October 27, 2015

Sylvia M. Burwell, Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

James Macrae, M.A., M.P.P., Acting Administrator
Health Resources and Services Administration
Department of Health and Human Services
5600 Fishers Lane, Parklawn Building, Mail Stop 10C-03
Rockville, Maryland 20857

Captain Krista M. Pedley, PharmD, M.S., USPHS, Director
Office of Pharmacy Affairs
Health Resources and Services Administration
Department of Health and Human Services
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BY ELECTRONIC SUBMISSION

Re: *340B Drug Pricing Program Omnibus Guidance* [RIN-9096-AB08][1]

Dear Secretary Burwell, Acting Administrator Macrae, and Director Pedley:

The Association of Community Cancer Centers (ACCC) appreciates the opportunity to comment on the 340B Drug Pricing Program Omnibus Guidance (the Guidance) proposed by the Health Resources and Services Administration (HRSA). ACCC is an institution-based membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members caring for millions of patients and families fighting cancer. ACCC represents more than 20,000 cancer care professionals from approximately 1,100 hospitals and 1,000 private practices nationwide. Our membership encompasses providers in academic and community-based settings, both for-profit and not-for-profit. Many ACCC members are currently participating in the 340B program.

[1] 80 Fed. Reg. 52,300 (Aug. 28, 2015)

An estimated sixty percent (60%) of US cancer patients receive their care from ACCC members. The diversity of our membership and breadth of our members' reach in cancer care uniquely positions ACCC to contribute a balanced, care-centered voice on the proposed Guidance and its impact on patients and providers fighting cancer. We are pleased to submit the comments outlined below for consideration as HRSA continues its efforts in ensuring the 340B program is administered with predictability, transparency, and clarity, and in a manner consistent with its Congressional mandate.

As HRSA considers final guidance, we ask that the Agency consider ACCC's recommendations and concerns, outlined below and detailed in the pages that follow.

- HRSA's changes to the definition of a "patient" must reflect the complexity of how cancer care is delivered today, and ensure cancer patients retain access to outpatient hospital facilities and community physicians relied upon to deliver appropriate, comprehensive anti-cancer therapy;
- HRSA should collect and consider data on the financial and operational impact the Guidance may have on 340B covered entities and their continued ability to provide quality cancer care to indigent populations, particularly in rural areas;
- HRSA should clarify the effective date for implementation of the Guidance; and
- Any final guidance should be issued as a Notice with Comment Period, both with respect to any areas of significant divergence from the proposed Guidance and the time required for impacted parties to reach compliance.

I. The Association of Community Cancer Centers (ACCC) Applauds HRSA for Providing Much-Needed Clarity on the 340B Program

ACCC has long advocated for clear, coherent and relevant direction on the 340B program to ensure the program remains sustainable in the future and so that our members have the clarity they need to appropriately implement and comply with the program.[2] We recognize the challenges the Agency has faced in this process and applaud HRSA's issuance of the Guidance for comment as a much-needed step toward an effective, sustainable 340B program.

Currently, more than 1,600 hospitals are enrolled in the program, contracting with over 25,000 pharmacies.[3] While the statute permits each outpatient department of a covered entity to utilize drugs purchased under 340B for any of their patients without regard to their insurance status or ability to pay, the overarching goal of the program is to allow hospitals to reinvest savings from discounted drugs into programs serving underinsured, uninsured, and Medicaid patient populations. HRSA's guidance should remain focused on this legislative intent, and preserve indigent patient access to "safety net" providers and medically necessary outpatient drugs.

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[2] Association of Community Cancer Centers Position Paper on the 340B Drug Discount Program, October 2013 , http://www.accc-cancer.org/advocacy/pdf/2013-position-paper-340B.pdf (accessed 10/16/15).

[3] Medicare Payment Advisory Commission Report to the Congress: Overview of the 340B Drug Discount Program, May 2015, vii-viii, http://www.medpac.gov/documents/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0 (accessed October 16, 2015).

II. Ensure the Complexity of Cancer Care is Reflected in Proposed Guidance on Patient Eligibility

HRSA's Guidance notably tightens the definition of a patient for the purposes of eligibility for 340B discounted drugs.[4] For cancer patients, the Guidance diverts covered entity attention from delivering quality, cost-effective, patient-centered care to ensuring that "enough" services are performed to establish or re-establish "patient" status. While ACCC supports efforts to better define the program, we want to ensure the final Guidance recognizes that there are times when the cancer patient journey between settings is necessary and/or cost-effective for the delivery of safe, effective, and efficient cancer care.

