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## Drugs for the Indigent: A Proposal to Revise the 340B Drug Pricing Program

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# NOTES

## DRUGS FOR THE INDIGENT: A PROPOSAL TO REVISE THE 340B DRUG PRICING PROGRAM

### TABLE OF CONTENTS

INTRODUCTION .....	638
I. THE 340B CONTEXT .....	641
<i>A. The History of 340B</i> .....	641
<i>B. The Current Scope and Growth of 340B</i> .....	646
II. 340B CHALLENGES .....	648
<i>A. Immediate Problems with 340B</i> .....	649
1. <i>Definition and Guidance on the Meaning of</i> <i>“Patient”</i> .....	649
2. <i>Hospital Profits</i> .....	652
<i>B. Fundamental Problems with 340B</i> .....	655
1. <i>Authority Structure</i> .....	655
<i>a. Orphan Drug Exemption: PhRMA Litigation and</i> <i>HHS’s Unclear Authority</i> .....	656
2. <i>Diverging Interests and the Purpose of 340B</i> .....	661
III. RETHINKING 340B: A FRAMEWORK .....	664
<i>A. Proposed Solution</i> .....	664
1. <i>Separating 340B from Medicaid</i> .....	664
2. <i>Creating New Eligibility Standards and Requirements</i> <i>for Covered Entities</i> .....	668
<i>a. Patient Eligibility</i> .....	668
<i>b. Requirements for Covered Entities</i> .....	669
3. <i>Authorizing HHS with the Proper Mandate</i> .....	670
<i>B. Potential Outcomes</i> .....	671
1. <i>Potential Benefits</i> .....	671
2. <i>Potential Critiques</i> .....	671
CONCLUSION .....	672

## INTRODUCTION

Everybody, at one point or another, needs medication; not everybody, however, can afford it. With this fact in mind, in 1992, Congress enacted the 340B drug pricing program,<sup>1</sup> a statutory scheme designed to reduce pharmaceutical costs for safety-net medical providers<sup>2</sup> and the indigent populations they serve. Under 340B, pharmaceutical manufacturers are required to offer discounts on certain medications to participating safety-net providers. In theory, the 340B program helps to alleviate part of the financial burden shouldered by medical providers serving indigent populations and creates a low-cost source of pharmaceutical medication for the indigent patients themselves.

Yet despite its intended benefits, the 340B program has proved to be less of a success than Congress originally hoped. To be sure, in the decades since its enactment, 340B has grown significantly. In 2015 alone, branded 340B sales in the United States at wholesale acquisition cost<sup>3</sup> are estimated to total over \$15 billion, 5 percent of

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1. Pub. L. No. 102-585, 106 Stat. 4943 (1992) (codified as amended at 42 U.S.C. § 256b (2015)). There is no hidden significance to the name of the program; “340B” merely denotes the section of the Public Health Service Act in which the program appears.

2. For the purposes of this Note, safety-net providers are healthcare providers that “have demonstrated a commitment to provide care to low-income persons, to those with special needs, and to other vulnerable populations regardless of their ability to pay.” Darrell J. Gaskin & Jack Hadley, *Population Characteristics of Markets of Safety-Net and Non-Safety-Net Hospitals*, 76 J. URB. HEALTH 351, 352 (1999). To that end, safety-net providers “are distinguished by the volume of care they provide to vulnerable populations,” and “[a] relatively high percentage of the patients of safety-net hospitals have low incomes or have conditions ... that require special medical services.” *Id.*

3. See 42 U.S.C. § 1395w-3a(c)(6)(B) (2015) (defining “wholesale acquisition cost” as “the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available”).

all outpatient drug sales in the United States.<sup>4</sup> Total 340B expenditures are expected to reach \$25 billion by 2019.<sup>5</sup>

The program's size, however, is not so much an issue as is its focus. Some analysts have questioned 340B's integrity and purpose, as safety-net hospitals may profit significantly from their participation in the program.<sup>6</sup> For example, suppose Hospital A qualifies for the 340B program and thus receives a significant discount on certain medications because of its status as a safety-net hospital. Under 340B, rather than pass these discounts on to its indigent patients in the form of lower prices for care, Hospital A may charge its patients full price for the drugs and pocket the difference. In this way, some safety-net hospitals have profited over \$100 million per year.<sup>7</sup> Although many safety-net providers undoubtedly need the proceeds, the question left unanswered is whether the indigent patients, for whom the 340B program was arguably created, are receiving any benefit.

Experts familiar with the 340B program recognize this problem, among others.<sup>8</sup> In early 2014, the Department of Health and Human Services (HHS) and the Health Resources and Services Administration (HRSA), the agency tasked with overseeing the 340B program, considered issuing a "mega rule" to resolve the program's internal conflicts and clarify points of dispute.<sup>9</sup> In the summer of 2014, however, a network of pharmaceutical manufacturers and advocacy groups successfully challenged HRSA's authority to publish

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4. AARON VANDERVELDE, BRG HEALTHCARE, MEASURING THE RELATIVE SIZE OF THE 340B PROGRAM 3 (2015), [http://www.thinkbrg.com/media/publication/606\\_Vandervelde\\_340B\\_Whitepaper\\_20150526.pdf](http://www.thinkbrg.com/media/publication/606_Vandervelde_340B_Whitepaper_20150526.pdf) [<http://perma.cc/E3BU-756P>]. This figure has risen significantly from \$6 billion in 2011. U.S. GOV'T ACCOUNTABILITY OFF., GAO-11-836, MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT 2 (2011), <http://www.gao.gov/assets/330/323702.pdf> [<http://perma.cc/MGD3-DS7W>] [hereinafter GAO 2011 REPORT].

5. VANDERVELDE, *supra* note 4, at 3. Earlier reports had estimated that 340B totals would reach \$12 billion in 2016. *See, e.g.*, BIOTECH. INDUS. ORG., THE 340B DRUG DISCOUNT PROGRAM: A REVIEW AND ANALYSIS OF THE 340B PROGRAM 14 (2013), <http://www.bio.org/sites/default/files/340B%20White%20Paper%20FINAL.pdf> [<http://perma.cc/5NXE-ZABR>] [hereinafter BIOTECH]. The 340B program has clearly outpaced those earlier predictions by a significant margin. *See infra* Part I.B for more information on the program's trending growth.

6. *See infra* Part II.A.2.

7. *See infra* Part II.A.2.

8. *See infra* Part II.

9. *See infra* note 73.

legislative rules on 340B, ultimately leaving HRSA on shaky ground to issue any substantive regulations.<sup>10</sup> HRSA scrapped the “mega rule” in November 2014,<sup>11</sup> instead publishing proposed “Omnibus Guidance” in the Federal Register on August 28, 2015.<sup>12</sup> Agency guidance, however, no matter how significant, is not sufficient to fix 340B.

A better solution is to rethink the current form of the 340B program. Simply put, 340B needs to be restructured if it is to fulfill the purpose for which it was originally intended. To date, neither Congress, nor the pharmaceutical industry, nor the expansive network of safety-net medical providers has put forth a realistic plan to comprehensively revise the 340B program. This Note seeks to fill that gap. First, this Note proposes a practical framework for revising 340B to best serve indigent patients, while simultaneously alleviating financial burdens on drug manufacturers and safety-net providers. Second, this Note seeks to spur practical and creative discussion and debate among the various interested parties engaged in the 340B program. The proposal outlined herein may provide a foundation for such discussion and, eventually, reform.

This Note proceeds in three parts. Part I describes the history of 340B—its intended purpose, enactment, and implementation—as well as the program’s current scope and trending growth. Part II evaluates many of the significant problems in the current scheme, which fall broadly into two categories: immediate and fundamental. Contributing to the former category are the insufficient guidance regarding what constitutes a “patient” under 340B<sup>13</sup> and the growing speculation and criticism over hospitals profiting millions of dollars through 340B discounts.<sup>14</sup> The latter category, though, speaks more to issues at the heart of the program: HHS’s lack of authority to properly administer 340B—illustrated through the litigation over the “orphan drug exception”<sup>15</sup>—and the countervailing interests between drug manufacturers and safety-net providers

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10. See *infra* Part II.B.1.a.

11. See *infra* note 73.

12. See 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52,300 (proposed Aug. 28, 2015).

13. See *infra* Part II.A.1.

14. See *infra* Part II.A.2.

15. See *infra* Part II.B.1.

over the purpose of the 340B program and the distribution of the 340B discounts.<sup>16</sup> Part III lays out a practical framework for revising the 340B program: first, unlinking 340B from Medicaid;<sup>17</sup> second, creating new standards for patient eligibility and requirements for covered entities;<sup>18</sup> and finally, granting HHS the proper authority to ensure effective implementation of the new changes and oversee the administration of the 340B program.<sup>19</sup>

## I. THE 340B CONTEXT

### A. *The History of 340B*

In 1992, Congress enacted the 340B drug discount program under the Veterans Health Care Act of 1992<sup>20</sup>—codified as Section 340B of the Public Health Service Act<sup>21</sup>—to help certain safety-net medical service providers “stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”<sup>22</sup>

Congress originally intended the 340B program to correct an unforeseen consequence of the 1990 Medicaid Drug Rebate Program (MDRP), “which required drug manufacturers to offer Medicaid discounts [in the form of rebates to state Medicaid agencies] on outpatient drugs that would at least match the ‘best price’ offered to any other buyer.”<sup>23</sup> Prior to the MDRP, drug manufacturers had voluntarily offered large discounts to Department of Veterans Affairs (VA) hospitals and other safety-net medical providers serving uninsured and indigent populations.<sup>24</sup> Under the MDRP, however, drug manufacturers were forced to extend rebates to Medicaid

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16. See *infra* Part II.B.2.

17. See *infra* Part III.A.1.

18. See *infra* Part III.A.2.

19. See *infra* Part III.A.3.

20. Pub. L. No. 102-585, § 340B, 106 Stat. 4943, 4967-71 (1992).

21. 42 U.S.C. § 256b (2015).

22. H.R. REP. NO. 102-384 (II), at 12 (1992); see also ANDREW W. MULCAHY ET AL., RAND CORP., THE 340B PRESCRIPTION DRUG DISCOUNT PROGRAM: ORIGINS, IMPLEMENTATION, AND POST-REFORM FUTURE 1 (2014), [http://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE121/RAND\\_PE121.pdf](http://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE121/RAND_PE121.pdf) [<http://perma.cc/EAM8-4ZWU>].

