify endometriosis, and not recognized as the best way to relieve pain in endometriosis patients long term.[46] As such, the standard of care that governs how a physician should treat a disease or patient, similar to their peers, does not mandate excision surgery.[47] Since there is no financial incentive or governing standard, surgeons rarely perform excisions, and insurance providers have no incentive to cover it.[48]

The lack of coverage has created a disparate impact on women suffering from endometriosis, including a Connecticut woman named Allie who was insured under the state's health plan.[49] Due to limited availability in the state, Allie was forced to search for surgeons out of state who informed her that it would take tens of thousands of dollars to pay for the excision surgery.[50] Allie appealed to receive out-of-network care, but because of the manner in which excision is coded, she would still have to pay $25,000 or more out of pocket.[51] However, Allie's appeal was denied because the insurance company claimed that there were some in-network providers capable of treatment.[52] The reality was that none of those providers actually performed excision surgeries.[53] Essentially, because excision is not recognized, has no standards, and is coded the same as all the lesser-effective procedures, Allie, like many other women, was denied coverage.[54]

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[45] *Id.*
[46] *Id.*
[47] *Id.*
[48] *Id.*
[49] Gilchrest, *supra* note 23.
[50] *Id.*
[51] *Id.*
[52] *Id.*
[53] *Id.*
[54] *Id.*

III. PROPOSED AMENDMENTS

Excision is a well-established approach for treating endometriosis.[55] Excision is the first and most important step in a multi-disciplinary approach to treat the disease.[56] Notably, it is commonly referred to as the "gold standard" for treating the disease, since most patients find that their pain significantly decreases over time.[57] Other methods of removal—including ablation and fulguration— are considered "limited" surgeries because only the top of the area of disease is burned off, leaving behind the bulk of it that is buried deep.[58] These methods usually result in poor outcomes and repeat procedures.[59] Conversely, excision allows for the removal of the entire tissue.[60] Through excision, pain decreases, symptoms usually no longer persist, and there is seldom need for a repeated procedure.[61]

Therefore, first and foremost, excision needs to be recognized as a specialty by the AMA and ACOG. Excision is an advanced surgical technique that requires extensive training to master.[62] During the procedure, the surgeon must be able to recognize all the signs of endometriosis, including those in subtle or less common areas.[63] If surgeons cannot recognize the disease in all its forms, they are not able to treat its entirety.[64] Proponents of excision surgery for endometriosis state that the procedure should only be one surgery done right, not a path of multiple surgeries.[65]

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[55] *Empowered by Education*, ENDOWHAT, https://www.endowhat.com/educate/.
[56] *Id.*
[57] Ken Sinervo, *Excision of Endometriosis*, CTR. FOR ENDOMETRIOSIS CARE (last updated Feb. 2023), https://centerforendo.com/lapex-laparoscopic-excision-of-endometriosis.
[58] *Id.*
[59] *Id.*
[60] *Id.*
[61] *Id.*
[62] *Id.*
[63] *Id.*
[64] *Id.*
[65] ENDOWHAT, *supra* note 55.

Therefore, it is important that the surgeon performing the excision is a specialist in that area.[66]

The AMA should recognize and list excision surgery, not just specific to endometriosis, as one of its many surgical specialties.[67] To change the code itself or the criteria for a code, a doctor, hospital, insurance company, or a medical society needs to submit an application suggesting this change.[68] Then, the AMA's CPT staff will review the request and, upon determining that the request is new, refer it to the CPT Advisory Committee. Taking the comments and advice of the committee, the AMA then presents the issues to a CPT panel to determine if the changes should be implemented.[69] Following approval, the AMA publishes annual updates to the CPT books that released in the fall following the January 1st implementation date.[70]

If the AMA, and especially the ACOG, recognize excision surgery as a specialty, they would have more leverage to compel insurance companies to provide coverage for the procedure.[71] Receiving adequate compensation for the lengthy and extensive procedure would therefore incentivize physicians to remain in-network for endometriosis care. The AMA should issue formal guidelines recognizing excision surgery as a specialty. Since these guidelines are regarded highly by healthcare administrative agencies, they will be the first step in making sure that excision surgery is considered by all physicians treating endometriosis and covered by insurance.

Along with recognizing excision as a specialty, the ACOG must also recognize it as the golden standard for endometriosis.[72] There are many

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[66] Sinervo, *supra* note 57.
[67] *The CPT Code Process*, AM. MED. ASSOC., https://www.ama-assn.org/about/cpt-editorial-panel/cpt-code-process.
[68] *Id.*
[69] *Id.*
[70] *Id.*
[71] Gilchrest, *supra* note 23.
[72] Sinervo, *supra* note 57.

clinical and peer-reviewed published articles that affirm that excision surgery is in fact the golden standard.[73] Advocacy organizations have also coined the term 'golden standard' when referring to the procedure.[74] Despite the efforts of proponents and researchers, without the ACOG's recognition, insurance companies are unlikely to instate coverage for laparoscopic excision procedures. The ACOG's recognition through written guidelines, similar to those of the AMA, would ensure that these companies start to instate coverage.

Most importantly—and what would most reasonably follow after appropriate recognition from the ACOG and AMA—the procedural coding of excision surgery must be amended. Currently, CPT code 58662 groups laparoscopic excisions with fulguration and ablation, which includes the entire procedure and all its pre- and post-operative tasks.[75] It is grouped under "Laparoscopic Procedures on the Oviduct/Ovary."[76] This itself is insufficient because endometriosis is not found in just the ovaries, but inside the pelvis, bladder, diaphragm, lungs, kidneys, and even the brain.[77] By grouping the procedure in a single, minimal section of the body, it undermines the extensive work required to excise all the tissues across the entire body. Instead, laparoscopic excisions should be coded under the same CPT group as all other surgeries.

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[73] *See e.g.,* Ray Garry, *The Effectiveness of Laparoscopic Excision of Endometriosis*, 16 CURRENT OPINION IN OBSTETRICS & GYNECOLOGY 299, 299-303 (Aug. 16, 2004), https://pubmed.ncbi.nlm.nih.gov/15232483/ (concluding that "laparoscopic excision is currently the 'gold standard' approach for the management of endometriosis"); *see also* Jyotsna Pundir et al., *Laparoscopic Excision Versus Ablation for Endometriosis-Associated Pain: An Updated Systematic Review and Meta-Analysis*, 24 J. OF MINIMALLY INVASIVE GYNECOLOGY 747, 747-756 (Apr. 26, 2017), https://www.jmig.org/article/S1553-4650(17)30263-7/fulltext (finding that chronic pelvic pain significantly improved when using laparoscopic excision versus ablation).
[74] *See e*.g., ENDOWHAT, *supra* note 55.
[75] Hathaway, *supra* note 25.
[76] *What is CPT*?, *supra* note 29.
[77] ENDOWHAT, *supra* note 55.

Since excision surgery takes substantially greater work and time, a modifier 22, which alerts insurance companies that there was more work than the standard procedure for this type of coding, is added to 58662.[78] Unfortunately, this modifier is abused very often.[79] As a result, most insurance companies have refused to cover it without further negotiation on behalf of the provider, extra documentation, and investigation by the insurance company.[80] Even so, the current billing practice and use of the modifier 22 still results in insufficient reimbursement.[81]

The AMA needs to re-code laparoscopic excision surgery to reflect the extensive work and expertise needed for performance. This can be done in several ways. At the bare minimum, fulguration, ablation, and excision surgery should be coded differently. They are all separate procedures with different levels of expertise and work required and should be coded as such. Additionally, the CPT code for the procedure specifically regarding endometriosis should not be confined to the oviduct and ovary since the disease itself is usually widespread.[82] It should encompass at least the entire pelvic and abdominal region. Most importantly, excision surgery should be coded the same as other forms of surgeries, such as general surgery procedures, because many other surgical specialties also used laparoscopic approaches to treat the ailment. By coding excision as a specialty procedure separate from ablation and fulguration, its reimbursement rate will reflect the requirements of the procedure. Most importantly, it will achieve the goal of incentivizing physicians to remain in-network and remove cost and access barriers for patients seeking this treatment.

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[78] Hathaway, *supra* note 25.
[79] *Id.*
[80] *Id.*
[81] *Id.*
[82] JOHNS HOPKINS MED., *supra* note 17.

IV. CONCLUSION

Laparoscopic excision surgery is the golden standard for endometriosis care.[83] While it is not the only step, it is the first and most essential step towards managing endometriosis.[84] Therefore, excision surgery should be recognized as a specialty and acknowledged for the expertise it requires. It needs to be coded individually from other treatments for the disease, and its scope should extend beyond the ovaries to the entire pelvic and abdominal region. Eliminating the cost and access barriers for women to receive proven treatment for endometriosis should be prioritized to ensure their well-being, which will have a beneficial outcome on society overall.

[83] Sinervo, *supra* note 57.
[84] ENDOWHAT, *supra* note 55.

Utilizing March-In Rights to Protect Vaccine Access

Bennett Murphy

I. INTRODUCTION

The COVID-19 pandemic has affected nearly every aspect of American life since March 2020.[1] Notably, over one million Americans have died due to the virus: an astonishing number that could have been significantly higher were it not for the global collaboration between governments and pharmaceutical companies to create fast and effective vaccines.[2] Unfortunately, as the COVID-19 pandemic evolves into an endemic—meaning it is present among populations at all times— pharmaceutical companies such as Pfizer and Moderna have expressed a desire to increase the price of each vaccine dose by nearly four-times the current price.[3] Senator Bernie Sanders, the new chairman of the Senate Health, Education, Labor, and Pensions (HELP) Committee, has pushed back on this plan due to the fact that American taxpayers helped fund the development and distribution of those vaccines.[4] This price hike is particularly concerning considering the recent FDA announcement regarding its plan to recommend annual vaccine doses.[5]

Due to the healthcare and economic impacts that an inflated vaccine price could trigger, the U.S. government must step in to ensure that the vaccines

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[1] CTR. ON BUDGET AND POL'Y PRIORITIES, THE COVID-19 ECONOMY'S EFFECTS ON FOOD, HOUSING, AND EMPLOYMENT HARDSHIPS (Oct. 2021), https://www.cbpp.org/research/poverty-and-inequality/tracking-the-covid-19-economys-effects-on-food-housing-and [hereinafter BUDGET PRIORITIES].

[2] CDC COVID DATA TRACKER, https://covid.cdc.gov/covid-data-tracker/#datatracker-home (last visited Feb. 18, 2023) [hereinafter COVID DATA].

[3] Cheyenne Haslett, *Companies look at increasing price of their COVID-19 vaccines. Bernie Sanders is not happy*, ABC NEWS (Jan. 11, 2023, 8:28 PM), https://abcnews.go.com/Health/companies-increasing-price-covid-19-vaccines-sen-bernie/story?id=96376817.

[4] *Id.*

[5] Karen Weintraub, *FDA vaccine panel to consider annual COVID shots: What we know*, USA TODAY (Jan. 26, 2023, 6:12 PM), https://www.usatoday.com/story/news/health/2023/01/26/fda-update-covid-vaccine-booster-guidelines/11106855002/.

remain reasonably priced and available to everyone, regardless of their insurance status. Accordingly, this article will discuss a method by which the government could do just that: namely, the implementation of march-in rights. If these measures fail, however, the government should at least use the lessons learned during the current pandemic to ensure that future government and institutional vaccine development partnerships include language that will prevent the institutions from price gauging their federally funded vaccines during the next public health crisis.

