



## Safety Net Hospitals for Pharmaceutical Access

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September 28, 2011

Dr. Donald M. Berwick, MD  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-9989-P  
P.O. Box 8010  
Baltimore, MD 21244-8010

**Re: Comments on Proposed Rule for Establishment of Exchanges and Qualified Health Plans (CMS-9989-P)**

Dear Dr. Berwick:

Safety Net Hospitals for Pharmaceutical Access (SNHPA) respectfully submits these comments in response to the proposed rule to establish exchanges and qualified health plans (QHPs) pursuant to the Patient Protection and Affordable Care Act (PPACA), published by the Centers for Medicare and Medicaid Services (CMS) in the Federal Register on July 15, 2011 (CMS-9989-P). Our comments specifically concern Section 156.235 of the proposed rule, which requires a QHP to include “essential community providers” (ECPs), such as 340B covered entities, within its network.

SNHPA represents nearly 800 public and private non-profit hospitals that qualify for and participate in the 340B drug discount program by virtue of serving a large number of uninsured and underinsured patients. Consistent with the intent of the 340B program, our member hospitals rely on the savings generated from the program to help finance their mission of serving low-income patients.

SNHPA appreciates that the proposed rule, as mandated by PPACA, explicitly recognizes all 340B covered entities as ECPs. Defining ECPs to include 340B covered entities affirms the vital role that Congress intended covered entities to play in meeting the health care needs of patients enrolled in QHPs. However, CMS must take steps to ensure QHPs do not undermine the purpose of the 340B program or the effectiveness of exchanges by offering discriminatory reimbursement to covered entities. *Therefore, we urge CMS to require that a QHP reimburse 340B covered entities at rates on par with the QHP’s payment rates for non-340B providers.*

SNHPA’s recommendation is consistent with Congressional intent. Congress created the 340B program to enable safety-net providers to stretch their scarce resources so that they may “reach more patients” and furnish “more comprehensive services.”<sup>1</sup> This purpose cannot be achieved if 340B covered entities have to pass on the savings they receive through the 340B program to

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<sup>1</sup> H.R. Rep. 102-384, pt.2, at 12 (1992).

QHPs. The Health Resources and Services Administration (HRSA), the agency that administers the 340B program, shares SNHPA's concerns about this threat to 340B. According to HRSA, the 340B program provides additional financial resources to providers without increasing the federal budget by lowering drug acquisition costs while maintaining revenue from health insurance reimbursements.<sup>2</sup> The difference between a 340B drug's lower acquisition cost and standard non-340B reimbursement represents the very benefit that Congress intended to give providers when it established the 340B program. HRSA explains that if "[providers] were not able to access resources freed up by the drug discounts when they . . . *bill private health insurance*, their programs would receive no assistance from the enactment of section 340B and there would be no incentive for them" to enroll or remain in the program.<sup>3</sup>

In addition to upholding the purpose of the 340B program, requiring QHPs to reimburse 340B covered entities at market rates is consistent with the plain language of the statute. PPACA states that a QHP must include ECPs within its network, unless "providers refuse[] to accept the generally applicable payment rates of" the QHP.<sup>4</sup> Congress intended to protect ECPs, including 340B providers, from such discriminatory practices by using the descriptor "generally applicable." Congress anticipated that QHPs might try to avoid contracting with ECPs by offering them below-market rates. Moreover, the PPACA language concerning payment rates does not distinguish between 340B covered entities and non-340B ECPs, meaning that there cannot be a lower rate that applies only to 340B covered entities, but not to other providers that offer similar services.

There are other examples of federal programs requiring private health plans to reimburse providers adequately to prevent government interests from being undermined. Medicare provides federally qualified health centers (FQHCs) with wrap-around payments "to ensure that [FQHCs] do not lose money in caring for Medicare beneficiaries."<sup>5</sup> To prevent Medicare Advantage (MA) plans from using the wrap-around payments as a justification for offering FQHCs lower payment rates, Congress requires MA plans "to provide . . . for a level and amount of payment to [an FQHC] . . . that is not less than the level and amount of payment that the plan would make . . . [to an] entity providing similar services that was not [an FQHC]."<sup>6</sup> Thus, MA plans are prohibited from requiring that providers pass on to the plans the financial benefit of a government program that is intended for the use of the providers and their patients.