23. MULCAHY ET AL., *supra* note 22, at 5; see also S. REP. NO. 102-259, at 6 (1992).

24. See MULCAHY ET AL., *supra* note 22, at 5; see also BIOTECH, *supra* note 5, at 6-7.

“disproportionate share hospitals” (DSHs)<sup>25</sup> and patients, and manufacturers consequently limited discounts to VA hospitals and other safety-net providers not covered by the MDRP in order to save costs.<sup>26</sup> Congress enacted 340B to fix this unintended consequence by preserving the drug discounts manufacturers previously offered safety-net providers. To that end, 340B “imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities,” many of which are “providers of safety-net services to the poor.”<sup>27</sup>

For the sake of clarity, the 340B program may be best understood in economics terminology as the interplay between supply and demand: supply from pharmaceutical manufacturers and demand from covered entities and patients. On the supply side, as a condition to receiving Medicaid matching funds under state Medicaid programs or participating in the Department of Defense and VA prescription drug contracting programs, any pharmaceutical manufacturer<sup>28</sup> that sells “covered outpatient drugs”<sup>29</sup> must enter into a Pharmaceutical Pricing Agreement (PPA) with the HHS Secretary to provide certain drugs to “covered entities” at a discounted rate.<sup>30</sup> The definition of a “covered drug” generally includes only certain

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25. *See infra* note 40.

26. BIOTECH, *supra* note 5, at 6; MULCAHY ET AL., *supra* note 22, at 5.

27. *Astra USA, Inc. v. Santa Clara Cty.*, 131 S. Ct. 1342, 1345 (2011).

28. “Manufacturer” is defined broadly by the Social Security Act as any entity that engages in—

(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

(B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

42 U.S.C. § 1396r-8(k)(5) (2015). 340B’s definition of “manufacturer” applies regardless of whether the entity participates in the Medicaid rebate program. Guidance Regarding Section 602 of the Veterans Health Care Act of 1992; Limitation on Prices of Drugs Purchased by Covered Entities, 58 Fed. Reg. 27,291 (May 7, 1993).

29. *See infra* note 31.

30. *See* 42 U.S.C. § 256b(a)(1); *Astra*, 131 S. Ct. at 1345; *Univ. Med. Ctr. of S. Nev. v. Shalala*, 173 F.3d 438, 439 (D.C. Cir. 1999). For a more thorough discussion of “covered entities,” see *infra* notes 38-54 and accompanying text.

outpatient drugs dispensed by a “covered entity”; inpatient services are not covered.<sup>31</sup>

Once a manufacturer has signed a PPA, it is barred from charging covered entities any drug price exceeding a cap set by HHS.<sup>32</sup> This price cap, called the ceiling price, is calculated by subtracting the Medicaid unit rebate amount<sup>33</sup> (essentially a minimum discount)<sup>34</sup> from the average manufacturer price (AMP).<sup>35</sup>

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31. See 42 U.S.C. § 256b(b)(2); U.S. GOV'T ACCOUNTABILITY OFF., GAO-15-442, MEDICARE PART B DRUGS: ACTION NEEDED TO REDUCE FINANCIAL INCENTIVES TO PRESCRIBE 340B DRUGS AT PARTICIPATING HOSPITALS 7 n.23 (2015), <http://www.gao.gov/assets/680/670676.pdf> [<http://perma.cc/Z5FJ-U2CV>] [hereinafter GAO 2015 REPORT] (noting that “outpatient covered drugs may include: prescription drugs approved by the Food and Drug Administration; certain over-the-counter drugs provided as prescriptions; biological products, other than vaccines, which can be dispensed only by a prescription; and insulin approved by the Food and Drug Administration”). The definition of a “covered drug” is linked to the Social Security Act’s (SSA) definition of “covered outpatient drug” in § 1927(k)(2). See 42 U.S.C. §§ 256b(b)(2)(A), 1396r-8(k)(2). The SSA requires that the covered drugs be dispensed only upon prescription and meet standard certification protocols. *Id.* § 1396r-8(k)(2). The Act also provides that some specific types of drugs may be excluded from coverage, *id.* § 1396r-8(d)(2), and limits coverage for drugs “provided as part of, or as incident to and in the same setting as,” among other things, “[i]npatient hospital services, [h]ospice services, [d]ental services, ... [or] [o]utpatient hospital services,” *id.* § 1396r-8(k)(3). The clear implication is that the definition of a covered drug is tied to the type of entity to which it is sold by the manufacturer; in other words, Drug A may be a “covered drug” for Entity A, but not for Entity B. Interestingly, the SSA’s definition of “covered entity” links directly to 340B’s definition of “covered entity,” bringing the definitional chain full circle. See *id.* § 1396r-8(a)(5)(B). In short, whether a manufacturer must offer a discount on a particular drug depends almost entirely on the nature of the entity to which the manufacturer sells the drug. In certain specific cases, however, the nature of the medication may be dispositive. See *infra* Part II.A.1.

32. See 42 U.S.C. § 256b(a)(1).

33. This is calculated under the complex statutory formula in 42 U.S.C. § 1396r-8(c). The total possible rebate percentage is capped at 100 percent of the price of the drug. *Id.* § 1396r-8(c)(2)(D). Because the rebate calculation is quite intricate, it is enough for current purposes to deal only with the minimum rebate possible, though it is important to note that the minimum rebate is only a floor.

34. From January 1, 2010, onward, the minimum discount for generic drugs and prescribed over-the-counter drugs is 13 percent of a drug’s AMP. See 42 U.S.C. §§ 256b(a)(2)(B), 1396r-8(c)(3)(B). The minimum discount for brand-name drugs is the greater of 23.1 percent of AMP, see *id.* § 1396r-8(c)(1)(B)(i), or AMP less the best price offered to any other purchaser, see *id.* § 1396r-8(c)(1)(C).

35. The AMP for a drug is calculated as the average price a manufacturer charges for the drug in the United States to wholesalers and retail community pharmacies. *Id.* § 1396r-8(k)(1). Manufacturers report these prices as proprietary information to the Center for Medicare and Medicaid Services (CMS) and may be subject to audit by HHS. See HHS, OFFICE OF INSPECTOR GEN., OEI-05-05-00240, MEDICAID DRUG PRICE COMPARISONS: AVERAGE MANUFACTURER PRICE TO PUBLISHED PRICES 4 (2005), <http://oig.hhs.gov/oei/reports/oei-05-05-00240.pdf> [<http://perma.cc/5V7A-4SJJ>].



For example, suppose a drug manufacturer (A-Corp) produces an innovator drug<sup>36</sup> called Rx-A, for which A-Corp receives an average price of \$100 from both wholesalers and retail pharmacies. Assuming that the applicable discount percentage is the statutory minimum discount of 23.1 percent for brand-name drugs, the ceiling price that A-Corp may charge covered entities for Rx-A is \$76.90. Unsurprisingly, manufacturers are completely free to charge less than the ceiling price if they choose.<sup>37</sup>

On the demand side, to qualify as a “covered entity” and receive 340B drug discounts, a provider must either receive money from one of ten types of federal grants or qualify as one of six specified types of hospitals.<sup>38</sup> All of the grantee eligibility criteria are specifically tied to certain patient groups that are targeted for special assistance.<sup>39</sup> Hospital eligibility is similarly linked to specific populations: disproportionate share hospitals (DSH),<sup>40</sup> children’s hospitals and free-standing cancer hospitals subject to certain

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36. An “innovator drug” is one that is “marketed under an original new drug application approved by the Food and Drug Administration.” 42 U.S.C. § 1396r-8(k)(7)(A)(ii).

37. *See id.* § 256b(a)(10).

38. *See id.* § 256b(a)(4); GAO 2011 REPORT, *supra* note 4, at 8; BIOTECH, *supra* note 5, at 7. In 2010, the Affordable Care Act (ACA) expanded the original eligibility list “to include free-standing cancer hospitals, critical access hospitals, sole community hospitals and rural referral centers.” MULCAHY ET AL., *supra* note 22, at 6.

39. For example, HIV patients, AIDS patients, black lung patients, hemophilia patients, Native Hawaiian Health Centers, and urban Indian organizations. 42 U.S.C. § 256b(a)(4)(D)-(I).

40. *Id.* § 256b(a)(4)(L). A disproportionate share hospital is one that:

is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act ... or eligible for assistance under the State plan under this subchapter.

*Id.* § 256b(a)(4)(L)(i). Additionally, to qualify as a DSH, a hospital must have had a disproportionate share adjustment percentage (DSAP) greater than 11.75 percent for the most recent cost reporting period as calculated under the SSA’s statutory formula. *Id.* § 256b(a)(4)(L)(ii). Rural referral centers and sole community hospitals are only required to have an 8 percent DSAP. *Id.* § 256b(a)(4)(O). Broadly speaking, the more Medicaid/Medicare patients a hospital treats as a percentage of the hospital’s total patient population, the higher the hospital’s DSAP. GAO 2011 REPORT, *supra* note 4, at 5 n.15. The DSAP is an established way to identify hospitals that expend large amounts of uncompensated service on indigent populations, making it a useful trigger for 340B eligibility.

provisions,<sup>41</sup> critical access hospitals,<sup>42</sup> sole community hospitals,<sup>43</sup> and rural referral centers.<sup>44</sup> DSHs were targeted by 340B from its original enactment; children's hospitals were included in 2006, and the other hospital types were added to the program under the Affordable Care Act (ACA).<sup>45</sup> Off-site clinics and other care facilities associated with 340B entities may also participate in the program if they are "integral part[s]" of the entity, included on the covered entity's most recent Medicare cost report.<sup>46</sup>

Covered entities must adhere to certain additional requirements under 340B to remain eligible. Among other criteria, covered entities may not claim both 340B price reductions and "medical assistance" under the MDRP: a so-called duplicate discount.<sup>47</sup> The HHS Secretary is tasked with establishing a mechanism to ensure compliance with this provision.<sup>48</sup> Additionally, if a covered entity receives a 340B discount on a drug, the entity may not "resell or otherwise transfer" the drug to anyone who is not a patient of the entity.<sup>49</sup> For example, Entity A cannot collect a discount on a drug, resell the drug on the open market for full market price, and profit from the difference.

To ensure compliance, 340B establishes auditing and sanction mechanisms for those entities that violate the double-discount and resell prohibitions.<sup>50</sup> Interestingly, the program ran nearly twenty years without any formal auditing by HRSA, instead relying primarily on "self-policing" by both manufacturers and covered entities.<sup>51</sup> HRSA increased its oversight only after the Government Accountability Office (GAO) released a report in 2011 concluding that HRSA's guidance to that point was "inadequate to provide reasonable assurance that covered entities and drug manufacturers are

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41. *Id.* § 256b(a)(4)(M).

42. *Id.* § 256b(a)(4)(N).

43. *Id.* § 256b(a)(4)(O).

44. *Id.*

45. GAO 2011 REPORT, *supra* note 4, at 9 n.24.

46. GAO 2015 REPORT, *supra* note 31, at 8 (citing 59 Fed. Reg. 47,884 (Sept. 19, 1994)).

47. 42 U.S.C. § 256b(a)(5)(A).

48. *Id.*

49. *Id.* § 256b(a)(5)(B). See *infra* Part II.A.1 for a discussion of the problems surrounding the ambiguous definition of a "patient."