II. COVID-19 OUTBREAK & RESPONSE

The first reported laboratory confirmed case of COVID-19 occurred in late January 2020.[6] The World Health Organization (WHO) subsequently declared COVID-19 a pandemic on March 11, 2020.[7] As of February 17, 2023, the Center for Disease Control (CDC) estimated that roughly 100 million cases of COVID-19 that have been confirmed resulted in over 1.1 million American deaths.[8] In addition, the economic impact of the pandemic cannot be understated. Massive flight cancellations, workforce and labor shortages, closed borders, and manufacturing shutdowns affected not only the Unites States, but the entire global economy.[9]

Within three weeks of the WHO declaration, the U.S. government under the Trump Administration declared a national emergency and developed and signed into law the Coronavirus Aid, Relief, and Economic Security (CARES) Act.[10] The CARES Act included stimulus checks, loan

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[6] DAVID J. SPENCER CDC MUSEUM, *CDC Museum COVID-19 Timeline* (Aug. 16, 2022), https://www.cdc.gov/ museum/timeline/covid19.html [hereinafter CDC MUSEUM].
[7] *Id.* (declaring COVID-19 a pandemic after more than 100,000 deaths across 114 countries).
[8] COVID DATA, *supra* note 2.
[9] Steve Buckman, *5 Challenges Facing the Logistics Industry Due to COVID-19 and How to Solve Them*, SYMBIA LOGISTICS (May 06, 2020), https://www.symbia.com/resources/challenges-facing-the-logistics-industry/.
[10] CDC MUSEUM, *supra* note 6.

forgiveness, and expanded funding for state and local governments to respond to the pandemic.[11] While these measures were timely and certainly helped the U.S. respond to the COVID-19 pandemic, it did not immediately address the fact that the world had no vaccine for this novel virus.[12] It was not until April 30, 2020, that the Trump Administration officially announced the launch of Operation Warp Speed (OWS),[13] a program that partnered the U.S. government with private pharmaceutical companies to facilitate the rapid development of a COVID-19 vaccine.[14] The program was initially funded with $10 billion through the CARES Act, but it was increased to $18 billion by October 2020.[15]

In April 2020, the Department of Health and Human Services (HHS) provided $483 million to Moderna via OWS to aid in the development of its mRNA vaccine.[16] In August 2020, President Trump announced an additional $1.53 billion deal with Moderna to purchase 100 million doses of its vaccine, with an additional option for 400 million more doses; in turn, pushing the total grant to $2.48 billion.[17] Similarly, in July 2020, HHS announced a

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[11] Sharon Parrott et al., *CARES Act Includes Essential Measures to Respond to Public Health, Economic Crises, But More Will Be Needed*, CTR. ON BUDGET AND POL'Y PRIORITIES (Mar. 27, 2020), https://www.cbpp.org/research/economy/cares-act-includes-essential-measures-to-respond-to-public-health-economic-crises.
[12] *Id.*
[13] CDC MUSEUM, *supra* note 6.
[14] DEP'T OF HHS, EXPLAINING OPERATION WARP SPEED (U.S. Dep't of Health and Human Services 2020), https://www.nihb.org/ covid-19/wp-content/uploads/2020/08/Fact-sheet-operation-warp-speed.pdf.
[15] Stephanie Baker & Cynthia Koons, *Inside Operation Warp Speed's $18 Billion Sprint for a Vaccine*, BLOOMBERG (Oct. 29, 2020 at 3:00 AM), https://www.bloomberg.com/news/features/2020-10-29/inside-operation-warp-speed-s-18-billion-sprint-for-a-vaccine.
[16] *See* Haslett, *supra* note 3 (increasing by an additional $472 million in July 2020).
[17] Noah Higgins-Dunn, *Trump says U.S. has reached deal with Moderna for 100 million doses of coronavirus vaccine*, CNBC (Aug. 11, 2020, at 5:50 PM), https://www.cnbc.com/2020/08/11/trump-says-us-has-reached-deal-with-moderna-for-100-million-doses-of-coronavirus-vaccine.html.

separate $1.95 million deal with Pfizer to both purchase 100 million doses of its mRNA vaccine and aid in such manufacturing and distribution.[18]

Both Moderna and Pfizer executives may argue that the underlying technology behind their COVID-19 vaccines, specifically the mRNA vaccine mechanism, has long been in development before the companies accepted funding from Operation Warp Speed.[19] However, both Moderna's and Pfizer's mRNA vaccines were made, in part, due to initial research that was funded by the National Institute of Health (NIH) that dates back over fifty years.[20] In fact, Moderna even acknowledged the government's role in the development of its mRNA technology when it recently settled an ongoing lawsuit with the NIH for $400 million.[21] Therefore, it is clear that not only has the U.S. government helped fund the initial research behind the COVID-19 vaccines, but also aided in the ramp-up and distribution of the vaccines themselves over the past few years.

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[18] *Id.*; *see also* Noah Higgins-Dunn, *The U.S. has already invested billions in potential coronavirus vaccines. Here's where the deals stand*, CNBC (Aug. 14, 2020, 9:53 AM), https://www.cnbc.com/2020/08/14/the-us-has-already-invested-billions-on-potential-coronavirus-vaccines-heres-where-the-deals-stand.html (including an option for the U.S. to purchase an additional 500 million doses).

[19] Catherine Clifford, *How the Moderna Covid-19 mRNA vaccine was made so quickly*, CNBC (Jul. 9, 2021, 11:55 AM), https://www.cnbc.com/2021/07/03/how-moderna-made-its-mrna-covid-vaccine-so-quickly-noubar-afeyan.html; PFIZER, COMPANY TIMELINE: A LEGACY OF INNOVATION, https://www.pfizer.com/about/history (last visited Feb. 18, 2023); Elie Dolgin, *The tangled history of mRNA vaccines*, NATURE (Oct. 22, 2021), https://www.nature.com/articles/d41586-021-02483-w.

[20] Arthur Allen, *For Billion-Dollar COVID Vaccines, Basic Government-Funded Science Laid the Groundwork*, SCIENTIFIC AMERICAN (Nov. 18, 2020), https://www.scientificamerican.com/article/for-billion-dollar-covid-vaccines-basic-government-funded-science-laid-the-groundwork/.

[21] Eric Sagonowsky, *Moderna pays US government $400M 'catch-up payment' under new COVID-19 vaccine license*, FIERCE PHARMA (Feb. 24, 2023, 10:20 AM), https://www.fiercepharma.com/pharma/moderna-pays-us-government-400m-catch-payment-under-new-covid-19-vaccine-license; *see also* Heidi Ledford, *What the Moderna–NIH COVID vaccine patent fight means for research*, NATURE (Nov. 30, 2021), https://www.nature.com/articles/d41586-021-03535-x (bringing suit after Moderna refused to include NIH researchers on its patent application for an mRNA sequence used in its COVID-19 vaccine).

A. COVID-19 Looking Forward

According to data provided by the CDC, sixty-eight percent of Americans have received the first two doses of the vaccine; however, that number drops dramatically to thirty-four percent when looking at the number of Americans who have received booster shots.[22] The number of Americans who are fully boosted is particularly concerning, given that the pandemic is evolving into an endemic. In January 2023, the FDA's Vaccine and Related Biological Products Advisory Committee (VRBPAC) met to discuss changes to its vaccine policy.[23] During the meeting, the committee unanimously voted to consolidate the vaccines in order to provide one version each year instead of having different vaccines for different variants.[24] However, some experts are concerned that annual vaccines may not be enough due to the rapidly evolving nature of the COVID-19 virus.[25] Indeed, since last October 2022, the main variant in the Unites States has already changed.[26] This FDA decision is backed by a study through Yale University that looked at the impact of the Pfizer and Moderna vaccines, based on different vaccination schedules.[27] In particular, this study indicated that a bi-annual dose of the vaccines lowers the risk of infection by 93 percent and an annual dose lowers

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[22] N.Y. TIMES, *See How Vaccinations Are Going in Your County and State* (Oct. 20, 2022), https://www.nytimes.com/interactive/2020/us/covid-19-vaccine-doses.html.
[23] CDC MUSEUM, *supra* note 6.
[24] *See* Scott Hensley, *An FDA committee votes to roll out a new COVID vaccination strategy*, NPR (Jan. 26, 2023, 4:42 PM), https://www.npr.org/sections/health-shots/2023/01/26/1151810765/fda-committee-votes-to-roll-out-new-covid-vaccination-strategy (including the formation of an annual public hearing when the FDA will decide which strains to instruct vaccine developers to focus on for the subsequent fall, reflecting what the FDA already does for annual flu shots).
[25] *Id.*
[26] CDC MUSEUM, *supra* note 6.
[27] Jeffry P. Townsend et al., *Infection by SARS-CoV-2 with alternate frequencies of mRNA vaccine boosting*, 95 J. OF MED. VIROLOGY 1, (Jan. 05, 2023), https://onlinelibrary.wiley.com/doi/full/10.1002/jmv.28461 (see Table 2).

the risk by 75 percent, while an 18-month dose cycle only lowers the risk by 55 percent.[28]

However, the January meeting of the FDA's VRBPAC was preempted by some concerning statements from both Moderna and Pfizer. During an interview between the CEO of Moderna and the *Wall Street Journal*, Moderna's CEO stated that they have plans to increase the price of their vaccine from $26 per dose to between $110 and $130 per dose.[29] This parallels a similar statement made by Pfizer during an investor call in October 2022.[30] The vaccines are currently paid for by the U.S. government, but this will end in May 2023 once the public health emergency ends.[31] Xavier Becerra, the current Secretary of HHS, was quoted as stating that the vaccine pricing "is something that is within the hands of those manufacturers and distributors."[32]

Senator Bernie Sanders responded to Moderna with a letter written directly to its CEO.[33] In this letter, Senator Sanders described his dismay at the corporate greed that may lead Moderna to charge up to $130 per vaccine dose, notwithstanding that it costs as low as $2.85 to produce.[34] Health insurance premiums can be directly affected by increased drug costs, as insurers must pay the manufacturer these increased costs and then pass on

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[28] *See id.* (indicating that bi-annual vaccines are most effective at mitigating breakouts).
[29] Peter Loftus, *Moderna Considers Price of $110-$130 for Covid-19 Vaccine*, THE WALL ST. J. (Jan. 9, 2023, 1:40 PM), https://www.wsj.com/articles/moderna-considers-price-of-110-130-for-covid-19-vaccine-11673289609.
[30] Kevin Dunleavy, *Pfizer eyes four-fold price hike for COVID vaccine in private US market*, FIERCE PHARMA (Oct. 21, 2022, 11:17 AM), https://www.fiercepharma.com/pharma/176fizer-set-charge-between-110-and-130-covid-vaccine-when-us-goes-commercial-model.
[31] Haslett, *supra* note 3.
[32] *Id.*
[33] Letter from Bernie Sanders, U.S. Senator, to Stéphane Bancel, CEO of Moderna (Jan. 10, 2023), https://www.sanders.senate.gov/wp-content/uploads/Moderna-Letter-01.09.20231.pdf [hereinafter Sanders Letter].
[34] *See id.* (stating that this increase in cost will not only prevent the uninsured and underinsured from affording the vaccine, but the increased cost will also affect those with insurance).

that cost to the insured, through increased premiums and out-of-pocket expenses.[35] In addition, the increased budget for Medicare and Medicaid due to this price increase will cost U.S. taxpayers billions of dollars.[36] Senator Sanders stated that, "[i]n other words, [Moderna] propose[s] to make the vaccine unaffordable for the residents of this country who made the production of the vaccine possible. That is not acceptable."[37] These concerns were also expressed by Senators Elizabeth Warren and Peter Welch in a different letter to CEO of Pfizer.[38]

III. MARCH-IN RIGHTS

In light of the impending FDA recommendations for annual vaccines, the U.S. government must step in to ensure that these vaccines remain available for the American people at a price that will not substantially increase an already expensive health care system. Therefore, the government should utilize march-in rights. March-in rights allow for the government to license out patents for drugs when the government subsidized their development.[39] Finally, if the government is unable to rein in big pharma, then they must use the lessons learned through their partnerships with pharmaceutical companies, like Pfizer and Moderna, to ensure that they retain some form of rights or licensing to vaccines during future pandemics.

