July 30, 2015

*Submitted via www.regulations.gov*

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attn: CMS-2390-P

P.O. Box 8016

Baltimore, MD 21244-8016

**Re: Proposed Rule for Medicaid and Children’s Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability, 80 Fed. Reg. 31098 (June 1, 2015)**

Dear Acting Administrator Slavitt:

The Mid-Atlantic Association of Community Health Centers (MACHC) appreciates the opportunity to provide comments on the above-referenced Notice of Proposed Rulemaking (“NPRM” or “Proposed Rule”) published by the Centers for Medicare & Medicaid Services (“CMS”) on June 1, 2015 (80 Fed. Reg. 31098).

MACHC is the federally designated Primary Care Association for Delaware and Maryland Health Centers. Its members consist of community, migrant and homeless health centers, local non-profit and community-owned healthcare programs, including all of Maryland’s federally qualified health centers (FQHCs). MACHC’s members provide health care services to the medically underserved and uninsured. MACHC is built on helping our members in the delivery of accessible, affordable, cost effective, and quality primary health care to those in need.

FQHCs in Maryland and Delaware serve thousands of Medicaid patients but also provide a stable, accessible medical home to individuals who churn between Medicaid, the commercial insurance market, and being uninsured. A fundamental characteristic of FQHCs is their commitment to serve all individuals, regardless of their insurance status or ability to pay. As a result, MACHC’s member FQHCs have a history of providing consistent, affordable care for vulnerable individuals even as their insurance status and income fluctuate.

The following is a summary of comments that are more fully discussed later in this correspondence. These comments mirror the comments submitted by the National Association of Community Health Centers (NACHC) but are particularly relevant for Maryland and Delaware FQHCs given that the vast majority of Maryland’s Medicaid population is enrolled in managed care organizations (MCE’s under federal language).

**SUMMARY OF COMMENTS**

**§438.3(s)(3) - Interaction of 340B and Medicaid managed care:**

* **MACHC requests that CMS add language to the preamble and regulatory text to:**
* **clarify that neither states nor MCEs may prohibit 340B providers who are in MCE networks from using 340B drugs for their patients.**
* **clarify that neither states nor MCEs may require providers to agree not to use 340B drugs to their patients as a condition of participating in an MCE’s network.**
* **prohibit MCEs from paying lower rates for drugs purchased by 340B covered entities than for the same drugs when purchased by other MCE network providers. Similarly, states should be prohibited from requiring MCEs to pay lower rates for drugs purchased by 340B covered entities than for the same drugs when purchased by other MCE network providers.**
* **prohibit MCEs from requiring 340B providers to use a methodology for identifying 340B claims that makes it highly difficult or impossible for these providers and their contract pharmacies to use 340B for Medicaid MCE patients.**
* **MACHC appreciates that CMS explicitly states that 340B providers are not legally responsible for protecting manufacturers from having to pay both a 340B discount and a Medicaid rebate on a managed care claim.**
* **CMS should permit 340B providers to report claims data directly to the state or the states’ rebate contractor, bypassing the MCEs, such as is currently done in Oregon.**

§438.3(s)(3) – Interaction of 340B and Medicaid Managed Care

*Please note that National Association of Community Health Centers co-signed a separate letter in conjunction with the 340B Coalition which outlines these issues in detail. MACHC endorses the comments reflected in the coalition letter signed by its national counterpart and reiterates the importance of the issues raised. The following is essentially an overview of the broader coalition letter.*

For many FQHCs, the 340B Drug Discount Program is critical to their financial stability. As a result, any policies or practices that restrict their long-standing ability to provide 340B drugs to their patients threaten their ability to keep their doors open. This is particularly true for policies involving Medicaid managed care patients. In Maryland approximately 45% of all FQHC patients are Medicaid beneficiaries, and of these, approximately 90% are in MCEs.

In the Affordable Care Act (ACA), Congress expanded the Medicaid Drug Discount program to Medicaid MCE patients. However, when doing so, Congress explicitly recognized – and protected – the important role that 340B plays for safety net providers such as FQHCs. It did so by explicitly excluding drugs purchased under 340B from the Medicaid rebates that were being expanded to other MCE drugs[[1]](#footnote-1).

Unfortunately, in the 5 years since the ACA was enacted, there have been no regulations (and only one small piece of sub-regulatory guidance) published to help clarify how this new ACA language interacts with long-standing 340B policy and practice. Given this void, some states and MCEs have imposed requirements that – perhaps unintentionally – are contrary to Congressional intent behind both the 340B and ACA laws. In addition, some MCEs and states have identified creative strategies for ensuring that the benefits of the 340B program accrue to them, as opposed to the safety net providers for whom Congress intended them.