50. 42 U.S.C. § 256b(a)(5)(C)-(D).

51. GAO 2011 REPORT, *supra* note 4, at 21; MULCAHY ET AL., *supra* note 22, at 7.

in compliance with program requirements.”<sup>52</sup> In the wake of the 2011 GAO Report, HRSA required that “covered entities [1] recertify their eligibility every year, [2] immediately notify HRSA if they experience changes in eligibility, [3] register new outpatient facilities and contract pharmacy agreements on a quarterly basis, and [4] perform annual internal audits of their 340B programs.”<sup>53</sup> The requirements for covered entities continue to evolve as HRSA issues additional guidance.<sup>54</sup>

### *B. The Current Scope and Growth of 340B*

By any measurement, the 340B program involves a significant amount of money and thousands of covered entities, and continues to grow at a rapid pace. According to the RAND Corporation, as of late 2014, there were an estimated 7898 covered entities enrolled in 340B, comprising 16,869 covered entity sites.<sup>55</sup> Other estimates report that, as of March 2015, there were over 30,000

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52. MULCAHY ET AL., *supra* note 22, at 7.

53. *Id.*

54. *See, e.g.*, Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52,300 (proposed Aug. 28, 2015). The Omnibus Guidance is ambitious in scope, covering eight general areas: (1) “Program Eligibility and Registration,” *id.* at 52,301-05, 52,316-19; (2) “Drugs Eligible for Purchase,” *id.* at 52,305-06, 52,319; (3) “Individuals Eligible to Receive 340B Drugs,” *id.* at 52,306-08, 52,319; (4) “Covered Entity Requirements,” *id.* at 52,308-10; (5) “Contract Pharmacy Arrangements,” *id.* at 52,310-11, 52,320-21; (6) “Manufacturer Responsibilities,” *id.* at 52,311-13, 52,321-22; (7) “Rebate Options for AIDS Drug Assistance Programs,” *id.* at 52,313-14, 52,322; and (8) “Program Integrity,” *id.* at 52,314-16, 52,322-24. The majority of the proposals are generally tangential, and thus not relevant, to the purposes of this Note. For a brief summary of these proposals, see Alan J. Arville et al., *Health Resources and Service Administration (HRSA) Issues Proposed “Omnibus Guidance,”* NAT’L L. REV. (Aug. 28, 2015), <http://www.natlawreview.com/article/health-resources-and-service-administration-hrsa-issues-proposed-omnibus-guidance> [<http://perma.cc/EN97-K985>]. The one portion relevant to this Note is the section clarifying the definition of a “patient” for 340B purposes. Part II.A.1 discusses this clarification and its implications in more depth.

55. MULCAHY ET AL., *supra* note 22, at 8; *see also* GAO 2011 REPORT, *supra* note 4, at 2-3. These numbers are estimated using the entity information from HRSA’s 340B dataset. *See generally* 340B Drug Pricing Program Database, HRSA OFF. OF PHARMACY AFF., <https://openet.hrsa.gov/340B/Default> [<http://perma.cc/YAN3-66RT>] (last visited Oct. 23, 2015). Covered entities may also disperse 340B covered drugs at “off-site facilities,” such as outpatient clinics, which are included within the 340B designation of the parent covered entity. *See* Notice Regarding Section 602 of the Veteran Health Care Act of 1992 Outpatient Hospital Facilities, 59 Fed. Reg. 47,884 (Sept. 19, 1994); *see also* GAO 2011 REPORT, *supra* note 4, at 10.

340B-participating sites.<sup>56</sup> Of these covered entities, 1673 are hospitals, amounting to roughly 40 percent of all hospitals nationwide.<sup>57</sup> 340B-participating hospitals account for roughly 48 percent of all U.S. outpatient hospital visits, and 38 percent by DSHs alone.<sup>58</sup> The scope of the 340B program is quite expansive, even if measured only by the sheer number of entities involved.

As to growth, the number of covered entity sites nearly doubled in the decade from 2001 to 2011, from 8605 to 16,572.<sup>59</sup> Section 340B contract pharmacy arrangements have also exploded in number: in 1999, there were 70 pharmacies contracted under 340B; in 2013, the number of contract pharmacies totaled 12,240.<sup>60</sup> Additionally, in light of the ACA's additions to the definition of "covered entity" and its expansion of the Medicaid program, there is no doubt that the number of 340B enrollees will continue to grow significantly.<sup>61</sup>

The amount of pharmaceutical medication purchased under the 340B program is sizable. The GAO estimated in 2011 that outpatient drug purchases under the 340B program totaled at least \$6 billion annually;<sup>62</sup> that number has risen to an estimated \$15 billion

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56. See AVALERE HEALTH, HOSPITAL ACQUISITIONS OF PHYSICIAN PRACTICES AND THE 340B PROGRAM, 3 (2015), <http://340breform.org/userfiles/Avalere%20Acquisition.pdf> [<http://perma.cc/W6QK-3FM9>].

57. Julia E. Tomkins, *Policy Statement on the 340B Drug Pricing Program*, 10 J. ONCOLOGY PRAC. 259, 259 (2014) [hereinafter *ASCO Statement*]; see also GAO 2015 REPORT, *supra* note 31, at 1.

58. MULCAHY ET AL., *supra* note 22, at 8.

59. GAO 2011 REPORT, *supra* note 4, at 8.

60. BIOTECH, *supra* note 5, at 13. Covered entities use contract pharmacies to distribute 340B prescriptions off-site, which allows greater flexibility in dealing with patient needs. *ASCO Statement*, *supra* note 57, at 260. HRSA originally allowed only entities without an on-site pharmacy to contract with an off-site pharmacy. Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,555 (Aug. 23, 1996). Shortly before the ACA was passed in 2010, HRSA amended their guidance and allowed all hospitals to enter into contract pharmacy arrangements. Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010). This accounts for the rapid expansion in contract pharmacies since 2010: 2646 to 6915 in the first year alone, a 161 percent increase. *ASCO Statement*, *supra* note 57, at 260.

61. BIOTECH, *supra* note 5, at 13-14; *ASCO Statement*, *supra* note 57, at 260. Recent data suggest that 340B entities may acquire physician practices in order to realize additional profits under the 340B program. See AVALERE HEALTH, *supra* note 56, at 2-3. Absent a fundamental change in the nature of the program, it can be expected to grow because strong incentives exist to maximize hospital profits.

62. GAO 2011 REPORT, *supra* note 4, at 2.

in 2015.<sup>63</sup> The industry frequently cites that 340B purchases total roughly 2 percent of all drug purchases in the United States,<sup>64</sup> but the real figure is likely closer to 5 percent and rising.<sup>65</sup> 340B purchases are conservatively expected to grow to \$18.5 billion by 2016, and \$25 billion by 2019.<sup>66</sup> Assuming that 340B discounts are similar to those under the Medicaid Prescription Drug Rebate program, 340B currently saves participating hospitals a conservatively estimated \$1.6 billion annually.<sup>67</sup>

## II. 340B CHALLENGES

The current 340B program contains problems that present difficult challenges for policymakers. This Note roughly categorizes these problems as either immediate or fundamental. Contributing to the former category are the insufficient guidance regarding the definition of a “patient,”<sup>68</sup> and the mounting skepticism and criticism of some 340B covered entities for profiting millions of dollars annually from the program.<sup>69</sup> These problems, however, are symptoms of more fundamental issues. The latter category strikes more at the heart of the program itself: HHS’s inability to properly administer 340B due to the lack of a congressional mandate, illustrated by the “orphan drug rule” litigation,<sup>70</sup> and the competing incentives and interests between drug manufacturers and safety-net hospitals.<sup>71</sup>

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63. See VANDERVELDE, *supra* note 4, at 3.

64. See, e.g., *340B Drug Pricing Program*, AM. HOSP. ASS’N, <http://www.aha.org/research/policy/infographics/340b.shtml> [<http://perma.cc/ZX9S-794R>] (last visited Oct. 23, 2015); CTRS. FOR MEDICARE & MEDICAID SERVS., NATIONAL HEALTH EXPENDITURES tbl. 16, <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/tables.pdf> [<http://perma.cc/D27U-S83B>].

65. See VANDERVELDE, *supra* note 4, at 3.

66. *Id.* It is important to note that these figures are in constant flux as a result of the rapid growth in the number of 340B-participating entities and the malleable nature of statistics. Other sources, even recently, have estimated lower totals. See, e.g., Travis Jackson, *A Matter of Interpretation: How the Orphan Drug Litigation Tests the Limits of 340B Program Guidance*, 16 J. HEALTH CARE COMPLIANCE 5, 5 (2014) (noting that 340B sales are “expected to hit \$16 billion by 2019”).

67. MULCAHY ET AL., *supra* note 22, at 8.

68. See *infra* Part II.A.1.

69. See *infra* Part II.A.2.

70. See *infra* Part II.B.1.

71. See *infra* Part II.B.2.

*A. Immediate Problems with 340B**1. Definition and Guidance on the Meaning of “Patient”*

In its 2011 340B report, the GAO concluded that “HRSA’s guidance on key program requirements often lacks the necessary level of specificity to provide clear direction, making it difficult for participants to self-police or monitor others’ compliance and raising concerns that the guidance may be interpreted in ways that are inconsistent with its intent.”<sup>72</sup>

Consistent with the GAO’s critique, ambiguous definitions and insufficient guidance have been and are problems within the 340B program. A prime example is that, despite repeated calls from stakeholders for clarification, HRSA has only recently offered guidance on the central definition of what constitutes a “patient.”<sup>73</sup> Although HRSA initially defined “patient” in 1996<sup>74</sup> and promised a more thorough treatment of the subject,<sup>75</sup> it was not until August 2015 that HRSA followed up on its promise.<sup>76</sup>

The 1996 definition gave covered entities wide discretion as to which patients could receive 340B drugs, creating unnecessary confusion. The 1996 guidance delineated three criteria for patient eligibility:

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72. GAO 2011 REPORT, *supra* note 4, at 22.

73. Jaimy Lee, *Expected 340B Drug Discount Rule May Tighten Program*, MOD. HEALTHCARE (May 15, 2014), <http://www.modernhealthcare.com/article/20140515/NEWS/305159940> [<http://perma.cc/CGU2-BNLN>]. In November 2014, HRSA scrapped the proposed “mega-reg” it had announced it would issue on definition issues and other problems. Ellyn L. Sternfield, *The 340B Mega-Reg Is Dead re: Drug Discount Program*, NAT’L L. REV. (Nov. 19, 2014), <http://www.natlawreview.com/article/340b-mega-reg-dead-re-drug-discount-program> [<http://perma.cc/F8DG-4VH2>]. HRSA likely dropped the proposal due to the tension between the orphan drug litigation and the D.C. District Court’s ruling that HHS did not have the congressional authority to issue legislative rules. *Id.*

74. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55,156, 55,156-58 (Oct. 24, 1996).

75. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of a “Patient,” 72 Fed. Reg. 1543, 1544 (Jan. 12, 2007).

76. See 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52,300, 52,319 (proposed Aug. 28, 2015).

(1) the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and

(2) the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and

(3) the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided.<sup>77</sup>

Three points are worth noting. First, the definition of patient—and therefore patient eligibility—is conditioned primarily upon entity eligibility, essentially qualifying all patients of an entity so long as the entity itself is qualified. Consequently, covered entities may reap significant profits from the discounts they receive. Part II.A.2 discusses this in greater detail. Second, absent anywhere in the definition is an income or insurance requirement. Although Congress's original intent for 340B may have been to help safety-net hospitals and indigent populations, any patient, regardless of their wealth, could qualify for 340B discounted drugs through a qualified entity. Perhaps this would not be a significant problem if covered entities distinguished between patients themselves, but as Part II.A.2 discusses, this does not seem to happen. Third, many of the terms in this definition are themselves left undefined and are vulnerable to a wide range of interpretation. For example, “maintain[ing] records of the individual's health care”<sup>78</sup> has become almost meaningless with the rise of digital medical records, which may be stored in an off-site server and accessed by multiple care providers.<sup>79</sup>

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77. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. at 55,156-58.

78. *Id.* at 55,157.

79. This ambiguity may be further exacerbated by the rise of Accountable Care Organizations (ACOs) and Health Information Exchanges (HIEs), which promote integrated service and the sharing of patient information between care providers. See generally Ctrs. for Medicare & Medicaid Servs., *Accountable Care Organizations*, CMS.GOV, <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ACO/index.html> [<http://perma.cc/T6A7-U6VV>] (last modified Jan. 6, 2015); *Health Information Exchange*, HEALTHIT.GOV, <http://www.healthit.gov/providers-professionals/health-information-exchange/what-hie> [<http://perma.cc/>]

HRSA's Omnibus Guidance updates, but does not fully resolve, the patient definition problem. The Omnibus Guidance narrows the scope of the 1996 definition by adding additional specific factors for patient eligibility.<sup>80</sup> With notable exceptions,<sup>81</sup> the proposals seem to clarify the scope and meaning of "patient," perhaps alleviating some of the problems discussed under the third point above. The first two points, however, apply with equal force to the new guidance, and further agency guidance is unlikely to sufficiently resolve the tension.

Fundamentally, if patient eligibility is contingent on covered entity eligibility, covered entities should have a way to distinguish

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B8TL-YXHH] (last updated May 12, 2014). The interplay of the rise of coordinated health care and the 340B program is not the focus of this Note. It is enough for present purposes to note that any ambiguities in 340B's definitions will likely be aggravated by the modernization and integration of the healthcare industry. At bottom, definitions that may have sufficed in 1996 do not necessarily harmonize well with modern medicine.

80. 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. at 52,319. The guidance delineates six factors:

(1) The individual receives a health care service at a covered entity site which is registered for the 340B Program and listed on the public 340B database;

(2) The individual receives a health care service from a health care provider employed by the covered entity or who is an independent contractor of the covered entity such that the covered entity may bill for services on behalf of the provider;

(3) An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in (2). An individual will not be considered a patient of the covered entity if the only health care received by the individual from the covered entity is the infusion of a drug or the dispensing of a drug;

(4) The individual receives a health care service that is consistent with the covered entity's scope of grant, project or contract;

(5) The individual is classified as an outpatient when the drug is ordered or prescribed. The patient's classification status is determined by how the services for the patient are billed to the insurer .... An individual who is self-pay, uninsured, or whose cost of care is covered by the covered entity will be considered a patient if the covered entity has clearly defined policies and procedures that it follows to classify such individuals consistently; and

(6) The individual has a relationship with the covered entity such that the covered entity maintains access to auditable health care records which demonstrate that the covered entity has a provider-to-patient relationship, that the responsibility for care is with the covered entity, and that each element of this patient definition in this section is met for each 340B drug.

81. For example, the guidance notes that "HHS interprets this section to include all patients that meet all of the following criteria on a prescription-by-prescription or order-by-order basis." *Id.* No indication is given as to how this ad hoc analysis impacts patient eligibility or how HRSA intends to implement this in the future, if at all.



between patients based on their ability to pay for medication. It makes little sense for covered entities, regardless of how they qualify for 340B, to receive the same discounts from manufacturers for medications prescribed to patients who are fully insured as those prescribed to patients with no ability to pay. This is true, of course, unless patients are not treated as a homogeneous class, meaning that covered entities could either collect or pass on different discounts to separately defined groups of patients based on their ability to pay. Part III.A.2.a discusses this possibility in more detail.

Considering the scope of 340B and the money at stake, ambiguity and tension within the definition of “patient” is problematic for both HRSA and covered entities. Further guidance cannot sufficiently resolve the patient definition problem, due to the inherent non-binding and ambiguous nature of agency guidance. More fundamental change is needed. Part III will discuss a better solution.

## 2. Hospital Profits

Section 340B-participating covered entities have recently suffered severe scrutiny from critics who argue that 340B entities are illegitimately profiting off the program’s discounts.<sup>82</sup> Two primary factors contribute to this debate. First, hospitals receiving 340B discounts are not required under the program to pass on any of the 340B savings to the patients purchasing the drugs.<sup>83</sup> Thus, covered

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82. See, e.g., Helen Adamopoulos, *Are Hospitals Abusing the 340B Drug Discount Program? New Study Reignites Controversy*, BECKER'S HOSP. CFO (Oct. 7, 2014), <http://www.beckershospitalreview.com/finance/are-hospitals-abusing-the-340b-drug-discount-program-new-study-reignites-controversy.html> [<http://perma.cc/3SSP-QYXJ>]; Scott Gottlieb, Opinion, *How ObamaCare Hurts Patients*, WALL ST. J. (July 30, 2013, 7:16 PM), <http://online.wsj.com/news/articles/SB10001424127887324110404578630522319113676> [<http://perma.cc/X3Y7-FK6T>]; Andrew Pollack, *Dispute Develops over Discount Drug Program*, N.Y. TIMES (Feb. 12, 2013), <http://www.nytimes.com/2013/02/13/business/dispute-develops-over-340b-discount-drug-program.html> [<http://perma.cc/Q9AF-74B9>].

83. See Rena M. Conti & Peter B. Bach, *Cost Consequences of the 340B Drug Discount Program*, 309 JAMA 1995, 1995 (2013), <http://jama.jamanetwork.com/article.aspx?articleid=1680369> [<http://perma.cc/NQ7F-FHJF>]. Critics of the 340B program characterize this revenue stream as “profit,” and argue that the lack of a “pass-on” requirement is a noticeable gap in the program and is a win for the hospitals and a loss for the patients. See Stephen T. Parente & Michael Ramlet, *Unprecedented Growth, Questionable Policy: The 340B Drug Program* (Med. Indus. Leadership Inst., Working Paper), <http://carlsonschool.umn.edu/faculty-research/medical-industry-leadership-institute/publications/working-papers-archives> [<http://perma.cc/B8YH-394V>]; Sally Pipes, *In Federal Drug Program, Hospitals and Pharmacies Use the Poor*

entities may purchase pharmaceuticals at 340B prices and resell the medication to their patients at full price.<sup>84</sup> Second, under the flexible definition of “patient,” participating hospitals can collect discounts on a wide variety of patients—from the uninsured to those with the best health insurance coverage.<sup>85</sup> Section 340B hospitals can therefore “generate profits by prescribing drugs to patients who have private insurance or Medicare.”<sup>86</sup>

In June 2015, the GAO published a report on the 340B program comparing Medicare Part B reimbursement to 340B covered entities with reimbursement to non-340B entities.<sup>87</sup> The report concluded that “[o]n average, per beneficiary Medicare spending on Part B drugs in 2008 and 2012 was substantially higher at 340B DSH hospitals compared with non-340B hospitals.”<sup>88</sup> Generally, this difference in spending could not be explained by “hospital characteristics or patients’ health status,” which suggests that, on average, “Medicare beneficiaries were prescribed more drugs, more expensive drugs, or both, at 340B DSH hospitals.”<sup>89</sup> These findings led the

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*to Get Rich*, FORBES (Aug. 15, 2014, 11:06 AM), <http://www.forbes.com/sites/sallypipes/2014/08/15/in-federal-drug-program-hospitals-and-pharmacies-use-the-poor-to-get-rich/> [<http://perma.cc/SQ97-M4H7>]. On the other hand, 340B’s proponents call the revenue “savings,” and contend that hospitals use the money to benefit their vulnerable patients. SAFETY NET HOSPS. FOR PHARM. ACCESS, SETTING THE RECORD STRAIGHT ON 340B: A RESPONSE TO CRITICS 4 (2013), [www.340bhealth.org/files/Setting\\_the\\_Record\\_Straight\\_Report.pdf](http://www.340bhealth.org/files/Setting_the_Record_Straight_Report.pdf) [<http://perma.cc/67EW-C79P>]. Both sides make some legitimate points, but because 340B is such a complex program and the competing interests are so intense, much of the nuance of the conflict is lost in both sides’ broad brushstrokes.

84. This is assuming, of course, that the covered entities fulfill all other requirements.

85. See, e.g., Letter from Sen. Charles E. Grassley, Ranking Member, S. Comm. on the Judiciary, to Mary K. Wakefield, Adm’r, HRSA (Mar. 7, 2013), <http://www.grassley.senate.gov/sites/default/files/about/upload/2013-03-27-CEG-to-HRSA-340B-Oversight-3.pdf> [<http://perma.cc/6XAJ-HQBJ>] [hereinafter Grassley Letter]. This stems in part from the lack of an income trigger in 340B’s definition of a patient. Because patient eligibility is conditioned primarily upon covered entity eligibility, hospitals have wide latitude in dispensing 340B drugs. See *supra* Part II.A.1.

86. Rena M. Conti & Peter B. Bach, *The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities*, 33 HEALTH AFF. 1786, 1786 (2014) (citing Conti & Bach, *supra* note 83, at 1995).

87. See GAO 2015 REPORT, *supra* note 31.

88. *Id.* at 30.

89. *Id.* at 20, 30. Specifically, the GAO reported that, “in 2012, average per beneficiary spending at 340B DSH hospitals was \$144, compared to \$60 and \$62 at non-340B DSH and other non-340B hospitals, respectively.” *Id.* at 20. This difference could severely impact indigent patients at 340B DSH hospitals through higher medication co-payments and resulting increased insurance premiums. *Id.* at 29.