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[35] *See* Stephen Barlas, *Are Specialty Drug Prices Destroying Insurers and Hurting Consumers?*, 39 PHARM. AND THERAPEUTICS 563 (Aug., 2014) (discussing the impact of high priced drugs on insurance costs).
[36] Sanders Letter, *supra* note 33.
[37] Sanders Letter, *supra* note 33.
[38] *See* Letter from Elizabeth Warren & Peter Welch, U.S. Senators, to Albert Bourla, C.E.O. Pfizer Inc. (Dec. 12, 2022), https://www.warren.senate.gov/imo/media/doc/ [hereinafter Warren & Welch Letter] (opining that Pfizer had a nearly 100% increase in profits in 2021, mainly due to the success of the COVID-19 vaccine and the advanced purchase agreement with the U.S. government, yet still want to increase the price during a deadly pandemic).
[39] John R. Thomas, *March-In Rights Under the Bayh-Dole Act*, CONG. RSCH. SERV. (2016), https://sgp.fas.org/crs/misc/R44597.pdf.

In 1980, Congress passed the Bayh-Dole Act (the Act) to "address concerns about the commercialization of technology developed with public funds."[40] The Act was initially used to promote university development of new medicine and technology.[41] The Act would allow universities who receive federal funding to develop new technology to retain intellectual property (IP) rights over that technology.[42] It was later expanded to include all federal contractors, not just universities.[43] While the Act allows federal contractors to retain IP rights, it also provides the federal government with a tool known as "march-in rights."[44] This statutory mechanism allows the federal government to require a contractor who developed technology using federal funding to grant a "nonexclusive, partially exclusive, or exclusive license" to a "reasonable applicant or applicants."[45] In the present situation, the U.S. should invoke march-in rights for the federally funded COVID-19 vaccines in order to license them out to third party manufacturers, on the condition that they sell the vaccine doses at a reasonable price.

There are four scenarios in which march-in rights may be invoked according to the Act: (1) when the patent assignee has not taken effective steps to achieve practical application of the patent; (2) when action is necessary to alleviate health or safety needs that are not reasonably satisfied by the patent assignee; (3) when action is necessary to meet the requirements of a federal regulation; and (4) when the patent assignee is not manufacturing the patent in the U.S. as required by section 204 of the Act.[46] Under the current circumstances, it would be reasonable for the government to invoke march-in rights under either scenarios one or two.

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[40] *Id.*
[41] *Id.*
[42] *Id.*
[43] *Id.*
[44] *Id.*
[45] *Id.*
[46] Thomas, *supra* note 39.

The government has a strong argument under scenario one. The practical application of a vaccine is to get as many people vaccinated as possible, in order to obtain herd immunity.[47] Raising the price of each vaccine dose by nearly four-hundred percent will limit the amount of people who can obtain the vaccine and is therefore counterintuitive to the application of a vaccine.[48] This is due to the concerns voiced by Senators Sanders, Warren, and Welch.[49] The price hike contemplated by the pharmaceutical companies would not only raise the budget of Medicare/Medicaid, thereby raising the cost to U.S. taxpayers, but it would also be passed on to beneficiaries of private insurance through increased premiums and out-of-pocket spending.[50]

The government may have an even stronger argument under scenario two because raising the cost of the vaccines could directly impact the health and safety of the American people. There were already issues with inoculating the U.S. population to when the vaccines and subsequent boosters were free.[51] Even though Moderna has stated that it will be creating a program to provide vaccines to the under and uninsured, Moderna CEO Stephane Bancel was unable to confirm in a Senate hearing whether or not there would still be administrative fees associated with obtaining the vaccine.[52] One can imagine that any sort of cost associated with the vaccine in the future, no matter how

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[47] Sandhya Pruthi et al., *Herd immunity and COVID-19: What you need to know*, MAYO CLINIC (Sept. 27, 2023), https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/herd-immunity-and-coronavirus/art-20486808?p=1.
[48] *See* Sanders Letter, *supra* note 33 (raising the price from $26.36 to $130 per dose).
[49] Sanders Letter, *supra* note 33; Warren and Welch Letter, *supra* note 38.
[50] Sanders Letter, *supra* note 33; Barlas, *supra* note 35.
[51] Irene A. Doherty et al., *COVID-19 vaccine hesitancy in underserved communities of North Carolina*, PLOS ONE (Nov. 1, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8559933/pdf/pone.0248542.pdf.
[52] Kyla Russell, *Sanders slams 'corporate greed' as Moderna CEO won't commit to lower Covid-19 vaccine cost*, CNN HEALTH (Mar. 22, 2023, 4:26 PM), https://www.cnn.com/2023/03/22/health/moderna-vaccine-price-hearing/index.html.

small, may result in further vaccine hesitancy, especially considering the economic impacts that the COVID-19 pandemic highlighted.[53] As a result, communities where the vaccines are not widely taken will be at a heightened risk for future breakouts and could end up being petri-dishes where the virus can thrive and mutate into new and dangerous strains.[54] New virus strains would not only affect the direct health and safety of Americans, but could have indirect effects on supply chains and create travel disruptions, labor shortages, and manufacturing shutdowns.[55]

If the federal government were to invoke march-in rights on the vaccine patents, neither Pfizer nor Moderna would actually lose the patent.[56] Instead, the NIH would identify a separate entity, such as a pharmaceutical manufacturer, who is then granted a license to the patent.[57] These licenses are "upon terms that are reasonable under the circumstances" and would award royalties to the owner of the patent, in this case Moderna and Pfizer.[58] Once other manufacturers have access to the vaccine patents, competitive market principals would play out, theoretically causing the different manufacturers to lower their vaccine prices in order to gain market share in the newly create vaccine market. The federal government and private insurers would also be able to negotiate prices with the different manufacturers in order to keep general healthcare costs down. Furthermore, in the event of a new COVID-19 strain or outbreak, having an affordable vaccine can prevent the types of infection numbers seen in early 2022.[59] These mitigated breakouts would not only positively affect the nation's

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[53] BUDGET PRIORITIES, *supra* note 1.
[54] Guihong Fan et al., *Impact of low vaccine coverage on the resurgence of COVID-19 in Central and Eastern Europe*, 14 ONE HEALTH (2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9119166/pdf/main.pdf.
[55] Buckman, *supra* note 9.
[56] Thomas, *supra* note 39.
[57] Thomas, *supra* note 39.
[58] Thomas, *supra* note 39.
[59] Townsend et al., *supra* note 27.

health, but also its economy, resulting in less supply chain disruption, less employment issues, and a decreased burden on emergency rooms and hospitals.[60]

While this seems like a logical way for the government to ensure that technology that was developed with public funds remains accessible to the public, the government has never enforced its march-in rights.[61] In fact, there have been only six instances when a march-in petition has been filed with the NIH and they were all denied; however, none of these petitions were for drugs that were developed to counter a global pandemic like COVID-19.[62] Two petitions were for AIDS/HIV treatment, but HIV infections in the U.S. fluctuated between 38,000 and 34,000 per year from 2015 to 2019.[63] Meanwhile, COVID-19 infections generally fluctuated between 194,000 and 900,000 per week in 2022, with the absolute peak cresting 5.5 million cases per week in January of 2022.[64] Therefore, because the current COVID-19 pandemic is unlike any of the previous petition diseases due to its severe rate of infection, and though the federal government has never before invoked march-in rights, they should do so now with the COVID-19 vaccines.[65]

March-in rights were created for a specific reason: to protect technology developed with public funding from being commercialized in a way that limits access to that technology.[66] By quadrupling the cost of COVID-19

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[60] Buckman, *supra* note 9.
[61] *See* Alexander Kersten & Gabrielle Athanasia, *March-In Rights and U.S. Global Competitiveness*, CSIS (Mar. 24, 2022), https://www.csis.org/analysis/march-rights-and-us-global-competitiveness (detailing that march-in rights have not been used since they were established in 1980).
[62] Thomas, *supra* note 39.
[63] Thomas, *supra* note 39.
[64] COVID DATA, *supra* note 2.
[65] *Id.*
[66] *Id.*

vaccines, Moderna and Pfizer threaten to burden an already stressed health care system and U.S. population. As Senator Sanders described in his letter to the Moderna CEO, increased costs for the vaccine will not only prevent the under and uninsured from accesses a vaccine that is recommended annually, but the increased price of each dose will cost taxpayers billions of dollars and will increase the premiums of private health plans.[67]

However, there are arguments against the use of march-in rights. First, IP protection is seen as vital in the biotechnology industry and incentivizes companies to innovate.[68] If biotech innovators believed that their products would simply be taken from them to be sold and marketed by competitors, the industry could grind to a halt as companies cease pouring money into research and development.[69] Furthermore, when looking directly at Moderna and Pfizer, both companies were developing their mRNA technology long before the U.S. government contracted with them to provide funds for development and distribution of their vaccines.[70] However, as previously mentioned, the underlying mRNA technology that both Pfizer and Moderna used to create their vaccines was partially funded by the NIH.[71] That being said, march-in rights not need be invoked for the entire pipeline of mRNA products, just for the COVID-19 specific vaccine. In addition, Pfizer contends that they did not receive any U.S. funding to develop the COVID-19 vaccine.[72] Instead, Pfizer claims that it merely took U.S. dollars for

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[67] Sanders Letter, *supra* note 33.
[68] *See* Thomas, *supra* note 39 (allowing private parties to gain a limited monopoly over a product that cost a fortune to develop).
[69] Jorge L. Contreras, *The Open COVID Pledge: Design, Implementation and Preliminary Assessment of an Intellectual Property Commons*, UTAH L. SCHOLARSHIP, Feb. 8, 2021, at 10.
[70] Clifford, *supra* note 19; Allen, *supra* note 20.
[71] Allen, *supra* note 20.
[72] Alexander Nazaryan, *So is Pfizer part of Operation Warp Speed or not? Yes and no.*, YAHOO!NEWS (Nov. 9, 2020), https://ca.news.yahoo.com/so-is-pfizer-part-of-operation-warp-speed-or-not-well-its-a-little-complicated-175429888.html?soc_src=social-sh&soc_trk=ma.

production and distribution purposes.[73] Therefore, it may be a harder sell to convince the NIH that utilization of march-in rights would be appropriate for Pfizer.