Another example relates to the Medicare Part B program. CMS reached the conclusion several years ago that 340B covered entities should be paid the same Part B rates as non-340B providers. One of the panels that advises CMS on these issues held a hearing in 2009 in which

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<sup>2</sup> Health Res. and Servs. Admin., Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act (2005).

<http://www.hrsa.gov/hemophiliatreatment/340Bmanual.htm>.

<sup>3</sup> *Id.* (emphasis added).

<sup>4</sup> Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1311(c)(1)(C)-(2), 124 Stat. 119, 174-175 (2010).

<sup>5</sup> Nat'l Ass'n of Cmty. Health Ctrs., Medicare Advantage: Considerations for Contracting with Health Plans 1, <http://www.nachc.com/client/documents/publications-resources/84.pdf>.

<sup>6</sup> Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 237(c)(3)(A), 117 Stat. 2066, 2212 (2003).

it reaffirmed Medicare policy on this issue, concluding that 340B covered entities should be paid the same rate as non-340B providers.<sup>7</sup> Their decision was based on the fact that commenters generally “felt [that] the intent of the program is to enable 340B hospitals to use the money they save on drug costs to pay for other services for the uninsured.”<sup>8</sup> The Department of Health and Human Services Office of Inspector General concurred in a 2009 report, noting that payment to 340B hospitals exceeds the hospitals’ acquisition costs, which “is an expected result given the purpose of the 340B program.”<sup>9</sup>

By applying similar standards to QHPs that contract with 340B entities, CMS can prevent QHPs from using the fact that 340B covered entities receive discounts on drugs as a rationale for offering them lower reimbursement rates. Such a requirement would protect both the integrity of the 340B program and the effectiveness of the exchanges by preventing plans from unilaterally extracting from providers the discounts that Congress established for the benefit of safety-net providers and their patients. This provision would also afford 340B covered entities the flexibility they need to share part of their 340B discounts with QHPs in appropriate circumstances.

For the above stated reasons, we urge CMS to require that a QHP reimburse 340B covered entities at rates on par with the QHP’s payment rates for non-340B providers. By doing so, CMS will further Congressional intent for the 340B program and exchanges, support the ability of 340B covered entities to treat indigent and underinsured patient populations, encourage covered entities to contract with QHPs, and, most importantly, increase access to care and enhance the exchanges’ capacity to meet the medical needs of patients enrolled in QHPs. We also encourage CMS to solicit input from HRSA on implementation of Section 156.235. HRSA, particularly its Office of Pharmacy Affairs, has extensive experience working with 340B covered entities and can attest to the importance of fair and adequate reimbursement to the 340B program, its participants, and their patients.

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<sup>7</sup> Ctrs. for Medicare and Medicaid Servs. Advisory Panel on Ambulatory Payment Classification (APC) Groups, APC Panel Meeting Report 19 (2009).

<sup>8</sup> *Id.* at 21.

<sup>9</sup> Dep’t of Health and Human Servs. Office of Inspector Gen., Payment for Drugs Under the Hospital Outpatient Prospective Payment System 10 (2010).

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SNHPA would like to thank CMS for the opportunity to comment on the proposed rule. We look forward to continuing to work with CMS to maximize the benefits of the 340B program and to improve the accessibility of health care for all Americans. If you have any questions or need additional information, please do not hesitate to contact SNHPA President and General Counsel William von Oehsen (202-872-6765 or [william.vonoehsen@snhpa.org](mailto:william.vonoehsen@snhpa.org)) or SNHPA Associate Counsel Greg Doggett (202-552-5859 or [greg.doggett@snhpa.org](mailto:greg.doggett@snhpa.org)).

Sincerely,



William von Oehsen  
President & General Counsel  
SNHPA



Greg Doggett  
Associate Counsel  
SNHPA

cc: Dr. Mary Wakefield, RN, PhD, Administrator, HRSA