GAO to conclude that “340B hospitals may be responding to [the] incentive to maximize Medicare revenues,” posing “serious consequences to the Medicare program and its beneficiaries.”<sup>90</sup>

Section 340B profits can be significant. In 2012, Senator Charles Grassley collected data from three North Carolina hospitals to discover how much revenue the hospitals collected as a result of participating in the 340B program.<sup>91</sup> In 2008, Carolinas Medical Center gained \$13 million from 340B savings, UNC Hospital gained \$33 million, and Duke University Health System gained \$89 million.<sup>92</sup> By 2012, those numbers had increased to \$21 million, \$65 million, and \$136 million, respectively.<sup>93</sup> Specifically, Duke’s 2012 340B revenue constituted 6 percent of its \$2.329 billion in net patient service revenue for the year.<sup>94</sup> Ninety-five percent of Duke’s patients were covered through Medicaid, Medicare, and commercial insurance.<sup>95</sup> The other two hospitals showed similar trends.<sup>96</sup> These findings indicate that, at least for these hospitals, 340B generates sizable profits or savings from insured populations.

In 2014, *Health Affairs* published a hotly contested study reporting that hospitals signing onto the 340B program after 2004 tended to be located in higher-income communities than those that joined earlier.<sup>97</sup> The data seem to fit with the rise in media complaints regarding illegitimate 340B profits.<sup>98</sup> As the study’s critics point out, however, the census data utilized by the study does not show the incomes of the patients the hospitals actually treated.<sup>99</sup> That said, if 340B is a program designed to alleviate the cost of

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90. *Id.* at 30.

91. See Grassley Letter, *supra* note 85.

92. *Id.*

93. *Id.*

94. See DUKE UNIV. HEALTH SYS., INC. & AFFILIATES, CONSOLIDATED FINANCIAL STATEMENTS (2013), <http://emma.msrb.org/ER710834-ER551226-ER952286.pdf> [<http://perma.cc/VVB6-FQJ9>].

95. See Grassley Letter, *supra* note 85. Duke responded that it reinvested at least some of its 340B earnings into “primary care wellness clinics within four Durham [North Carolina] public schools.... These []clinics operate during the school year and provide medical and mental health services, including medical coverage during weekends and school holidays.” *Id.*

96. *Id.*

97. Conti & Bach, *supra* note 86, at 1789-90.

98. See Adamopoulos, *supra* note 82; Pollack, *supra* note 82.

99. See Maureen Testoni & Charles Hart, *Drug Discount Analysis Misses the Mark*, HEALTH AFF. BLOG (Oct. 8, 2014), <http://healthaffairs.org/blog/2014/10/08/drug-discount-analysis-misses-the-mark/> [<http://perma.cc/S5B7-VTFL>].

expensive medication for safety-net hospitals and indigent patients, one would likely expect the majority of participants to be located in lower-income areas. Although the absence of such a finding is certainly not definitive proof of unfair profit seeking by 340B participants, it does call into question the purpose of the program and whether its current scope is appropriate.

Regardless of the validity of either side's arguments, the very existence of this debate betrays more fundamental competing interests. As 340B continues to expand, these mini-debates will continue to churn.<sup>100</sup>

## *B. Fundamental Problems with 340B*

### *1. Authority Structure*

HHS—and HRSA by extension—does not have the necessary grant of authority from Congress to properly implement the 340B program.<sup>101</sup> Congress granted HHS authority to issue legislative rules regarding the 340B program in three very limited circumstances only: (1) establishing an administrative dispute resolution process;<sup>102</sup> (2) regulating the precise standards for calculating 340B ceiling prices;<sup>103</sup> and (3) imposing monetary civil sanctions.<sup>104</sup> Thus, HHS's administrative hands are often tied when it comes to updating and implementing 340B. The litigation over the “orphan drug rule” is illustrative.

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100. This discussion does not touch on fraud, another opportunity for significant profit for 340B covered entities. The purpose of this Note, however, is to explore problems and solutions within the legitimate bounds of the 340B program. Considering the current self-policing nature of the program, there is ample opportunity for 340B fraud, but attempting to close all loopholes is outside the scope of this Note.

101. *See generally* Pharm. Research & Mfrs. of Am. v. HHS (*PhRMA I*), 43 F. Supp. 3d 28, 39-45 (D.D.C. 2014).

102. *See* 42 U.S.C. § 256b(d)(3)(A) (2015).

103. *See id.* § 256b(d)(1)(B)(i)(I).

104. *See id.* § 256b(d)(1)(B)(vi).

*a. Orphan Drug Exemption: PhRMA Litigation and HHS's Unclear Authority*

In 1983, Congress passed the Orphan Drug Act (ODA) as an amendment to the Federal Food, Drug, and Cosmetic Act.<sup>105</sup> Congress intended the ODA “to facilitate the development of drugs for rare diseases and conditions.”<sup>106</sup> A “rare disease or condition” is defined as one which “affects less than 200,000 persons in the United States, or ... affects more than 200,000 ... and for which there is no reasonable expectation that the cost of developing and making available ... a drug for such disease or condition will be recovered from sales.”<sup>107</sup> To encourage production of so-called orphan drugs, the ODA created incentives for pharmaceutical manufacturers: “(1) a seven-year market exclusivity period for the orphan drug[,] ... (2) a clinical tax credit for any expenses incurred in developing an orphan drug, ... (3) research grants for clinical testing, ... and (4) an exemption from new drug application fees.”<sup>108</sup>

Outside the 340B context, the ODA presents legitimate incentives for pharmaceutical manufacturers. However, because 340B and the ODA incentivize countervailing and logically inconsistent actions—340B imposes a price ceiling on pharmaceutical sales, while the ODA grants drug manufacturers short-term monopoly power—Congress exempted orphan drugs from 340B discounts in 2010 to maintain the ODA’s incentives within 340B.<sup>109</sup> In short, 340B covered entities would not receive program discounts for ODA pharmaceuticals.

Because many orphan drugs are also used for non-orphan purposes,<sup>110</sup> HHS published a rule on July 23, 2013,<sup>111</sup> establishing

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105. Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (Jan. 4, 1983).

106. *PhRMA I*, 43 F. Supp. 3d at 31.

107. 21 U.S.C. § 360bb(a)(2).

108. *PhRMA I*, 43 F. Supp. 3d at 31.

109. 42 U.S.C. § 256b(e). The exemption only applied to entities newly eligible for coverage under the ACA; namely, free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals. *Id.* The orphan drug exception reads: “the term ‘covered outpatient drug’ shall not include a drug designated by the Secretary ... for a rare disease or condition.” *Id.*

110. For example, Prozac is commonly used to treat depression (a non-orphan purpose), but is also labeled an orphan drug when used to treat autism and body dysmorphic disorder in children. *PhRMA I*, 43 F. Supp. 3d at 30, 32-33; see also HRSA, ORPHAN DRUG DESIGNATIONS AND APPROVALS LIST 72 (2015), [www.hrsa.gov/opa/programrequirements/orphandrug](http://www.hrsa.gov/opa/programrequirements/orphandrug)

that orphan drugs are not exempted from 340B discounts when “they are transferred, prescribed, sold, or otherwise used for any medically-accepted indication other than treating the rare disease or condition for which the drug was designated.”<sup>112</sup> The practical upshot of the rule was to place orphan drugs used for orphan purposes outside the 340B scope (maintaining statutory profit incentives for manufacturers), while applying 340B discounts to orphan drugs used for non-orphan purposes. For example, if DSH Hospital A prescribed Prozac for an autistic child (an orphan drug designation),<sup>113</sup> the hospital would not be eligible for a 340B discount. Hospital A would receive a discount, however, if it bought Prozac to treat an adult diagnosed with depression (a non-orphan drug designation).<sup>114</sup> The HHS Rule also required that hospitals regulate their sales of medication so as to ensure that no orphan drugs were used for non-orphan purposes, essentially prohibiting hospitals from applying for a discount for orphan drugs.<sup>115</sup> For example, it is illegal for a hospital to buy Prozac, claiming it is for an autistic child (and thereby purchasing the drug for a discount), and then prescribe it for an adult suffering from depression. This rule essentially requires all covered entities to track all medications to make sure that “orphan drugs” go to “orphan patients” and “non-orphan drugs” go to “non-orphan patients.”<sup>116</sup>

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exclusion/orphandruglist.pdf [http://perma.cc/MA42-2MMY].

111. Exclusion of Orphan Drugs for Certain Covered Entities Under 340B Program, 78 Fed. Reg. 44,016 (July 23, 2013) (codified at 42 C.F.R. § 10.21).

112. Orphan Drug Exemption, 42 C.F.R. § 10.21(a) (2013).

113. Prozac has both orphan and non-orphan designations. *See supra* note 110. The reasoning behind Prozac’s “double designation” is odd, considering that the market for Prozac’s depression treatment was \$180 million in 2012. THOMSON REUTERS, SPOTLIGHT ON DEPRESSION 9 (2014), [http://images.info.science.thomsonreuters.biz/Web/ThomsonReutersScience/%7B913944e2-377c-450b-a9e6-9a11bf8146b7%7D\\_SpotlightOn-cwp-en\\_issue15-low\\_res.pdf](http://images.info.science.thomsonreuters.biz/Web/ThomsonReutersScience/%7B913944e2-377c-450b-a9e6-9a11bf8146b7%7D_SpotlightOn-cwp-en_issue15-low_res.pdf) [http://perma.cc/5WJ9-DA34]. Prozac’s thriving market already provides the incentive for the manufacturer to produce the drug, regardless of its orphan drug designation for other purposes. Thus, for Prozac, and other drugs like it, the orphan drug designation may be a windfall that, under current law, benefits the manufacturer at the expense of providers and indigent patients.

114. In this case, because Prozac is considered a brand-name drug, the minimum discount is 23.1 percent. *See PhRMA I*, 43 F. Supp. 3d at 44 n.15.

115. *See* 42 C.F.R. § 10.21(c)(1).

116. As one can imagine, this process can be more guesswork than anything else, considering that the exact same drug can be an orphan drug or a non-orphan drug depending on the patient to whom it is prescribed.

The Pharmaceutical Research and Manufacturers of America (PhRMA)<sup>117</sup> sued HHS over the orphan drug rule, arguing that HHS did not have the statutory authority to issue the rule in the first place.<sup>118</sup> HHS contended that Congress had granted it legislative authority in three separate provisions: “(1) the establishment of an administrative dispute resolution process, (2) the ‘regulatory issuance’ of precisely defined standards of methodology for calculation of ceiling prices, and (3) the imposition of monetary civil sanctions.”<sup>119</sup> In the alternative, HHS argued that the Orphan Drug Rule should be upheld as an interpretive, rather than a legislative, rule.<sup>120</sup>

Giving appropriate deference to HHS as the administering agency,<sup>121</sup> the district court examined each provision in turn and found that “though ... the agency’s proactive, prophylactic rule [is] the most reasonable way of administering the statute, Congress has not given HHS the broad rulemaking authority to do so, and ‘[w]here Congress has established a clear line, the agency cannot go beyond it.’”<sup>122</sup> The court held that HHS did have congressional authority to implement a few specific provisions within 340B, but on the whole, “HHS lack[ed] statutory rulemaking authority to promulgate the orphan drug rule at issue.”<sup>123</sup> In granting summary judgment and an injunction to the plaintiffs, however, the court declined

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117. PhRMA is a trade group representing “the country’s leading biopharmaceutical researchers and biotechnology companies,” which advocates strongly for: “[1] [b]road patient access to safe and effective medicines through a free market, without price controls; [2] [s]trong intellectual property incentives; [3] [a]nd transparent, effective regulation and a free flow of information to patients.” *About PhRMA*, PhRMA, <http://www.phrma.org/about> [<http://perma.cc/29AR-G2S7>].