IV. CONCLUSION

While there is no clear precedent for how and when march-in rights can be invoked, the law was created to protect the public health of the nation.[74] Utilizing march-in rights to keep a vaccine for a highly contagious disease affordable and available would seemingly fall in line with the purpose behind march-in rights.[75] In order to invoke the rights, the petitioner would need to prove to the NIH that (1) Moderna and/or Pfizer have not taken effective steps to achieve practical application of the patent, and/or (2) that action is necessary to alleviate health or safety needs that have not been reasonably satisfied by Modern and/or Pfizer.[76] The invocation of march-in rights on the COVID-19 vaccines could then be used as precedent for future pandemics and may even serve as a deterrent for pharmaceutical companies to increase the price of vaccines.

If the U.S. government is unable to come to terms with Pfizer or Moderna over their COVID-19 vaccine prices, it should amend how it contracts with pharmaceutical vaccine developers when the next pandemic hits. Scientists around the world are increasingly concerned about the potential for another pandemic to sweep the world.[77] Recent studies have shown that the

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[73] *Id.*
[74] Thomas, *supra* note 39.
[75] Thomas, *supra* note 39.
[76] Thomas, *supra* note 39.
[77] Priya Joi, *New study suggests risk of extreme pandemics like COVID-19 could increase threefold in coming decades*, GAVI THE VACCINE ALLIANCE (Sept. 05, 2022), https://www.gavi.org/vaccineswork/new-study-suggests-risk-extreme-pandemics-covid-19-could-increase-threefold-coming.

probability of a pandemic with a similar impact as COVID-19 is two percent in a year.[78] That probability indicates that there is a thirty-eight percent chance of someone experiencing a COVID-like global pandemic in their lifetime.[79]

If the presence of another pandemic becomes clear, the federal government should immediately contract with pharmaceutical companies in order to rapidly develop vaccines, just like it did with OWS. However, in these next negotiations, the government needs to include provisions in the contract limiting pharmaceutical companies' ability to drastically raise the price of the finished product. By requiring cost-limiting clauses or price caps early in the negotiations, both parties can build reasonable expectations for how pricing will change throughout the duration of the health care emergency. The world is still healing from the effects of COVID-19 and may never be fully rid of the virus, so it is imperative that the U.S. government utilize march-in rights, to keep these federally funded vaccines available and affordable. Failing that, the government must use Moderna and Pfizer as a lesson for their future collaborations.

[78] *Id.*
[79] *Id.*

2023: Too Little Too Late for Rural Healthcare Providers

Kathryn Van Sistine

I. INTRODUCTION

The financial burdens on rural healthcare providers due to decreasing reimbursement and the COVID-19 pandemic are mounting. Although the Consolidated Appropriations Act, 2023[1] took steps to address the 2023 CMS Physician Fee Schedule's (PFS) decrease in physician reimbursement,[2] these steps are not enough. Accordingly, the 2024 CMS PFS should include language reverting to the 2022 conversion factor (CF) of $34.6062 per relative value unit (RVU) while continuing the Rural Emergency Hospital (REH) designation that provides additional reimbursement for rural emergency hospitals. Furthermore, the Consolidated Appropriations Act, 2024 should confirm the 2024 CMS PFS.

II. BACKGROUND ON MEDICARE & CMS PHYSICIAN FEE SCHEDULES

Medicare is the federal health insurance program for people who are sixty-five or older, certain younger people with disabilities, and people with End-Stage Renal Disease.[3] The program is administered by the U.S. Department of Health and Human Services (HHS) through the Centers for Medicare and Medicaid Services (CMS).[4] Medicare payment for physicians and other

[1] Consolidated Appropriations Act, 2023, Pub. L. 117-328, §§ 4112, 1175 (2023) (amending Section 1848 of the Social Security Act 42 U.S.C. 1395w-4); Social Security Act 42 U.S.C. 1395w-4 § 4112 (outlining payment for physicians' services).
[2] 2023 CMS Physician Fee Schedule, 42 C.F.R. §§ 405, 410, 411, 414, 415, 423, 424, 425, 255 (2022). (Table 146 contains the calculation of the CY 2023 PFS conversion factor when it was originally released in November 2022; however, CMS modified the CY 2023 PFS conversion factor after the Consolidated Appropriations Act, 2023).
[3] *What's Medicare?* MEDICARE.GOV, https://www.medicare.gov/what-medicare-covers/your-medicare-coverage-choices/whats-medicare (last visited Feb. 17, 2023).
[4] *See What's the difference between Medicare and Medicaid?*, DEP'T OF HEALTH & HUM. SERVS. (Dec. 8, 2022), https://www.hhs.gov/answers/medicare-and-medicaid/what-is-the-difference-between-medicare-medicaid/index.html (explaining that Medicare is administered by CMS which operates within HHS).

billing professionals is determined by the annual physician fee schedule.[5] Physicians are reimbursed by Medicare for the care they provide Medicare beneficiaries through a system involving RVUs and CFs.[6] Specifically, an RVU is the amount Medicare pays for the procedure or service,[7] while the CF is the number of dollars assigned per RVU.[8] The PFS is established through rulemaking, but it is only revised annually, which means it is slow to respond to inflation, supply shortages, and increases in labor costs due to staffing shortages which all increase the cost of care throughout the year. [9]

Medicare physician reimbursement rates have dropped by twenty-two percent between 2001 and 2021, adjusted for inflation.[10] This is partially due to Congress passing the Medicare Access and CHIP Reauthorization Act (MACRA) in 2015.[11] Under MACRA, CMS implements annual physician reimbursement cuts to offset rising payments for other services.[12] For years,

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[5] *Fact sheet: Calendar Year (CY) 2023 Medicare Physician Fee Schedule Final Rule,* CTRS. FOR MEDICARE & MEDICAID SERVS. (Nov. 1, 2022), https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2023-medicare-physician-fee-schedule-final-rule.

[6] D.J. Seidenwurm & J.H. Burleson, *The Medicare Conversion Factor*, 35 AM. J. NEURORADIOLOGY, 242-43 (2014).

[7] *Id.*

[8] *Id.*

[9] *Id.*; Benjamin Finder, *Four Reasons Medicare Is an Inadequate Benchmark for Commercial Health Plans*, AM. HOSP. ASS'N (Apr. 29, 2022, 10:36 AM), https://www.aha.org/news/blog/2022-04-29-four-reasons-medicare-inadequate-benchmark-commercial-health-plans.

[10] Jack Resneck Jr., MD, *Medicare physician payment reform is long overdue*, AM. MED. ASS'N (Oct. 3, 2022), https://www.ama-assn.org/about/leadership/medicare-physician-payment-reform-long-overdue.

[11] *See* Matthew Coffron & Carrie Zlatos*, Medicare physician payment on the decline: It's not your imagination*, BULL. OF THE AM. COLL. OF SURGEONS (Sept. 1, 2019), https://bulletin.facs.org/2019/09/medicare-physician-payment-on-the-decline-its-not-your-imagination/ (explaining how MACRA decreased the Conversion Factor which results in decreased Medicare physician reimbursement)*; See* Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Pub. L. No. 114-10, 129 Stat. 87 (explaining that MACRA was passed in 2015).

[12] *See* Hyun Soo Lee, *Medicare payment cuts 'very harmful for care' in Schuylkill County*, LONGVIEW NEWS-J. (Jan. 21, 2023), https://www.news-journal.com/medicare-payment-cuts-very-harmful-for-care-in-schuylkill-county/article_0d304196-a529-51a7-b7c6-b147efe13164.html (explaining how MACRA cuts in physician reimbursement are intended to combat rising costs for other health care services such as primary care).

the American Hospital Association (AHA) has pointed out that the Medicare reimbursement rates fall below the cost of care for many services which heavily contributes to the financial burden hospitals face.[13] Medicare paid only eighty-four cents for every dollar spent by hospitals caring for Medicare patients in 2020, which strikingly resulted in $75.6 billion in underpayments for Medicare services provided in 2020.[14] As a result, more than two-thirds of medical practices reported that Medicare payments would not cover the cost of delivering care to Medicare beneficiaries.[15]

III. HOW THE 2023 CMS PHYSICIAN FEE SCHEDULE ENDANGERED AN ALREADY PRECARIOUS FINANCIAL SITUATION FOR RURAL HEALTHCARE PROVIDERS

The 2023 CMS PFS[16] decreased physician reimbursement by 4.47 percent[17] from 2022, which decreased the value of an RVU from $34.6062 per RVU to $33.0607 per RVU.[18] Additionally, doctors would also face a four percent reimbursement reduction because of Pay-As-You-Go (PAYGO)

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[13] *Medicare Rates as a Benchmark: Too Much, Too Little or Just Right?* 40 ALTARUM HEALTHCARE VALUE CLUB (2020), https://www.healthcarevaluehub.org/application/files/3615/8334/0179/RB_40_-_Medicare_Rates_as_a_Benchmark.pdf.; *Underpayment by Medicare and Medicaid Fact Sheet*, AM. HOSP. ASS'N (Jan. 2019), https://www.aha.org/system/files/2019-01/underpayment-by-medicare-medicaid-fact-sheet-jan-2019.pdf.

[14] Finder, *supra* note 9.

[15] Drew Voytal, MPA & Mollie Gelburd, JD, *Medicare reimbursement falls short of care delivery costs*, MED. GRP. MGMT. ASS'N (Jan. 16, 2019), https://www.mgma.com/data/data-stories/2019-medicare-reimbursement-rates.

[16] 42 C.F.R. §§ 405, 410, 411, 414, 415, 423, 424, 425, 255 (Table 146 contains the calculation of the CY 2023 PFS conversion factor when it was originally released in November 2022; however, CMS modified the CY 2023 PFS conversion factor after the Consolidated Appropriations Act, 2023).

[17] Deborah Godes et al., *Policy Update: CMS Updates CY 2023 Physician Conversion Factor to $33.8872*, MCDERMOTT PLUS CONSULTING (Jan. 6, 2023), https://www.mcdermottplus.com/insights/cms-updates-cy-2023-physician-conversion-factor-to-33-8872/.