The Health Resources and Services Administration (HRSA) has tried to provide clarity on these issues and crack down on many of these creative strategies. However, they lack the statutory or regulatory authority to do so. Fortunately, ***CMS has the authority to address these issues, and this regulation provides the appropriate vehicle.*** MACHC appreciates that in §438.3(s)(3), CMS provides some clarity by explicitly stating that 340B providers are not legally responsible for protecting manufacturers from having to pay both a 340B discount and a Medicaid rebate on a managed care claim. However, there are still numerous issues where further official guidance is needed to ensure that practices on-the-ground conform to Congressional intent. Therefore, we ask that CMS expand this section to include language that will:

* + reiterate and protect FQHCs’ (and other 340B providers’) statutory right to use 340B drugs for MCE patients, and
  + prohibit practices that effectively transfer the benefits of 340B from the safety net providers (as Congress intended) to a MCE or state.

**§438.3(s)(3) Specifically, MACHC requests that CMS add language to the preamble and regulatory text to:**

* **state explicitly that neither states nor MCEs may prohibit 340B providers who are in MCE networks from using 340B drugs for their patients.**
* **state explicitly that neither states nor MCEs may require providers to agree not to use 340B drugs to their patients as a condition of participating in an MCE’s network.**
* **prohibit MCEs from paying lower rates for drugs purchased by 340B covered entities than for the same drugs when purchased by other MCE network providers. Similarly, states should be prohibited from requiring MCEs to pay lower rates for drugs purchased by 340B covered entities than for the same drugs when purchased by other MCE network providers.**
* **prohibit MCEs from requiring 340B providers to use a methodology for identifying 340B claims that makes it highly difficult or impossible for these providers and their contract pharmacies to use 340B for Medicaid MCE patients.**

With regards to the last bullet, some States and MCEs currently require providers to use specific methodologies for identifying 340B claims, and some of these methodologies are making it difficult or impossible for 340B providers to use 340B drugs for their patients. For example, pharmacies that use a virtual 340B inventory normally do not know at the point of-sale (POS) if a claim is 340B, so requiring them to identify all 340B drugs at POS effectively prohibits these providers from using 340B drugs for MCE patients.

In addition, MACHC offers the following comments on the interaction of the 340B and Medicaid Managed Care programs:

* **MACHC appreciates that CMS explicitly states that 340B providers are not legally responsible for protecting manufacturers from having to pay both a 340B discount and a Medicaid rebate on a managed care claim.** We believe that this interpretation is consistent with the statute, and also is logical from an operational standpoint. However, since there has been some confusion in the field on this issue, MACHC appreciates CMS addressing it explicitly in the regulation.
* **MACHC recommends that CMS permit 340B providers to report claims data directly to the state or the states’ rebate contractor, bypassing the MCEs, such as is currently done in Oregon.** For many states, it may be more efficient and cost-effective for 340B providers to report their claims data directly to the state or its rebate contractor, instead of MCEs. For example, some MCEs do not possess the technical capability to handle reporting, and/or do not have the necessary relationships with entities to develop successful reporting mechanisms. While this approach may not be appropriate for all states, we recommend that CMS grant states the flexibility to pursue the option if they deem it most appropriate. Any state-created methodology also should allow covered entities to carve in or out on an MCE-by-MCE basis.

Thank you for the opportunity to comment on the NPRM. If you require any clarification on these comments, please feel free to contact me at 301-577-0097 ext. 126 or [jlapinski@machc.com](mailto:jlapinski@machc.com).

Sincerely,

Judy Lapinski

Chief Operating Officer

Mid-Atlantic Association of Community Health Centers

cc: Senator Barbara A. Mikulski

Senator Benjamin L. Cardin

Representative C.A. Dutch Ruppersberger

Representative Andy P. Harris

Representative Chris Van Hollen Jr.

Representative Donna F. Edwards

Representative Elijah E. Cummings

Representative John K. Delaney

Representative John P. S. Sarbanes

Representative Steny H. Hoyer

Van T. Mitchell, Secretary, Maryland Department of Health and Mental Hygiene

Shannon McMahon, Deputy Secretary, Health Care Financing, Maryland

Department of Health and Mental Hygiene

1. 42 USC §256b(a)(5)(A)(i). [↑](#footnote-ref-1)