118. *PhRMA I*, 43 F. Supp. 3d at 30-31; *see also* Plaintiff’s Complaint for Declaratory and Injunctive Relief ¶ 8, *PhRMA I*, 43 F. Supp. 3d 28 (No. 13-1501).

119. *PhRMA I*, 43 F. Supp. 3d at 41.

120. *Id.* at 45-46. For a more thorough treatment of the implications of legislative versus interpretive rule theories, especially in this context, *see generally* Jackson, *supra* note 66, at 5.

121. The district court determined that *Skidmore* deference was appropriate in this case because the agency’s decision was beyond Congress’s grant of authority and thus was “beyond the *Chevron* pale.” *PhRMA I*, 43 F. Supp. 3d at 36 (quoting *United States v. Mead*, 533 U.S. 218, 234 (2001)).

122. *Id.* at 45 (quoting *City of Arlington v. FCC*, 133 S. Ct. 1863, 1874 (2013)).

123. *Id.* at 37; *see also* Thomas Barker & Igor Gorlach, *PhRMA v. HHS Scales Back HRSA Rulemaking Power*, LAW360 (June 10, 2014, 12:08 PM), <http://www.law360.com/articles/545512/phrma-v-hhs-scales-back-hrsa-rulemaking-power> [<http://perma.cc/EM4S-WBVN>].

to address HHS's "interpretive rule" theory, leaving HHS an argument to pursue in the future.<sup>124</sup>

Unsurprisingly, exactly two months after the district court's ruling, HHS reissued the previously vacated orphan drug rule, this time retitled as an "interpretive rule."<sup>125</sup> PhRMA sued HHS on October 9, 2014, challenging the rule under the Administrative Procedure Act (APA) as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."<sup>126</sup> Reviewing cross motions for summary judgment, the court ruled in PhRMA's favor on October 14, 2015, holding (1) that HHS's Interpretive Rule was a final order and thus justiciable under the APA,<sup>127</sup> and (2) that HHS was not entitled to any deference because the Interpretive Rule was contrary to the plain language of the 340B statute.<sup>128</sup>

Of particular note, the court specifically clarified that although PhRMA's suit challenged "the merits of the Interpretive Rule," PhRMA did not contest "HHS's *authority* to issue an Interpretive Rule prospectively setting forth the agency's reading of the statute."<sup>129</sup> In fact, the court reasoned, HHS must be able to interpret the 340B statute if it is to properly administer the program.<sup>130</sup> Consequently, the court held that "even though this Court concluded [in *PhRMA I*] that HHS lacks the authority to promulgate the rule as a binding statement of law, HHS is not forbidden altogether from proffering its interpretation of the statute."<sup>131</sup> Yet, the court also recognized that the Interpretive Rule at issue in *PhRMA II* was not merely interpretive: "[t]he Interpretive Rule very clearly requires manufacturers and covered entities alike to change their behavior

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124. *PhRMA I*, 43 F. Supp. 3d at 46. The court was "inclined to think [HHS's interpretive rule theory was] wrong," but needed additional briefing if HHS was to pursue the theory further. *Id.*

125. *See* Availability of Interpretive Rule: Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program, 79 Fed. Reg. 42,801 (July 23, 2014).

126. *See* 5 U.S.C. § 706(2)(A) (2015); *see also* Pharm. Research & Mfrs. of Am. v. HHS (*PhRMA II*), No. 14-1685 (RC), 2015 WL 5996374, at \*5 (D.D.C. Oct. 14, 2015).

127. *PhRMA II*, 2015 WL 5996374 at \*12.

128. *Id.* at \*17.

129. *Id.* at \*6.

130. *Id.*

131. *Id.*



in a not insignificant way.”<sup>132</sup> Thus, HHS’s interpretive power seems quite limited, at least in practice.

The district court’s holdings in *PhRMA I* and *PhRMA II* lay out a problematic path going forward. HHS may not issue general legislative rules regarding 340B’s implementation, outside of the few specific areas in which HHS has an explicit congressional mandate. HHS may issue interpretive rules. In light of the practical holding of *PhRMA II*, however, HHS’s interpretive powers likely do not extend very far beyond its own doors. Consequently, HHS’s authority to administer the 340B program is unclear at best. When HHS’s interpretive rules run contrary to the interests of involved 340B stakeholders, PhRMA’s previous success in litigation opens the door for additional challenges to HHS’s rulemaking. In the words of the district court in *PhRMA I*:

The rulemaking authority granted HHS by Congress under the 340B program has thus been specifically limited, and HHS has not been granted broad rulemaking authority to carry out all the provisions of the 340B program. Instead, Congress has limited HHS’s rulemaking authority ... not to engag[e] in prophylactic non-adjudicatory rulemaking regarding the 340B program altogether.<sup>133</sup>

For a program of this size and scope, HHS needs a broad grant of statutory authority to implement the program well, especially in light of 340B’s significant recent growth. The lack of a clear congressional mandate merely creates opportunities for large stakeholders in 340B, manufacturers and hospitals, to find and exploit loopholes in the existing program. Without a clear congressional mandate for HHS to administer 340B, the real question seems to be whether the

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132. *Id.* at \*10. The court examined in detail the fact that manufacturers’ failure to comply with 340B’s requirements—“as interpreted by [HHS’s] Interpretive Rule”—would “expose manufacturers to significant penalties in future enforcement proceedings. *Id.* at \*11. HHS, through HRSA, had sent letters to pharmaceutical manufacturers warning them in essence that failure to comply with the Interpretive Rule would constitute failure to comply with the statutory requirements themselves, thus equating the rule and the statute, and exposing manufacturers to significant liability for diverging from HHS’s interpretation. *Id.* at \*9.

133. *PhRMA I*, 43 Supp. 3d 28, 42-43 (D.D.C. 2014).

manufacturers and covered entities, rather than HHS, are actually running the program.<sup>134</sup>

## 2. *Diverging Interests and the Purpose of 340B*

The fundamental issue within the 340B program is the clashing interests between the parties involved, primarily manufacturers and hospitals. Currently, manufacturers and hospitals are playing what is essentially a zero-sum game: increased savings for hospitals equates to decreased profits for drug corporations, and vice versa. Considering their opposing incentives, manufacturers and hospitals consequently offer differing explanations for what Congress originally intended 340B to be: manufacturers claim that 340B discounts were intended primarily to help indigent patient populations, while hospitals contend that 340B's purpose was to aid hospitals by offering them drugs savings, and that patients benefit only indirectly.<sup>135</sup>

Absent 340B, market pressure and government regulation would incentivize drug manufacturers to maintain a balance between a

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134. On March 25, 2015, the House Energy & Commerce Committee held a hearing on the 340B program to investigate alleged problems within its structure. *See Examining the 340B Drug Pricing Program*, ENERGY & COMM. COMMITTEE (Mar. 24, 2015, 10:00 AM), <http://energycommerce.house.gov/hearing/examining-340b-drug-pricing-program> [<http://perma.cc/KWV9-A9SB>]. The testimony in that hearing focused on the lack of transparency and accountability within 340B. *Id.* Members of the committee drafted provisions to be included in the 21st Century Cures bill, but 340B stakeholders clearly were not impressed with the nature of the measures and caused the amendments to be removed. Ellyn L. Sternfield & Bridgette A. Wiley, *HRSA Takes Its First Steps on 340B Rules*, NAT'L L. REV. (June 22, 2015), <http://www.natlawreview.com/article/hrsa-takes-its-first-steps-340b-rules> [<http://perma.cc/DF43-VUK5>]. Congress may likely take further action to "fix" the program in the future; Part III proposes a framework for such future legislation.

Furthermore, it should be noted that HRSA issued a notice of proposed rulemaking on June 17, 2015, finally following up on its Advance Notice of Rulemaking from September 2010. *Id.* The proposed rules focus exclusively on topics clearly within HRSA's limited rulemaking authority: calculating ceiling prices and civil monetary penalties. *Id.* Generally, the rules are not major substantive changes and thus are beyond the scope of this Note. *See id.* Considering the current ambiguous status of HRSA to issue rules, litigation may again ensue over HRSA's authority. There is unlikely to be significant resolution to this merry-go-round until Congress amends the 340B program from the top down.

135. *Compare, e.g.,* BIOTECH, *supra* note 5, at 6 ("Congress created the 340B program to help federal grantees and true safety net hospitals serving low-income, uninsured patients by reinstating the deep discounts that manufacturers had voluntarily provided to these facilities before enactment of the 1990 Medicaid drug rebate statute."), *with* SAFETY NET HOSPS., *supra* note 83, at 2 (arguing that "340B providers are using their program savings to benefit their vulnerable patients, consistent with congressional intent").

competitive price and profit. Prior to 340B and MDRP, manufacturers voluntarily offered heavy discounts to hospitals serving low-income, uninsured patients.<sup>136</sup> Under 340B, however, manufacturers must offer discounts to covered entities for certain outpatient drugs, thus forcing manufacturers to operate with a lower profit margin than they would otherwise, even assuming the minimum discounts at play. Consequently, the 340B program perversely incentivizes manufacturers to focus distribution to non-340B entities, for which the profits are larger.<sup>137</sup> Additionally, considering the expanding scope of 340B discounts, manufacturers are likely to raise prices of non-340B medications so as not to be overly burdened by the 340B discount.<sup>138</sup> Manufacturers contend that Congress originally intended the 340B program to help primarily indigent uninsured patients, not the hospitals serving them.<sup>139</sup> Because manufacturers lose profits under any iteration of 340B, presumably this contention arises more out of opposition to hospitals collecting larger discounts than it does out of concern for the patients involved.

Covered entities—including contract pharmacies—are incentivized under the 340B program to collect the largest discount possible and keep it. Physicians may even shift their prescriptions to more expensive outpatient drugs to collect a larger profit.<sup>140</sup> This may be reasonable in light of the statutory scheme; covered entities have no reason to pass on the discounts to their patients, especially because many hospitals provide significant amounts of uncompensated care every year.<sup>141</sup> As justification, hospital associations point to the fact

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136. See SAFETY NET HOSPS., *supra* note 83, at 2.