[18] 42 C.F.R. §§ 405, 410, 411, 414, 415, 423, 424, 425, 455 (Table 146 contains the calculation of the CY 2023 PFS conversion factor when it was originally released in November 2022; however, CMS modified the CY 2023 PFS conversion factor after the Consolidated Appropriations Act, 2023).

sequestrations.[19] Congress suspended the sequestrations at the beginning of the COVID-19 pandemic; however, the sequestrations are expected to resume at the end of 2023 without congressional intervention.[20] Therefore, without congressional intervention, doctors receiving Medicare reimbursement would suffer nearly an 8.5% reimbursement decrease.[21]

Rural hospitals historically receive the bulk of their revenue from government payers.[22] Medicare makes up about half of that amount.[23] Federal government payers, however, reimburse hospitals at a rate lower than the cost of caring for beneficiaries.[24] Consequently, rural hospitals are less able to offset the low government payer reimbursement rates with revenue from patients with commercial coverage.[25] A rural hospital is a hospital that is "not located within a metropolitan area designated by the U.S. Office of Management and Budget and the Census Bureau."[26] According to the Health Resources and Services Administration (HRSA), the Census Bureau considers "rural" to "include all people, housing, and territory that are not

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[19] *Medicare's 2023 fee schedule: cuts in reimbursement, expanded payments for behavioral health*, MED. ECON. (Nov. 2, 2022), https://www.medicaleconomics.com/view/medicare-s-2023-fee-schedule-cuts-in-reimbursement-expanded-payments-for-behavioral-health; *see Fact Sheet: Statutory PAYGO Sequester Relief Needed for Health Providers*, AM. HOSP. ASS'N (Sept. 2022), https://www.aha.org/system/files/media/file/2022/09/Fact-Sheet-Statutory-PAYGO-Sequester-Relief-Needed-for-Health-Providers.pdf (explaining that PAYGO sequestrations require that spending and revenue legislation not increase the federal budget over a 5- or 10-year period. To accomplish this, the Office of Management and Budget (OMB) would need to implement sequestration (across-the-board reductions) in certain types of mandatory federal spending including some components of Medicare spending).

[20] *Medicare's 2023 fee schedule: cuts in reimbursement, expanded payments for behavioral health*, *supra* note 19.

[21] *Id.*

[22] Jacqueline LaPointe, *Low Reimbursement, Staffing Shortages Lead to Rural Hospital Closures*, REVCYCLE INTEL. (Sept. 13, 2022), https://revcycleintelligence.com/news/low-reimbursement-staffing-shortages-lead-to-rural-hospital-closures.

[23] *Id.*

[24] *Id.*

[25] *Id.*

[26] *Fast Facts: U.S. Rural Hospitals Infographic*, AM. HOSP. ASS'N (2022), https://www.aha.org/infographics/2021-05-24-fast-facts-us-rural-hospitals-infographic.

within an urban area."[27] An urban area is defined as an area with 50,000 or more people.[28]

A fifty-state study published in the Health Affairs Journal revealed that rural hospitals' financial status started declining even before the COVID-19 pandemic.[29] The U.S. Government Accountability Office reported that from 2013 to 2017, sixty-four rural hospitals closed; notably, this is more than twice as many as the previous five-year period. [30] In 2017, rural hospitals' median profit margin was less than half of urban hospitals'.[31] In 2019, one in five rural hospitals were at risk of closing due to financial difficulties.[32] A report from the Center for Healthcare Quality and Payment Reform reported, as of January 2023, almost every state has a rural hospital at risk of closing.[33]

The pandemic made this precarious financial situation even more tenuous.[34] Hospital revenues decreased when government executive orders and patient concerns about exposure led to income-generating elective services being cancelled or deferred.[35] Additionally, the cost of spending for

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[27] *Defining Rural Population*, HEALTH RES. & SERVS. ADMIN. (March 2022), https://www.hrsa.gov/rural-health/about-us/what-is-rural.
[28] *Id.*
[29] *See COVID-19 And The Financial Viability Of US Rural Hospitals*, HEALTH AFFAIRS (July 1, 2020), https://www.healthaffairs.org/do/10.1377/forefront.20200630.208205/full/ (citing the June 2020 issue of the Health Affairs journal which includes the article, *Varying Trends In The Financial Viability Of US Rural Hospitals, 2011-17* analyzing both rural and urban hospitals' financial status before the pandemic through a fifty-state study from 2011 through 2017); *see* Bai et al., *Varying Trends In The Financial Viability Of US Rural Hospitals*, 2011-17, 39 HEALTH AFFAIRS J. 942 (2020).
[30] *Rural Hospital Closures: Number and Characteristics of Affected Hospitals and Contributing Factors*, U.S. GOV'T ACCOUNTABILITY OFF. (Aug. 29, 2018), https://www.gao.gov/assets/gao-18-634.pdf.
[31] *COVID-19 And The Financial Viability Of US Rural Hospitals*, *supra* note 29; *see* Bai et al., *supra* note 29.
[32] David Mosley & David DeBehnke, MD, *Rural Hospital Sustainability: New Analysis Shows Worsening Situation for Rural Hospitals, Residents*, NAVIGANT (Feb. 2019), https://guidehouse.com/-/media/www/site/insights/healthcare/2019/navigant-rural-hospital-analysis-22019.pdf.
[33] *Rural Hospitals at Risk of Closing*, CTR. FOR HEALTHCARE QUALITY & PAYMENT REFORM (2022), http://ruralhospitals.chqpr.org/downloads/Rural_Hospitals_at_Risk_of_Closing.pdf.
[34] *COVID-19 And The Financial Viability Of US Rural Hospitals*, supra note 29; Bai et al., *supra* note 29.
[35] *Id.*

personal protective equipment (PPE) and other equipment required to provide care increased.[36] Even though Congress enacted the REH designation,[37] which allows CMS-recognized rural emergency hospitals to receive additional funding if they meet certain criteria, not all rural hospitals are emergency rural hospitals.[38]

In 2022, the AHA released a new report highlighting the variety of causes that resulted in 136 rural hospital closures from 2010 to 2021.[39] In 2020 alone, a record nineteen rural hospitals closed.[40] Almost thirty percent of rural hospitals in America are at risk of closing within the next six years.[41] Over 200 of these hospitals are at immediate risk of closing, which means they would be unable to pay for their expenses within the next two to three years.[42] Years of decreased physician reimbursement in CMS physician fee schedules contributed to rural hospital closures.[43] Although rural hospitals were bolstered by emergency funding during the pandemic, this funding is not permanent, and the existing financial hardships pre-pandemic will continue and likely worsen once that funding stops.[44] In February 2023, more

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[36] *Id.*
[37] *See CY 2023 Medicare Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment System Final Rule (CMS 1772-FC) Rural Emergency Hospitals – New Medicare Provider Type*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Nov. 1, 2022), https://www.cms.gov/newsroom/fact-sheets/cy-2023-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-1 (establishing the REH distinction on January 1, 2023).
[38] *Rural Emergency Hospitals*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Oct. 2022), https://www.cms.gov/files/document/mln2259384-rural-emergency-hospitals.pdf.
[39] *See Rural Hospital Closures Threaten Access – Solutions to Preserve Care in Local Communities*, AM. HOSP. ASS'N (Sept. 2022), https://www.aha.org/system/files/media/file/2022/09/rural-hospital-closures-threaten-access-report.pdf (explaining that the nineteen hospital closures in 2020 was the most of any year in the past decade).
[40] *Id.*
[41] *The Impact of the Pandemic on Rural Hospitals*, CTR. FOR HEALTHCARE QUALITY & PAYMENT REFORM (Jan. 2023), https://chqpr.org/downloads/Pandemic_Impact_on_Rural_Hospitals.pdf.
[42] *Id.*
[43] *Rural Hospital Closures, supra* note 30.
[44] *The Impact of the Pandemic on Rural Hospitals, supra* note 41.

than 100 American physician and clinician organizations petitioned Congress to fix the broken Medicare payment systems and decreased physician reimbursement through the fee schedules because physicians "face an increasingly challenging environment providing Medicare beneficiaries with access to timely and quality care, which is particularly important for underserved and rural areas."[45]

IV. CONGRESS' REVISIONS TO THE 2023 CMS PHYSICIAN FEE SCHEDULE THROUGH THE CONSOLIDATED APPROPRIATIONS ACT, 2023

In response to the outrage over decreased physician reimbursement, Congress and President Biden positively adjusted the 2023 CMS PFS reimbursement CF by 2.5 percent for 2023 and 1.25 percent for 2024 in the Consolidated Appropriations Act, 2023.[46] The anticipated PAYGO sequestrations were staved off for 2023 and 2024.[47] On January 5, 2023, CMS announced the updated CY 2023 physician conversion factor (CF) of $33.8872, reflecting the 2.5 percent positive adjustment from the original 2023 CMS PFS CF of $33.0607 which was a 4.47 percent cut from the CY 2022 CF of $34.6062.[48] After the changes announced in the Consolidated Appropriations Act, the actual CY 2023 CMS physician reimbursement decrease will be 2.08 percent,[49] resulting in a CF of $33.8872.[50]

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[45] Kevin O'Reilly, *New Congress brings new call for Medicare physician pay overhaul*, AM. MED. ASS'N (Feb. 9, 2023), https://www.ama-assn.org/practice-management/medicare-medicaid/new-congress-brings-new-call-medicare-physician-pay-overhaul.
[46] Godes et al., *supra* note 17; *see* LaPointe, *supra* note 22.
[47] Godes et al., *supra* note 17; *see* LaPointe, *supra* note 22.
[48] Godes et al., *supra* note 17; *see* LaPointe, *supra* note 22.
[49] Godes et al., *supra* note 17; *see* LaPointe, *supra* note 22.
[50] Godes et al., *supra* note 17; *see* LaPointe, *supra* note 22.

V. A ZERO PERCENT DECREASE IN PHYSICIAN REIMBURSEMENT FOR RURAL HEALTHCARE PROVIDERS IN THE 2024 CMS PHYSICIAN FEE SCHEDULE AND THE CONSOLIDATED APPROPRIATIONS ACT, 2024 WOULD HELP RURAL PROVIDERS

The Consolidated Appropriations Act, 2023 did not go far enough. The 2024 CMS PFS and the Consolidated Appropriations Act, 2024 should positively adjust the physician reimbursement rate for rural healthcare providers to a zero percent decrease because they are impacted the most by the fluctuating physician reimbursement rates.[51] Since the populations rural hospitals serve likely relies on Medicare and Medicaid for insurance, rural hospitals receive most of their revenue from government payers.[52] However, since Medicare and Medicaid both reimburse for less than the actual costs of services, rural hospitals are continually operating at a loss and cannot recuperate the losses with revenue from commercial insurance payers.[53] The AHA found that rural hospitals incurred $5.8 billion in Medicare underpayments and $1.2 billion in Medicaid underpayments in 2020.[54] Additionally, the hospitals also provided $4.6 billion in uncompensated care.[55]

Among other factors, when Medicare payments do not cover the cost of care for Medicare beneficiaries, hospitals are forced into the red.[56] On behalf of the AHA, Kaufman Hall reported that anywhere from fifty-three percent to sixty-eight percent of American hospitals would end 2022 with their operations in the red compared to thirty-four percent reported in 2019.[57] The

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[51] *Rural Hospital Closures Threaten Access, supra* note 39.
[52] *Id.*
[53] *Id.*
[54] *Id.*
[55] *Id.*
[56] *Id.*
[57] Dave Muoio, *'Unsustainable' losses are forcing hospitals to make 'heart-wrenching' cuts and closures, leaders warn*, FIERCE HEALTHCARE (Sept. 16, 2022, 9:00 AM), https://www.fiercehealthcare.com/providers/unsustainable-losses-are-forcing-hospitals-make-heart-wrenching-cuts-and-closures-leaders.