ACCC encourages HRSA to consider a definition of "patient" that recognizes the inherent complexities in delivering quality cancer care and the important role office-based oncologists, hospital outpatient facilities, and community cancer centers play for patients fighting cancer. To the extent that the proposed Guidance creates a substantive change, particularly one that has the potential to directly impact uninsured, underinsured, and/or Medicaid patient access to 340B program discounted drugs or the cancer treatments managed or prescribed by an office-based physician and appropriately administered within an outpatient hospital department, we encourage HRSA to consider the multi-site reality of today's cancer care infrastructure and retain appropriate oncology patient access to 340B discounted drugs.

A. Resource and infrastructure constraints often require patients, particularly those in rural areas, to move between sites of care to receive comprehensive, quality oncology services.

It has long been a fact of oncology care delivery that some office-based practices manage and direct cancer care while relying upon outpatient departments to provide and administer therapy. Although it would be difficult to list all of the factors that may drive referrals between physician offices and outpatient departments, the factors listed below provide examples of medically-appropriate referrals that are made without consideration of, or incentives from, the 340B program:

1. Cancer therapies are ever-evolving, and may require special handling in the form of hoods, specialized equipment, or protocols that are relatively cumbersome and impracticable for some office-based providers;
2. Many anti-cancer therapies require long infusion times. Physician offices do not always have the staff required to monitor a patient throughout an infusion and, instead, rely upon outpatient departments specifically staffed to administer these therapies;
3. Outpatient departments may determine that an office-based oncologist, cancer center, or other non-affiliated provider would be an important asset for treatment decisions or identify alternative approaches to an existing treatment regimen;
4. Patients may travel great distances to specialized cancer centers for treatment decisions and/or care management and be unable to return to the prescribing provider for treatment administration; and

[4] 80 Fed. Reg. at 52,319.

5. Some anti-cancer therapies consist of multiple modalities (e.g., infusion and radiology).

The examples given above illustrate patient-centered referrals between physicians and outpatient facilities for cancer care decisions, care management, and treatment administration that reflect continuity of care. In some of the above examples, the patient would receive ongoing treatment within the outpatient department while continuing a relationship with their prescribing oncologist. In these situations, the prescribing physician and her patient neither intend, nor should be required, to transfer care management or responsibility for any other treatment or treatment decision to the outpatient facility.

B. The proposed definition of "patient" may present unintended challenges in patient access to quality cancer care.

The definition of eligible patient for purposes of the 340B program[5] has long permitted the referral care model, outlined above, that is for many providers an appropriate part of quality cancer care. For the cancer care community, the proposed change to patient eligibility substantially and significantly diverges from the implementing guidance, discouraging referrals between outpatient departments and office-based physicians that are often an important part of quality cancer care.

The care delivery model reflected in HRSA's Guidance would appear to significantly impact uninsured, underinsured, and Medicaid patients wishing to utilize an office-based oncologist for care management and treatment throughout their fight against cancer. For the oncology practices that deliver quality cancer care but do not have the infrastructure to administer all cancer therapies, the proposed Guidance will impact patient access to a continuity of care with a physician they have relied upon and grown to trust. Moreover, it is difficult to imagine that an office-based oncologist would be comfortable treating underinsured, uninsured, and/or Medicaid patients knowing that their continued decision-making and care management relationship could end with selection of a treatment regimen.

Similarly, if a covered entity refers a patient to an outside provider who prescribes 340B covered drugs, the referred patient is no longer an eligible patient for that drug.[6] Requiring the patient to return to the covered entity for an office visit and/or laboratory testing for the sole purpose of creating a "patient" relationship, and/or duplicating the outside provider's service in re-prescribing the drug would appear to ensure compliance. It is however, a potential waste of healthcare dollars as well as of questionable medical necessity, and perhaps more importantly, needlessly inconveniences the patient and subjects the patient to unnecessary procedures and costs. For uninsured and underinsured patients, covered entities may feel pressure to avoid making referrals or decline to absorb the financial burden associated with an insufficiently reimbursed service to re-establish a "patient" relationship.

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[5] Notice Regarding Sec. 602 of the Veterans Health Care Act of 1992: Patient and Entity Eligibility, 61 Fed. Reg. 55156-8 (Oct. 24, 1996).

[6] 80 Fed. Reg. at 52,319.

HRSA's proposed constriction in patient eligibility for 340B discounted drugs will likely impact cancer care and treatment decisions fairly broadly. The greatest impact with respect to access, however, will likely fall primarily on indigent patients and those living in rural areas, in direct conflict with the original intent of the program.

Despite continuing advances in cancer diagnosis and treatment, uninsured, underinsured, and Medicaid patients are less likely to survive cancer than privately-insured patients.[7] ACCC is concerned that HRSA's proposed constriction of 340B patient eligibility will exacerbate hurdles to underserved patients' access to quality cancer care. In the event that HRSA determines to implement the proposed definition of "patient," ACCC urges the Agency to conduct a patient-impact study to ensure that referrals to/from covered entities and 340B discount drug access are not disrupted, regardless of insurance status.