137. 340B's negative incentives are very clearly demonstrated in the orphan drug context. The orphan drug rule was intended to incentivize orphan drug production where natural market incentives would not otherwise exist. See *supra* notes 106-09 and accompanying text. Section 340B, however, incentivizes manufacturers not to focus on the discounted drugs. HHS exempted orphan drugs from the 340B program, because otherwise the incentives from the Orphan Drug Act would disappear and manufacturers would focus their attention elsewhere. See *supra* note 109 and accompanying text.

138. Conti & Bach, *supra* note 83, at 1996.

139. See, e.g., AIR 340B, UNFULFILLED EXPECTATIONS: AN ANALYSIS OF CHARITY CARE PROVIDED BY 340B HOSPITALS 1 (2014), <http://340breform.org/userfiles/Final%20AIR%20340B%20Charity%20Care%20Paper.pdf> [<http://perma.cc/CNT9-KELN>]; BIOTECH, *supra* note 5, at 6.

140. Conti & Bach, *supra* note 83, at 1995.

141. In 2012, the American Hospital Association estimated that, nationally, registered community hospitals dispensed \$45.9 billion in uncompensated care—6.1 percent of total expenses. AM. HOSP. ASS'N, UNCOMPENSATED HOSPITAL CARE COST FACT SHEET 3 (2014), <http://www.aha.org/content/14/14uncompensatedcare.pdf> [<http://perma.cc/H9DP-LXKZ>]. Generally,

that 340B was created to help safety-net providers “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”<sup>142</sup>

Reality depicts a picture different from those painted by both manufacturers and the covered entities. It is generally true that 340B DSH hospitals provide more charity care and uncompensated care as a proportion of total facility revenue.<sup>143</sup> However, the GAO has also identified that there are “notable numbers of 340B DSH hospitals that provide[] low amounts of uncompensated care and charity care.”<sup>144</sup> Specifically, the GAO found that 14 percent of 340B DSH hospitals “were among the hospitals that provided the lowest amounts of uncompensated care across all hospitals” in its analysis.<sup>145</sup> This finding was coupled with the GAO’s conclusion that 340B entities are generally incentivized under the program to prescribe patients “more drugs, more expensive drugs, or both.”<sup>146</sup> Consequently, the GAO recommended that “Congress should consider eliminating the incentive to prescribe more drugs or more expensive drugs.”<sup>147</sup>

Lost in this discussion, however, are the patients themselves. If the GAO’s analysis is to be believed, on the one hand, indigent patients<sup>148</sup> benefit from the 340B program through additional services and uncompensated care offered by 340B entities.<sup>149</sup> On the other

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uncompensated care refers to both “charity care” and “bad debt.” GAO 2015 REPORT, *supra* note 31, at 5 n.16. The former category “represents services for which a hospital demonstrates that a patient is unable to pay, and is based on a hospital’s policy to provide all or a portion of services free of charge to patients who meet certain financial criteria.” *Id.* The latter designation “represents services for which a hospital determines that a patient has the financial capacity to pay, but is unwilling to do so.” *Id.*

142. SAFETY NET HOSPS., *supra* note 83, at 8 (quoting H.R. REP. NO. 102-384, pt. 2, at 12 (1994)).

143. GAO 2015 REPORT, *supra* note 31, at 12. The GAO also reported that, “among 340B DSH hospitals, the median amount of uncompensated care provided by major teaching hospitals was less than the median amount provided by all hospitals in the group, despite the fact that the major teaching hospitals in this group tended to have the highest DSH adjustment percentages.” *Id.*

144. *Id.*

145. *Id.* at 14.

146. *Id.* at 20, 30.

147. *Id.* at 30.

148. Although the GAO’s analysis focused specifically on Medicare Part B beneficiaries, there is no reason to suggest that the indigent patient populations generally would not fall under a similar analysis.

149. *Id.* at 13.

hand, however, indigent patients are harmed by higher medication co-payments, higher insurance premiums, and physicians' compromised incentives to overprescribe medication.<sup>150</sup> One has to assume that, in the main, individual patients would not prefer a significant increase in the cost of medication and insurance premiums<sup>151</sup> even if accompanied by an increase in the range of offered services. Yet, to the patients at the margins, an increase in services could be lifesaving, regardless of any increase in cost. The countervailing interests of drug manufacturers and safety-net providers come to practical terms at the level of the individual indigent patient. It is the patients who are caught in the middle of the overarching debate over the future of 340B.

In sum, policymakers are presented with a distinct challenge in implementing the 340B program: how to balance competing interests and incentives to find a solution that benefits the parties who most need 340B savings, namely safety-net providers and indigent patients, without unnecessarily or excessively burdening drug manufacturers.

### III. RETHINKING 340B: A FRAMEWORK

#### *A. Proposed Solution*

With consideration to the problems highlighted above, this Section proposes a framework for revisions to 340B that may guide policymakers seeking to improve the program. The proposal is laid out in three parts: first, unlinking and separating 340B from Medicaid; second, creating new eligibility standards for covered entities and patients; and third, authorizing HHS with the proper mandate to oversee and implement the new 340B effectively.

##### *1. Separating 340B from Medicaid*

Under the current regime, 340B overlaps significantly with the MDRP, which creates opportunities for fraud and unnecessary redundancy. Although the two programs operate slightly

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150. *Id.* at 29.

151. *See supra* note 89 and accompanying text.

differently—340B provides entities an upfront discount, while the MDRP operates with a post-sale rebate—covered entities are prohibited under 340B from requesting a program discount if the drug is “subject to the payment of a rebate to the State under [the MDRP].”<sup>152</sup>

Congress created the 340B scheme to be a patch that closes the incentive loopholes created in the MDRP.<sup>153</sup> Thus, in crafting 340B, Congress specifically linked many of its definitions and calculations to the Medicaid statute.<sup>154</sup> This duplicative overlap, though perhaps understandable from the legislative history, is unnecessary and creates more problems than it solves. For example, the HHS Secretary is tasked under 340B with establishing a mechanism to ensure that 340B covered entities do not request duplicate discounts.<sup>155</sup> In previous years, this provision was enforced mostly via self-policing by both sellers and buyers—a relatively costless, albeit eyebrow-raising, enterprise.<sup>156</sup> Since the 2011 GAO Report, and despite HRSA’s adopted auditing procedures,<sup>157</sup> the opportunity for duplicate discount fraud is still viable, and the cost of auditing will only increase in the future as the number of covered entities continues to rise. If Congress removes the overlap between the two programs, however, the opportunity for fraud would be mitigated and auditing costs could theoretically be reduced.

The basic thrust of this change would be to supplement the program with a second eligibility trigger for 340B participation. First, healthcare providers would have to qualify as covered entities.<sup>158</sup> Second, covered entities would have to certify that the recipients of

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152. 42 U.S.C. § 256b(a)(5)(A) (2012) (“Prohibiting duplicate discounts or rebates.”).

153. See, e.g., *Public Health Clinic Prudent Pharmaceutical Purchasing Act: Hearing Before the S. Comm. of Labor & Human Res.*, 102d Cong. 54 (1991) (statement of Gerald J. Mossingoff, President, Pharmaceutical Manufacturers Association) (“We understand that the introduction of the bill is a reaction to the price increases to the covered entities caused by the best-price provisions of the Medicaid Rebate Program. That could be addressed by adopting the same approach that is contained in the Department of Veterans Affairs Appropriation Act; namely, to exempt the prices to the covered entities from the Medicaid rebate best price calculations.”).

154. See, e.g., *supra* note 31.

155. 42 U.S.C. § 256b(a)(5)(A)(ii).

156. See *supra* note 51 and accompanying text.

157. See *supra* notes 51-53; see also HRSA AUDIT REPORTS, <http://www.hrsa.gov/opa/programintegrity/auditresults/> [<http://perma.cc/S2DR-VU57>].

158. See *supra* notes 38-54 and accompanying text.

the drugs are qualifying patients: in other words, those who meet HRSA's definition of "patient" and are not covered by Medicaid. Thus, patients would be either eligible or ineligible for 340B drugs based on their insurance coverage, rather than being automatically qualified based on the status of their care provider.

There are three primary provisions that should be addressed if 340B is to be separated from Medicaid.<sup>159</sup> First, the double covered provision should be revised. Any given patient of a covered entity should only be covered by one drug discount or rebate.<sup>160</sup> Although covered entities currently may claim either a 340B discount or a Medicaid rebate,<sup>161</sup> the fact that 340B and the MDRP cover some of the same patients—those covered by Medicaid—is duplicative. Instead, the MDRP should apply only to Medicaid patients, and 340B should only apply to non-Medicaid patients. Eliminating this unnecessary redundancy will reduce 340B's administration expenses by removing the opportunity for covered entities to request double discounts. Additionally, this revision could reverse 340B's current trend of expanding concurrently with Medicaid. If 340B covers only those not covered by Medicaid—namely, patients that are uninsured, privately insured, or on Medicare—340B's extraneous growth may halt and begin to decline as Medicaid eligibility expands post-ACA.<sup>162</sup>

Second, the eligibility trigger incentivizing manufacturers to opt in to 340B<sup>163</sup> should remain untouched. Under the current regime, manufacturers must sign 340B PPAs with HHS to be eligible for any

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159. This proposal does not address the multiple linked definitions between the Medicaid statute and 340B. *See, e.g.*, 42 U.S.C. § 256b(a)(1) (definition of "average manufacturer price"); *id.* § 256b(a)(2)(B) (definition of "over the counter drug"); *id.* § 256b(a)(4)(A) (definition of "federally-qualified health center"). These definitions are used more for ease of use, however, than they are used to actually link the two programs together, and so are not of major concern.

160. The distinction between Medicaid drugs and 340B drugs already exists as the former are specifically exempted from the 340B scheme. *See id.* § 256b(a)(1), (3). It makes sense to tether the patients receiving the drugs to the drugs themselves so that hospitals do not have to decide whether to claim the MDRP rebate or the 340B discount.

161. *See id.* § 256b(a)(5)(A)(i).

162. This may be an overly rosy outlook. If, however, illegitimate profit incentives are removed from the program as well, hospitals will no longer be incentivized to continue expanding their patient bases to collect 340B profits.

163. *See supra* note 30 and accompanying text.

state Medicaid funding.<sup>164</sup> This condition resulted from manufacturers raising drug prices for certain entities—especially the VA—in the immediate aftermath of the passage of the MDRP.<sup>165</sup> Without this condition, there are few other incentives for manufacturers to offer 340B-type discounts, especially considering that manufacturers must pay out rebates under the MDRP. Thus, very few manufacturers would opt in to the 340B program, and its intended beneficiaries would be left without aid.