Medicare Payment Advisory Commission reported that hospitals experienced an –8.5 percent margin on Medicare services in 2020.[58] The margin is projected to fall to –9 percent in 2022.[59] The AHA explained, "[b]ecause rural hospitals are more likely to serve a population that relies on Medicare and Medicaid, rural hospitals are not able to offset low public program payment rates with revenue from patients with commercial coverage, which often has higher reimbursement rates than government payers."[60] Although there are government assistance programs for Medicare-Dependent Hospitals (MDH), these provisions are temporary.[61]

Often, rural hospitals serve not only as the emergency care providers in the community, but also as the primary providers of all other health care services.[62] When the hospitals close, the majority of the community's healthcare resources disappear.[63] The AHA articulated the severity of problem, saying that when rural hospitals close, they "have an outsized impact" on the rural population's health and economic well-being.[64]

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[58] *Fact Sheet: Majority of Hospital Payments Dependent on Medicare or Medicaid*, AM. HOSP. ASS'N (May 2022), https://www.aha.org/fact-sheets/2022-05-25-fact-sheet-majority-hospital-payments-dependent-medicare-or-medicaid.
[59] *Id.*
[60] *Rural Hospital Closures Threaten Access, supra* note 39.
[61] *Id.*
[62] *See The Crisis in Rural Health Care*, CTR. FOR HEALTHCARE QUALITY & PAYMENT REFORM, https://ruralhospitals.chqpr.org/ (last visited Apr. 6, 2023) (explaining that rural hospitals provide emergency care in addition to other health care services such as maternity care, laboratory testing, rehabilitation, and primary care).
[63] *Id.*
[64] *Rural Hospital Closures Threaten Access, supra* note 39.

Relative to urban areas, Americans living in rural areas have a higher rate of poverty,[65] and unemployment,[66] and are more likely to be uninsured.[67] The rural communities are shrinking,[68] which means there are fewer patients[69] and less money[70] flowing into rural hospitals. Further, when fewer patients have insurance, rural hospitals must cover the cost of uncompensated care.[71] Even if a patient has Medicare or Medicaid, hospitals are not paid as much from federal health insurance programs as they would be from commercial insurers.[72] Commercial insurers pay nearly double what Medicare pays for all hospital services.[73] Lower reimbursement rates from federal health insurance programs are coupled with populations in rural areas requiring more care because rural residents are generally older,[74] maintain higher rates

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[65] *Rural Poverty & Well-Being*, ECON. RSCH. SERV. U.S. DEP'T OF AGRIC. (Nov. 29, 2022), https://www.ers.usda.gov/topics/rural-economy-population/rural-poverty-well-being/#historic; Jen Christensen, *How the pandemic killed a record number of rural hospitals*, CNN HEALTH (July 31, 2021, 3:42 PM), https://www.cnn.com/2021/07/31/health/rural-hospital-closures-pandemic/index.html.

[66] *Rural Poverty & Well-Being*, *supra* note 65; Christensen, *supra* note 65.

[67] Jennifer Cheeseman Day, *Health Insurance in Rural America*, U.S. CENSUS BUREAU (Apr. 9, 2019), https://www.census.gov/library/stories/2019/04/health-insurance-rural-america.html; Christensen, *supra* note 65.

[68] Kim Parker et al., *Demographic and economic trends in urban, suburban and rural communities*, PEW RSCH. CTR. (May 22, 2018), https://www.pewresearch.org/social-trends/2018/05/22/demographic-and-economic-trends-in-urban-suburban-and-rural-communities/; Christensen, *supra* note 65.

[69] *COVID-19 And The Financial Viability Of US Rural Hospitals*, supra note 29; Christensen, *supra* note 65; *see* Bai et al., *supra* note 29.

[70] Alex Kacik, *Reinventing a Hospital: 'If we had to drive to Albuquerque or Las Vegas, she might not have made it.'*, MOD. HEALTHCARE INDEPTH (2018), https://www.modernhealthcare.com/indepth/rural-hospitals-look-for-help-to-survive/; Christensen, *supra* note 65.

[71] *Underpayment by Medicare and Medicaid Fact Sheet*, *supra* note 13; Christensen, *supra* note 65.

[72] *Underpayment by Medicare and Medicaid Fact Sheet*, *supra* note 13; Christensen, *supra* note 65.

[73] Eric Lopez et al., *How Much More Than Medicare Do Private Insurers Pay? A Review of the Literature*, KAISER FAM. FOUND. (Apr. 15, 2020), https://www.kff.org/medicare/issue-brief/how-much-more-than-medicare-do-private-insurers-pay-a-review-of-the-literature/; Christensen, *supra* note 65.

[74] Amy Symens Smith & Edward Trevelyan, *The Older Population in Rural America: 2012-2016*, AM. CMTY. SURV. REP. (Sept. 2019), https://www.census.gov/content/dam/Census/library/publications/2019/acs/acs-41.pdf; Christensen, *supra* note 65.

of chronic conditions,[75] are more likely to have a disability, and have less access to primary care as compared to urban populations.[76] Furthermore, rural populations are more likely to suffer possibly preventable deaths from heart disease, cancer, and stroke compared to urban and suburban residents.[77] Rural populations are also likely to experience higher rates of smoking, hypertension, and obesity.[78]

Not only does decreased Medicare physician reimbursement impact physicians, but it also threatens patients' access to care: "physicians are the only Medicare providers without annual inflation-based updates. [The American Medical Association is] deeply worried that many practices will be forced to stop taking new Medicare patients—at a time when access to care is already inadequate."[79]

COVID-19 appropriations for rural hospitals bolstered faltering rural hospitals.[80] Therefore, an abrupt end to additional federal funding plus a decrease in physician reimbursement could expedite the impending closure of hundreds of rural hospitals.[81] In addition to keeping the CMS rural emergency hospital (REH) distinction for additional reimbursement, a zero percent decrease in physician reimbursement would cushion the fall from

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[75] *Chronic Disease in Rural America*, RURAL HEALTH INFO. HUB (May 20, 2022), https://www.ruralhealthinfo.org/topics/chronic-disease; Christensen, *supra* note 65.
[76] *Rural Communities*, CTRS. FOR DISEASE CONTROL & PREVENTION (July 7, 2021), https://public4.pagefreezer.com/browse/CDC%20Covid%20Pages/11-05-2022T12:30/https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/other-at-risk-populations/rural-communities.html; Christensen, *supra* note 65.
[77] *Payment & Delivery in Rural Hospitals*, AM. MED. ASS'N (2021), https://www.ama-assn.org/system/files/issue-brief-rural-hospital.pdf.
[78] *Id.*
[79] *See* Lee, *supra* note 12 (explaining why a decrease in Medicare physician fee reimbursement coupled with the increasing costs of care could decrease Medicare patients' access to care).
[80] *Federal Support for Financially Distressed Hospitals*, CONG. RSCH. SERV. (Dec. 1, 2022), https://crsreports.congress.gov/product/pdf/IN/IN12057.
[81] *See* Jeff Lagasse, *Rural hospitals in trouble if Congress doesn't renew funding programs, AHA says*, HEALTHCARE FIN. (Sept. 12, 2022), https://www.healthcarefinancenews.com/news/rural-hospitals-trouble-if-congress-doesnt-renew-funding-programs-aha-says (warning that if federal funding programs expire there would likely be more rural hospital closures).

federal funding for rural hospitals because the reimbursement rate will be in place for an entire year compared to the temporary pandemic appropriations.[82]

The 2024 CMS PFS should include language about reverting to the 2022 CF of $34.6062 per RVU while containing the REH distinction providing additional reimbursement to rural emergency hospitals. Proposed language could state: "After analyzing the impact of the COVID-19 pandemic and the rising cost of care's disproportionate harm to rural hospitals (hospitals located in an area with fewer than 50,000 people), the Centers for Medicare & Medicaid Services (CMS) will raise the conversion factor (CF) back to the $34.6062 per relative value unit (RVU) rate. In addition, CMS will retain the rural emergency hospital (REH) distinction for Critical Access Hospitals (CAHs) and other rural emergency hospitals who converted to follow the REH Conditions of Participation (CoPs) to further bolster their ability to provide care for patients despite challenging economic conditions."

To promulgate this language in the 2024 CMS PFS, CMS will need to proceed through the notice and comment rulemaking process dictated by the Administrative Procedure Act (APA) § 553(b) and (c)[83] since it is part of the administrative agency, HHS.[84]

Accordingly, CMS must (1) issue general notice of the proposed rule (the proposed 2024 CMS PFS) published in the Federal Register that includes (a) a statement of the time, place, and nature of public rule making proceedings; (b) reference to the legal authority under which the rule is proposed; and (c) include either the terms or substance of the proposed rule or a description of

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[82] *See Overview of the Medicare Physician Fee Schedule*, AM. SPEECH-LANGUAGE-HEARING ASS'N (2023), https://www.asha.org/practice/reimbursement/medicare/overview-of-the-medicare-physician-fee-schedule/ (explaining that the CMS Physician Fee Schedule is in place for the entire calendar year).
[83] Administrative Procedure Act, 5 U.S.C. § 553 (b) and (c).
[84] *About CMS*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/About-CMS/About-CMS (last visited Apr. 6, 2023).

the subjects and issues involved; (2) provide the public with an opportunity to comment; (3) review the comments; and (4) promulgate the final rule with a concise general statement of the rule's basis and purpose.[85]

Furthermore, the 2024 CMS PFS language should be codified in the Consolidated Appropriations Act, 2024, for additional safeguards. The language could state: "The federal government agrees with the Centers for Medicare & Medicaid's (CMS) assessment that rural hospitals require additional federal government assistance to continue to provide care to patients in rural populations. Therefore, the federal government supports CMS' decision to raise the conversion factor (CF) back to the $34.6062 per relative value unit (RVU) rate. Additionally, the federal government supports CMS retaining the rural emergency hospital (REH) distinction for Critical Access Hospitals (CAHs) and other emergency rural hospitals who converted to follow the REH Conditions of Participation (CoPs) to further bolster their ability to provide care for patients despite challenging economic conditions." This language could be included through the appropriations bill process that occurs annually.[86]

VI. CONCLUSION

[85] Administrative Procedure Act, 5 U.S.C. § 553 (b) and (c).

[86] *See Appropriations*, U.S. SENATE, https://www.senate.gov/reference/reference_index_subjects/Appropriations_vrd.htm, (last visited Apr. 6, 2023) (explaining how annually the president submits the federal government's proposed budget to Congress. Following this, Congress passes appropriations bills to fund government programs for the upcoming year.); *See A Brief Guide to the Federal Budget and Appropriations Process*, AM. COUNCIL ON EDUC., https://www.acenet.edu/Policy-Advocacy/Pages/Budget-Appropriations/Brief-Guide-to-Budget-Appropriations.aspx (last visited Apr. 6, 2023) (explaining that the president signs the congressional budget into law for the upcoming year).