C. HRSA should consider the potential administrative burden the definition of "patient" presents for covered entities.

ACCC is concerned that the proposed definition of "patient" injects inherent, and unintended, operational complexities for covered entities. From an administrative standpoint, covered entities would be required to carefully examine their referral practices and develop protocols to ensure that patient status does in fact meet HRSA's new requirements and, if disrupted, was re-established prior to administering a therapy. For example, if a cancer patient was diagnosed within a covered entity, received an initial course of treatment and follow-up within that same covered entity, but upon relapse was referred to a geographically distant outside physician who prescribed a subsequent treatment regimen, how does the covered entity meet their patient's expectation of continued care? To the extent that an "incident to" injection or infusion alone is not sufficient to re-establish patient status and a covered entity's evaluation and management service prior to therapy would be required, ACCC urges HRSA to coordinate with the Centers for Medicare and Medicaid Services (CMS) to ensure that covered entities understand when claims for these additional services will be reimbursed or denied as not medically necessary and/or bundled into the treatment administration service.

With respect to maintenance of medical records, ACCC expects that covered entities administering anti-cancer therapies on referral from an office-based physician do, and should continue to, maintain information in medical records as a part of their ordinary practices in ensuring patient safety. If HRSA has specific requirements with respect to the content of a covered entity's patient medical records for 340B program purposes, ACCC urges the agency to detail those requirements, solicit comments, and provide covered entities with a reasonable period of time to implement any change in their usual business practices.

[7] See, American Cancer Society, Cancer Action Network, Cancer Disparities: A Chartbook, 2009, http://action.acscan.org/site/DocServer/cancer-disparities-chartbook.pdf (accessed October 27, 2015).

III. ACCC Urges HRSA to Work with Stakeholders to Collect Data on Financial and Operational Impact of Proposed Guidance

The proposed Guidance creates a number of administrative and accountability requirements for covered entities. ACCC strongly encourages HRSA to work with stakeholders to collect data on the financial and operational impact of these new requirements on covered entities. Specifically, ACCC urges the Agency to carefully examine the impact on covered entities' (particularly those in rural areas) ability to continue providing high quality cancer care to underinsured and uninsured patients.

ACCC is eager to work with HRSA, and can facilitate access to our covered entity members or otherwise partner with the Agency to ensure it has the information and data to ensure that its efforts to increase accountability and compliance do not impede access to the quality cancer care our members provide and our organization is committed to preserve.

IV. ACCC Requests that HRSA Issue Final Guidance with Comment Period, Clarify Effective Date(s), and Solicit Comments on Sufficiency of Time for Compliance

ACCC strongly supports HRSA's issuance of 340B program Guidance. HRSA's Proposed Notice characterizes the guidance as "intended to assist 340B covered entities and drug manufacturers in complying with the statute" and that any final notice would similarly be intended as a tool to assist participants in complying with the 340B statute. In addition to the points outlined above, we are concerned that the proposed Guidance did not provide an effective date other than for those related to the AIDS Drug Assistance Program (ADAP).[8] Similarly, there was no Agency indication of whether any final guidance would apply prospectively only, or retrospectively (as may be the case for the ADAP provision).

ACCC urges HRSA to clarify that any guidance in the proposal would apply prospectively and no sooner than the date HRSA issues its Final Guidance. To the extent that any language creates new requirements on impacted entities or diverges administratively from previously issued guidance, ACCC is concerned that the burden on providers and time required for compliance justifies an additional comment period. We strongly urge HRSA to set forth reasonable timeframes for compliance – at least 12 months from publication of the final guidance – and consider comments from impacted parties on the sufficiency of the time period proposed. Similarly, to the extent that any provisions of HRSA's final guidance diverge significantly or materially from the proposed Guidance, ACCC urges the Agency to solicit and consider stakeholder comments on such provisions.

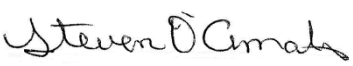
Thank you for this opportunity to share the oncology care provider perspective on the proposed changes in and clarifications to the 340B Drug Discount Program. As the association representing the multidisciplinary cancer team, ACCC is uniquely suited to participate in this

[8] See 80 Fed. Reg. at 52,313 ("Therefore, to allow for the development of systems and any other necessary changes in order to make qualified payments on behalf of an ADAP client for those states utilizing the rebate option, HHS is proposing to delay the effective date of section (b) of Part G, defining qualified payment, for 12 months after the publication date of the final guidance.").

dialogue. Please feel free to contact Leah Ralph, Director of Health Policy, at (301) 984-5071 if you have any questions or need any additional information.

Thank you again for your attention to this very important matter.

Respectfully submitted,



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