In light of the first proposed revision, to remove Medicaid patients from 340B, it may seem odd to leave Medicaid funding as the mechanism by which to incentivize manufacturers to opt in to the 340B program. This mechanism, however, is merely an incentive scheme. Once manufacturers opt in to 340B, the Medicaid condition would no longer affect the program.<sup>166</sup>

The third implicated provision is that of the eligibility standard for hospitals: the disproportionate share adjustment percentage (DSAP).<sup>167</sup> The DSAP for a hospital is dependent upon a statutory formula for the “disproportionate patient percentage,” calculated as “the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.”<sup>168</sup> Thus, a hospital’s eligibility for 340B is based in part on the total assistance the hospital dispenses to patients eligible for Medicaid.<sup>169</sup> If Medicaid is uncoupled from 340B, and Medicaid patients are not eligible for 340B discounts (and vice versa) it would seem strange to maintain a 340B eligibility requirement for hospitals based partly on Medicaid patients who would not be eligible for 340B discounts themselves.<sup>170</sup>

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164. See *supra* note 30 and accompanying text.

165. See H.R. REP. NO. 102-384 (I), at 2-4 (1991); *supra* notes 23-32 and accompanying text.

166. There is no preference for the Medicaid funding incentive as opposed to any other incentive, except for the fact that it is currently operable. There seems to be no reason to disturb this existing incentive mechanism unless a much better one exists.

167. Calculated under 42 U.S.C. § 1395ww(d)(5)(F). See *supra* note 40.

168. Ctrs. for Medicare & Medicaid Servs., *Disproportionate Share Hospital*, CMS.GOV, <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html> [<http://perma.cc/MCQ4-H5ZF>] (last modified Oct. 26, 2015).

169. See 42 U.S.C. § 1395ww(d)(5)(F)(II).

170. The other categories of covered entities under 340B would not be affected by any changes to this provision, as the DSAP calculation does not play a role in their eligibility



There are reasons for and against including Medicaid-eligible individuals in the 340B eligibility trigger. First, DSAP calculation is only partially, not wholly, determined by a hospital's percentage of patients eligible for Medicaid.<sup>171</sup> Second, the percentage of patients eligible for Medicaid is a simple and efficient measurement to determine how much care a hospital dispenses to low-income patients—insured or not. On the other hand, tying 340B hospital eligibility to Medicaid will cause 340B to continue to grow with the expansion of Medicaid: not necessarily a significant negative concern, but one that should perhaps give pause in a world of rapidly growing healthcare costs.<sup>172</sup>

Alternatively, Congress could create a DSAP formula that would rely on the Medicare patient percentage used in the original formula, and the percentage of the hospital's patients that are uninsured and have incomes below 400 percent of the federal poverty level. This formula would achieve the same purpose of identifying safety-net hospitals, but would not rely on the traditional DSAP formula involving Medicaid patients.<sup>173</sup>

## *2. Creating New Eligibility Standards and Requirements for Covered Entities*

### *a. Patient Eligibility*

Section 340B patients should be separated into three different categories: indigent, privately insured, and Medicare patients. First, indigent patients would be defined by insurance and income criteria, specifically targeting patients uninsured through any means, and who are unable to pay for any necessary outpatient medication out

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criterion. *See id.* § 256b(a)(4).

171. *See id.* § 1395ww(d)(5)(F) (statutory formula).

172. For example, a hospital whose low-income patients are all eligible for Medicaid would qualify for 340B discounts, but would not be eligible to actually collect 340B discounts because Medicaid patients themselves would not be eligible for 340B. However, non-Medicaid patients on Medicare would still be eligible for 340B discounts from the hospital.

173. Consequently, as Medicaid eligibility continues to expand in the wake of the ACA, the number of DSH hospitals under 340B would contract. However, under this definition of DSAP, a hospital that treats a very small number of uninsured, low-income patients would not qualify for 340B discounts, defeating the purpose of 340B. This fact speaks more in favor of leaving 340B's hospital eligibility criterion tied to Medicaid patient percentage.

of pocket. Second, privately insured patients would be those who are insured through some means other than Medicaid or Medicare, or who have enough income to pay for medication out of pocket.<sup>174</sup> Third, Medicare patients would be those who are eligible for Medicare benefits, are not covered by Medicaid,<sup>175</sup> and are otherwise eligible to receive 340B discounts.

The current definition of “patient” and the guidance offered by HRSA<sup>176</sup> would be nearly sufficient when paired with the income and insurance requirements of the new plan. That said, HRSA should still clarify a few of the ambiguous provisions in its current guidance.

Each patient category would be linked to a different sized discount from the manufacturer, depending on the relative ability of the patient to pay. Indigent patients would receive the largest discount (for example, 50 to 80 percent of AMP). Privately insured patients would receive a discount similar to the current 340B standards (for example, 20 to 50 percent of AMP). Medicare patients would also receive discounts similar to the current program. The purpose of delineating patient groups in this way is to more specifically match an appropriate discount to the relative ability of each patient group to purchase medication, thereby tailoring the program more neatly to each patient’s needs.

#### *b. Requirements for Covered Entities*

Currently, covered entities are not required to pass on any 340B discounts to the patient.<sup>177</sup> For example, Entity A may purchase a drug from the manufacturer at a 23.1 percent discount—the minimum discount for brand-name drugs—and resell the drug to the patient at full price (AMP), thereby keeping the difference. Under the new program, however, covered entities would be required to pass on at least some of the discount so that both covered entities and patients could share in the benefit.

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174. To be considered “privately insured” likely would require income of higher than 400 percent of the poverty level.

175. Patients covered by both Medicaid and Medicare would be covered under the Medicaid Drug Rebate Program.

176. See *supra* Part II.A.1.

177. See *supra* note 83 and accompanying text.

Entities would be required to pass on different percentages of 340B discounts, conditioned on the category of patient who purchased the underlying drugs.<sup>178</sup> For indigent patients, the covered entity would be required to pass on a high percentage of the discount (for example, 60 to 100 percent). For privately insured patients, entities could pass on as much or as little of the discount as they would like. For Medicare patients, entities would be required to pass on a small percentage of the discount (for example, 20 to 40 percent).

There are a few reasons for creating such a sliding scale to pass on 340B discounts. First, it would require entities to share discounts with patients, reducing the significant cost burdens of outpatient medication for the most vulnerable populations. Second, it would give covered entities some degree of discretion in passing on discounts, creating competition in the pharmaceutical provider market between multiple 340B entities in a given area. Third, it would allow entities to collect savings (or profits) only from those patient populations that can afford to pay a higher percentage of AMP. In short, this sliding scale approach would balance between helping safety-net providers and indigent populations.

### *3. Authorizing HHS with the Proper Mandate*

In addition to unlinking 340B from Medicaid and revising the eligibility standards and entity requirements, the new 340B program should include the requisite authority for HHS to administer the program as needed. Under the current program, HHS cannot issue legislative rules to solve conflicting schemes like the orphan drug exemption.<sup>179</sup> Although Congress should not grant unlimited authority to run 340B, HHS must have more leeway than it has under its current grant of power.

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178. The percentages suggested in this section are certainly not final—they are merely suggestions.

179. Giving HHS the proper mandate would resolve the debate over the orphan drug exception. *See supra* notes 117-34 and accompanying text.

## *B. Potential Outcomes*

### *1. Potential Benefits*

This proposal attempts to balance 340B's competing interests and incentives and place the program in a position where it can more effectively serve all parties involved.

Manufacturers would likely be as strongly incentivized as they were under the original program to opt in to 340B due to the Medicaid funds condition. Manufacturers, however, would not be required under the new plan to offer discounts under 340B for Medicaid patients, saving manufacturers costs that they would otherwise incur. As Medicaid expands, the number of patients eligible for 340B discounts would decrease, setting a limit on the total number of discounts manufacturers would be required to dispense. This trend could significantly benefit manufacturers in the long run.

Covered entities likely would also benefit from this plan. 340B hospitals and clinics would be required under the new plan to pass on discounts to the poorest of their patients, but would be allowed to keep a percentage of the savings for patients who could afford to pay a higher price for medication. The larger discounts given to indigent patients would allow entities to offer safety-net services at a lower cost, while the savings the entities could collect from privately insured patients would allow covered entities to offer a wider range of safety-net services, keeping with the intent of the original 340B program.

Patients would likely benefit from the new 340B because they could collect currently unseen discounts from the manufacturer through the covered entity. Additionally, the discretion covered entities would have as to the exact percentage of the discounts to pass on could create competition between entities, and the marginal patient could shop for the best price.

### *2. Potential Critiques*

No legislation is perfect, however, and the new 340B plan does have a downside. The administrative cost of implementing the program would likely be substantially the same as, or perhaps even

greater than it is currently. HRSA likely would still have to audit covered entities to ensure they would not divert 340B drugs intended for one patient group to another. As the middleman retailers, covered entities would still be required to track 340B drugs through their pipelines to ensure that the appropriately discounted drugs reached the correct recipients. Additionally, hospitals would have to create a new system for categorizing patients based upon the new criteria. The information necessary for that process, however, is information hospitals already collect,<sup>180</sup> so presumably the added administrative cost would not be overly burdensome.

An appropriate cost-benefit analysis of the proposed revision to 340B cannot be determined until actual data can be obtained and evaluated. Theoretically, however, this proposal's benefits outweigh its administrative costs, especially over the long term, as HHS would have the authority to update 340B as necessary to make it more efficient.

#### CONCLUSION

In light of its history, rapidly expanding size and scope, and immediate and fundamental internal problems, the 340B drug pricing program needs revision to better serve all the parties involved. Currently, competing incentives between manufacturers and covered entities in a highly profitable marketplace drive the 340B discussion. To truly serve the indigent populations covered by the safety-net providers, however, Congress needs to rethink 340B and balance the program more appropriately.

First, Congress should untether 340B from the Medicaid drug rebate program, allowing 340B to target only the specific populations within its scope and thus more appropriately serve its intended beneficiaries. Second, Congress should recognize the inherent differences among the patient populations currently served by 340B and tailor drug discounts to match each group's ability to pay. Third, Congress needs to authorize HHS with the appropriate mandate to administer the 340B program effectively.

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180. The new patient groups would be pegged primarily to types of insurance coverage. Healthcare providers already collect insurance data.

The proposal above is a practical framework for a fresh perspective on the 340B program. Moreover, it provides a foundation for future discussion, identifying key issues and possible solutions to the 340B scheme. Moving forward, Congress and HHS should conduct research and cost-benefit analyses on each provision of the current program and any proposed revisions to ensure that implemented changes help the program take strides in the appropriate direction. Considering the size, scope, and purpose of 340B, both indigent patients and safety-net hospitals could derive significant benefits from a properly functioning and appropriately targeted drug discount program. To that end, Congress should rethink 340B's implementation and seek to revise the program to become one that appropriately balances the interests of manufacturers and covered entities, and provides much-needed discounted drugs to the indigent.

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