The Consolidated Appropriations Act, 2023[87] took steps to address the 2023 CMS PFS' decrease in physician reimbursement.[88] However, the Consolidated Appropriations Act, 2023 did not go far enough to help rural providers and hospitals who are harmed the most by decreases in physician reimbursement. Therefore, the 2024 CMS PFS and the Consolidated Appropriations Act, 2024 should include language that codifies a zero percent decrease in physician reimbursement for rural providers for 2024. In effect, the 2024 CMS PFS should revert to the 2022 CF of $34.6062 per RVU to make the decrease in physician reimbursement zero percent. Furthermore, the 2023 CMS PFS should continue the REH designation providing additional support for rural emergency hospitals. A zero percent decrease in the 2024 CMS PFS affirmed in the Consolidated Appropriations Act, 2024, will serve as a lifeline for rural hospitals already struggling to provide the care their communities desperately need.

[87] *See* Consolidated Appropriations Act, 2023, §§ 4112, 1175 (amending Section 1848 of the Social Security Act 42 U.S.C. 1395w-4); Social Security Act 42 U.S.C. 1395w-4 § 4112 (outlining payment for physicians' services).
[88] *See* 42 C.F.R. §§ 405, 410, 411, 414, 415, 423, 424, 425, 455 (Table 146 contains the calculation of the CY 2023 PFS conversion factor when it was originally released in November 2022; however, CMS modified the CY 2023 PFS conversion factor after the Consolidated Appropriations Act, 2023).

Chronic Disease Prevention as a Tool for Reducing U.S. Healthcare Spending

Chloe Warren, MPH

I. INTRODUCTION

The United States spends more on healthcare than any other country, but its healthcare outcomes do not reflect its investment.[1] While there are many contributing factors to this significant expenditure and multiple stakeholders involved, preventative healthcare services can serve as a means of reducing overall spending for insurers, patients, and hospitals.[2] Specifically, chronic diseases are a particularly high-yield area to focus on because chronic diseases are the leading cause of death and disability and are among the costliest diseases in the United States.[3] Fortunately, however, chronic diseases are also among the most preventable.[4] Preventative behaviors such as a healthy diet, routine physical activity, and not using tobacco products can prevent eighty percent of premature heart disease, stroke, and type two diabetes, in addition to preventing forty percent of cancer diagnoses.[5]

In an effort to address chronic diseases as a major contributor to healthcare spending in the United States, this article proposes amending the Affordable Care Act's (ACA) out-of-pocket maximum requirement. In particular, the proposed amendment would offer patients an opportunity. If the individual uses preventative services that avoid or mitigate the development of chronic illnesses, the insurer would be required to offer that individual a lower out-of-pocket maximum cost before full insurance reimbursement payments kick

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[1] Eric Schneider et al., THE COMMONWEALTH FUND, MIRROR, MIRROR 2021, REFLECTING POORLY: HEALTH CARE IN THE U.S. COMPARED TO OTHER HIGH-INCOME COUNTRIES, 2 (2021).
[2] THE HEALTHCARE IMPERATIVE: LOWERING COSTS AND IMPROVING OUTCOMES: WORKSHOP SERIES SUMMARY 219-20 (Pierre L. Yong et al. eds., Nat'l Acad. of Sci. 2010).
[3] *Public Health and Chronic Disease Cost Savings and Return on Investment*, AM. PUBLIC HEALTH ASS'N,https://www.apha.org/~/media/files/pdf/factsheets/chronicdisease fact_final.ashx.
[4] *Id.*
[5] *Chronic Diseases*, ILL. DEPT. PUBLIC HEALTH, https://dph.illinois.gov/topics-services/diseases-and-conditions/chronic-diseases.html.

in. This out-of-pocket maximum would be decreased by a percentage that Congress or the Department of Health and Human Services (HHS) determines is appropriate.

The proposed amendment would be of interest to individuals because, once an individual reaches the out-of-pocket maximum, the health insurance plan will pay for all healthcare costs for that individual for the remainder of that year.[6] A significant number of Americans voice healthcare costs as a barrier to care.[7] Taking preventative measures in exchange for a lower out-of-pocket maximum would mean that both the individual and their family could meet overall healthcare needs that otherwise would have been avoided due to cost concerns.

II. ANALYSIS

A. Why is the Proposed Amendment in the Interest of Insurers?

It is in the interest of insurers to reward their beneficiaries for preventative behaviors because doing so furthers insurer goals of making money and managing exposure to risk.[8] Historically, the most costly and preventable chronic conditions have cost the U.S. as much as thirty percent of the total healthcare spending.[9] Additionally, seventy-five percent of health care

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[6] Les Masterson, *What's the Difference Between a Deductible vs. Out-of-Pocket Maximum,* FORBES ADVISOR (Oct. 31, 2022), https://www.forbes.com/advisor/health-insurance/deductible-vs-out-of-pocket-maximum/.

[7] Alex Montero et al., *Americans' Challenges with Health Care Costs*, KAISER FAM. FOUND. (July 14, 2022), https://www.kff.org/health-costs/issue-brief/americans-challenges-with-health-care-costs/.

[8] Adrian Gore et al., *Can Insurance Companies Incentivize their Customers to be Healthier?* HARV. BUS. REV. (June 23, 2017), https://hbr.org/2017/06/can-insurance-companies-incentivize-their-customers-to-be-healthier ("Of all industries, insurance has a unique opportunity to align its commercial interests with preventive behaviors. Insurers, along with public services, can directly 'monetize' better individual behavior as healthier or safer individual outcomes, lower claims costs, and improve risk pools, which can be translated into lower-priced premiums and a competitive advantage in the marketplace."); *see also* , Amy B. Monahan, *The Regulatory Failure to Define Essential Health Benefits*, 44 AM. J. L. & MED. 529, 530 (2018).

[9] AM. PUBLIC HEALTH ASS'N, *supra* note 3.

dollars in the United States go towards treating preventable chronic diseases.[10]

Moreover, of the eighty-six percent of individuals in the United States who have health insurance, about three-quarters are covered through either an employer-provided plan or a privately purchased plan.[11] Solutions that focus on chronic conditions could help employers to manage costs over time, especially since chronic conditions are responsible for a significant proportion of medical claims for employers.[12]

Preventative services also benefit the employer-based subgroups of insurers because chronic diseases have an impact on workforce patterns, including absenteeism.[13] For example, chronic diseases can impact the economic productivity of individuals.[14] When chronic diseases interfere with an individual's ability to work and earn an income, wage gaps are created, and productivity is subsequently reduced.[15]

For public insurers, investing in preventative services is similarly beneficial because chronic diseases also make up a significant amount of their spending.[16] Specifically, Medicare spends ninety-six cents per dollar

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[10] *Disease Prevention*, HARVARD T.H. CHAN SCH. OF PUBLIC HEALTH (2023), https://www.hsph.harvard.edu/nutritionsource/disease-prevention/; Wullianallur Raghupathi & Viju Raghupathi, *An Empirical Study of Chronic Diseases in the United States: A Visual Analytics Approach to Public Health*, INT. J. ENVIRON. RES. PUBLIC HEALTH (Mar. 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5876976/.

[11] Christopher Limbacher, *Healthcare Price Transparency: Reintroducing Competition*, 53 HOUS. L. REV. 939, 943 (2016).

[12] *Small Population, Large Expense: Managing High-Cost Claimants*, UNITEDHEALTHCARE (May 21, 2021), https://www.uhc.com/broker-consultant/news-strategies/resources/small-population-large-expense-managing-the-high-cost-2-percent.

[13] Raghupathi & Raghupathi, *supra* note 10, at 1; *Absenteeism*, MERRIAM WEBSTER, https://www.merriam-webster.com/dictionary/absenteeism (defining absenteeism as "chronic absence (as from work or school)").

[14] AM. PUBLIC HEALTH ASS'N, *supra* note 3.

[15] Don Beyer, *Chronic Conditions Pose Growing Health, Economic, and Equity Challenges*, JOINT ECON. COMM. DEMOCRATS 1, 1 (July 8, 2022), https://www.jec.senate.gov/public/_cache/files/05d4343b-91e3-4c0f-bd50-9376fa86a2ce/jec-chronic-conditions-final.pdf.

[16] *Health and Economic Costs of Chronic Diseases*, CTR. FOR DISEASE CONTROL & PREVENTION (Sept. 8, 2022), https://www.cdc.gov/chronicdisease/about/costs/index.htm.

treating chronic diseases, and Medicaid spends eight-three cents per dollar treating chronic diseases.[17]

B. What is an Out-of-Pocket Maximum?

The annual out-of-pocket maximum is a requirement for almost all plans.[18] Specifically, an out-of-pocket maximum puts a cap on the total amount of cost-sharing that individuals and their families are responsible for paying, whether it be co-insurance, co-payments, or deductibles.[19] Once an individual or family reaches the specified limit, the health plan is required to cover one hundred percent of the health care costs for the remainder of the year.[20] For example, in 2017 this limit was $7,150 for individuals and $14,300 for families.[21]

The calculation of out-of-pocket maximums does not include premiums and out-of-network services.[22] The cap only applies to "essential health benefits."[23] At a minimum, the "essential health benefits" must include: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services (including behavioral health treatment); prescription drugs; rehabilitative services and devices; laboratory services; preventative and wellness services and chronic disease management; and pediatric services, including oral and vision care.[24]

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[17] Raghupathi & Raghupathi, *supra* note 10, at 1.
[18] Erin C. Fuse Brown, *Consumer Financial Protection in Healthcare*, 95 WASH. U. L. REV. 127, 142 (2017).
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *Id.*
[23] *Id.* at 143.
[24] 42 U.S.C. §18022 (2022)*; see also,* 1 Health Care Reform: Law and Practice, §3.02(9)(b)(ii) (2022) (noting that Section 1302(b) of the ACA requires these Essential Health Benefits coverage categories).

C. The Structure of the Proposed Amendment

The proposed amendment to the ACA will decrease out-of-pocket maximums for people who take steps to mitigate or prevent the development of chronic diseases. Examples of such measures may include but are not limited to: 1) screenings for blood pressure, cholesterol, colorectal cancer, diabetes (type 2), hepatitis B and C, lung cancer, obesity, and tuberculosis; 2) counseling services for tobacco cessation, substance use and diet; and 3) immunizations (such as Hepatitis A and B, measles, mumps, and rubella). If the insured participates in a qualifying preventative measure and a corresponding claim is submitted to the insurer, the ACA would then require that the individual's out-of-pocket maximum be decreased.

1. How the Proposed Amendment to the ACA Would Apply to the Current Structuring of the Out-of-Pocket Maximum Requirement

Plans included under the Employee Retirement Income Security Act (ERISA) offer an example of how existing insurance infrastructure could be used to educate patients about the opportunity provided to them through the proposed amendment. Plans that fall under ERISA are required to detail, in their summary plan description, which benefits are not covered and included toward a participant's out-of-pocket maximum.[25] The proposed amendment could take an alternative approach to ERISA's outlining of what is not covered as part of the out-of-pocket maximum.[26] Instead, the proposed amendment could also require that the summary of the plan include details about the preventive measures the participants can take to lower their out-of-pocket maximum.

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[25] Sandy Niespodzianski, *More Frequently Asked Questions Issued About the ACA*, 16 LAWYERS J. 10, 10 (2014); *see Employee Retirement Income Security Act (ERISA)*, U.S DEPT. LABOR, https://www.dol.gov/general/topic/retirement/erisa ("ERISA requires plans to provide participants with plan information including important information about plan features and funding. . .").

[26] *Id.*

2. How the ACA Preventative Services Mandate Can Inform this Article's Proposed Amendment

A non-grandfathered group health plan previously had to cover preventative services outlined in U.S. Preventative Task Force recommendations without cost-sharing requirements such as co-payment, deductible, or co-insurance.[27] However, the recent *Braidwood Management Inc. v. Becerra* case found that the actions of the Task Force violated the Appointments Clause.[28] With the Task Force struck down, the future of the preventative services mandate under the ACA is uncertain.

In the event that the preventative service mandate loses its ability to operate, the proposed amendment could replace a practice of preventative services being covered at no cost-sharing to the participant with one that lowers the individual's out-of-pocket maximum. Specifically, chronic disease-based preventative services that were included in the preventative services mandate and that would be included under the proposed changes are blood pressure screening, cholesterol screening, colorectal cancer screening, diabetes (type 2) screening, diet counseling (especially for those at higher risk for chronic disease), hepatitis B and C screening, immunizations (such as Hepatitis A and B, measles, mumps, and rubella), lung cancer screening, obesity screening and counseling, and tuberculosis screening.[29]

An example of a service that could carry forward under this article's proposed plan would be one related to tobacco cessation. The Task Force had clinicians ask adults about tobacco use and provide cessation interventions for those that used tobacco.[30] Group health plans and health insurance issuers satisfied their requirement to cover tobacco use counseling

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[27] *Id.*
[28] Braidwood Mgmt. Inc. v. Becerra, 4:20-CV-00283-O, 2022 WL 4091215, at *37 (N.D. Tex. Sept. 7, 2022).
[29] *Preventative care benefits for adults*, HEALTHCARE.GOV, https://www.healthcare.gov/preventive-care-adults/.
[30] Niespodzianski, *supra* note 25, at 10.

and interventions if the insurer covered screening for tobacco use and a minimum of two tobacco cessation attempts per year, where each attempt consisted of tobacco cessation counseling sessions and FDA-approved tobacco cessation medications.[31] While many people associate tobacco use with a risk of lung cancer, smoking also causes a risk of chronic obstructive pulmonary disease, heart disease, and stroke.[32] Under the proposed amendment, informing healthcare participants that engaging in tobacco cessation care would qualify them for a reduction in their out-of-pocket maximum could help reduce chronic diseases associated with smoking in the U.S.

D. Implementation of the Proposed Amendment

1. The Role of the Insurer in the Proposed Amendment

a. Example of the Role the Insurer Could Play in Optimizing Success of the Proposed Amendment

The proposed amendment acknowledges that insurers are already playing a role in chronic disease management in the area of prescription painkillers. Such infrastructure can be leveraged for additional chronic disease prevention measures that will qualify for out-of-pocket maximum reduction under the proposed amendment.

Insurers play a significant role in the healthcare system because they are the primary gatekeeper to healthcare products, such as prescription painkillers, and insurers have a unique ability to influence prescriber behaviors and to evaluate patient behavior.[33] Insurers are the healthcare stakeholder that pays for most of the opioids that doctors prescribe.[34]

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[31] *Id.*
[32] AM. PUBLIC HEALTH ASS'N, *supra* note 3.
[33] Valarie K. Blake, *Engaging Health Insurers in the War on Prescription Painkillers*, 11 HARV. L. & POL'Y REV. 485, 511 (2017).
[34] *Id*. at 495.

Furthermore, insurance claims data provide a tool for identifying who fills prescriptions, with what frequency, and in what location.[35] This information can and has already been used to intercept negative prescribing relationships.[36] Part of addressing chronic disease is figuring out who is at risk by gaining access to data about the population and using that knowledge to coach patients through healthier choices.[37] For instance, insurers can use claims data and drug utilization reviews to monitor patients at risk of addiction or overdose because the patient was either prescribed high doses of opioids at high frequencies or received opioids from many pharmacies and prescribers.[38] The proposed amendment would leverage such existing infrastructure and claims data already used in everyday operations to identify and educate patients about health behaviors they can take to reduce their out-of-pocket maximum.

In the prescription opioid example, one preventative solution is for insurers to cover proven alternatives to painkillers that they have historically refused to cover, such as physical therapy, psychological therapy, and aerobic or aquatic training.[39] Such alternatives are good examples of what could be sufficient as part of this article's proposed amendment because if a patient were to submit claims for these types of alternatives to addictive painkillers, this article's proposed amendment would reduce that patient's out-of-pocket maximum.

Since insurers are the ones frequently paying for medications, they hold the power to influence prescribing patterns.[40] For example, insurers can work with hospitals, providers, and public health agencies to provide continuing education opportunities and collaborative guidelines that inform patients that

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[35] *Id.* at 497.
[36] *Id.*
[37] Raghupathi & Raghupathi, *supra* note 10, at 2.
[38] *Id.* at 499.
[39] Blake, *supra* note 33, at 497.
[40] *Id.*

by adopting preventative behaviors they can reduce their out-of-pocket maximum.[41]

2. Role of the Individual or the Beneficiary

a. Patient Decision-making Related to Insurance

It is not a fair assumption that people have the experience or information to navigate complicated decisions about which insurance to purchase.[42] Similarly, people may not have an option about decisions such as choosing their insurer, access to out-of-network care, or access to physicians with the ability to negotiate with insurers.[43] For example, people whose insurance comes from an employer often have minimal or no choice as to which insurer provides their coverage.[44]

If patients are making a decision about an insurance plan and coverage, they must predict the nature of the medical care they will need in the upcoming year, which can be a challenging endeavor.[45] Additionally, it is often impossible for a patient to analyze and account for how much a physician or pharmacy charges for treatment of someone who has insurance versus someone who does not.[46]

Young, healthy individuals with no dependents nor a significant disposable income may need more assistance to learn why it is in their interest and a worthy investment to sign up for health insurance.[47] The proposed amendment will not be able to incentivize individuals to engage in

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[41] *Id.*
[42] Jacqueline R. Fox, *The Lived Experience of Health Insurance*: *An Analysis and Proposal for Reform*, 14 NE. U. L. REV. 429, 435 (2022).
[43] *Id.* at 436.
[44] *Id.* at 455.
[45] *Id.* at 451.
[46] *Id.* at 454.
[47] Brietta Clark, *Symposium: Health Care Reform: The State of the States Roundtable: Symposium: Getting People to Make the Right Choice Under the ACA: The Most Important "Sales Pitch" of Obama's Presidency*, 17 J. HEALTH CARE L. & POL'Y 3, 7 (2014).

measures that will prevent or mitigate chronic diseases if they do not have insurance in the first place.

To help younger people understand the importance of presently investing in health insurance, the government and related parties must educate young people on the factors that should inform their decision-making and help them to contextualize the roles that insurance, health, and financial security play in their life.[48] For instance, President Biden led a health care insurance coverage campaign in 2021 that conveyed similar messages.[49] This multi-media campaign spanned across television, digital, email, radio, and streaming networks, and was targeted to reach uninsured individuals who lost coverage, did not speak English, or historically lacked access to health insurance.[50] Congress could use a similar approach to help beneficiaries understand the role of health insurance and the importance of having it.

b. For the Out-of-Pocket Maximum to Motivate Decision-Making, it Must be Achievable

If a patient is unlikely to reach their out-of-pocket cap, this amendment's incentive will be irrelevant. Existing legislation has already considered the issue of ensuring that there be accessible quality care that counts toward an individual's out-of-pocket maximum.[51] One example is that of the requirements that a large group or self-insured plan must meet when using a reference pricing structure.[52]

Reference pricing is when a provider accepts a fixed price as payment in full for a particular procedure.[53] When a reference pricing structure is in

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[48] *Id.* at 27.
[49] Justine Coleman, *Biden's HHS Commits Another $50M to Ad Campaign Touting Expanded Healthcare Coverage*, THE HILL (Mar. 31, 2021), https://thehill.com/policy/healthcare/545845-bidens-hhs-commits-another-50-million-to-ad-campaign-touting-expanded/.
[50] *Id.*
[51] 1 HEALTH CARE REFORM: LAW AND PRACTICE, § 3.02(9)(b)(iii) (2022).
[52] *Id.*
[53] *Id.*

place, and an individual uses an in-network provider that has not agreed to the reference price, the individual faces two consequences: 1) pay the difference between whatever the provider charges and the reference price, and 2) the amount the individual pays does not count towards the out-of-pocket maximum.[54] An insurer in a large group or self-insured market will satisfy out-of-pocket maximum requirements when the only in-network provider accepts reference pricing, provided that the plan uses a "reasonable method" to provide access to quality doctors at that reference price.[55] In enforcing the reasonable standard, the government will evaluate a totality of circumstances using categories of factors such as type of service, reasonable access, quality standards, exceptions process, and disclosure.[56] Assuming the insurer has met the reasonable method standard to secure the reference pricing physician, the patient will have access to a quality provider and treatment method and the associated payment will count towards the patient's out-of-pocket maximum.[57] This is important because, for patients to be motivated to use preventative services to reduce their out-of-pocket maximum, achieving their out-of-pocket maximum must be attainable.

E. A Related Alternative to Using the Out-of-Pocket Maximum to Motivate Preventative Care

In the alternative to a solution involving out-of-pocket maximums, policymakers should consider whether it makes more sense to reduce high deductibles as a motivator for patients to engage in preventative care. A healthcare deductible is a dollar amount paid for healthcare prior to the health insurance plan paying for care.[58] Patients consider deductibles when

[54] *Id.*
[55] *Id.*
[56] *Id.*
[57] *Id.*
[58] Les Masterson, *supra* note 6.

deciding on a healthcare plan.[59] In addition, patients will encounter a deductible before they can think about reaching their out-of-pocket maximum.[60]

Whether through a reduction of the out-of-pocket maximum or a reduction in the deductible amount an individual is responsible for, the proposed amendment aims to make a dent in the healthcare financial landscape by incentivizing patients to engage in behaviors that prevent chronic illness. This amendment targets chronic disease prevention in particular because chronic diseases have dramatic health and economic costs in the United States, and prevention is a means of reducing that cost.[61] It will also inspire and incentivize individuals to engage in preventative healthcare measures because a lower out-of-pocket maximum means they will reach the point where their insurer pays for all their healthcare costs sooner.[62]

III. CONCLUSION

The proposed amendment aims to incentivize individuals to engage in behaviors that will prevent chronic illness. Tethering of out-of-pocket maximum costs to preventative care will save and improve the quality of human lives and reduce overall healthcare spending in the United States. The infrastructure to make this amendment possible is already in place. The next step is for legislators to take action to adopt this amendment.

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[59] Gary Claxton et al., *The Cost of Care with Marketplace Coverage*, KAISER FAM. FOUND. (Feb. 11, 2015), https://www.kff.org/health-costs/issue-brief/the-cost-of-care-with-marketplace-coverage/ (noting that "aside from the premium, deductibles are one of the main features that consumers look to when shopping for a health plan").

[60] Les Masterson, *supra* note 6 (stating that someone is more likely to be concerned with a health insurance deductible than the out-of-pocket maximum because an out-of-pocket maximum is mainly a concern in a year where someone encounters significant healthcare costs).

[61] CTR. FOR DISEASE CONTROL & PREVENTION, *supra* note 16.

[62] Masterson, *supra* note 6.