WYATT TARRANT & COMBS LLP

Client Update

Comments on 340B Drug Pricing Program Omnibus Guidance (RIN 0906–AB08)

October 27, 2015
By: Daniel C. Soldato

VIA ELECTRONIC MAIL
Krista Pedley
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
Email: 340BGuidelines@hrsa.gov

RE: Comments on 340B Drug Pricing Program Omnibus Guidance (RIN 0906–AB08)

Dear Ms. Pedley,

Wyatt, Tarrant & Combs, LLP ("WTC") is hereby submitting the comments below to the proposed 340B Drug Pricing Program Omnibus Guidance ("Guidance"). WTC appreciates the opportunity to submit these comments. WTC is a law firm that represents a number of 340B covered entities, including hospitals that participate in the 340B Drug Pricing Program (the "Program"). WTC has experience advising several of our hospital clients regarding issues related to the Program, including compliance matters. WTC has spoken with a number of our hospital clients regarding the Guidance and their concerns with the Guidance.

While the Office of Pharmacy Affairs ("OPA") has clarified certain aspects of the Program through the Guidance, we believe that several of the proposed changes in the Guidance will be overly burdensome to hospitals that participate in the Program without any corresponding benefit, will result in increased costs to such hospitals, and will limit the scope of the Program in a manner not intended by Congress. These results are contrary to the intent of the 340B legislation, the aim of which was to stretch the already limited resources of safety net hospitals. Our specific concerns and recommendations to address those concerns are outlined below.

Definition of Patient

OPA has proposed a significant change to the definition of "patient" in the proposed Guidance. As noted in the Guidance, the current definition of patient is set forth in a guidance document issued by OPA in 1996. This current three-part definition generally requires that (i) the covered entity participating in the Program has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; (ii) 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 with the covered entity; and (iii) 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 to the entity (this third element does not apply to disproportionate share hospitals).

The proposed Guidance sets forth a more complex, six-part test that must be analyzed on a "prescription-by-prescription or order-by-order basis" to determine whether an individual qualifies as a patient. 80 Fed. Reg. 52306 (August 28, 2015). The proposed test to determine whether an individual is a "patient" of a covered entity requires that an individual meet the following six elements: (i) the individual receives a health care service at a facility which is registered for the Program and is listed on the 340B database; (ii) the individual receives health care services from a health care professional who is either employed by the covered entity or is an independent contractor of the covered entity, such that the covered entity may bill for services on behalf of the provider; (iii) the individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in item (ii) above; (iv) the individual's health care is consistent with the scope of the Federal grant, project, designation or contract (for covered entities whose eligibility is based upon such criteria); (v) the individual's drug is ordered or prescribed pursuant to a health care service that is classified as outpatient; and (vi) the individual's patient records are accessible to the covered entity and demonstrate that the covered entity is responsible for care.

This proposed six-part test materially changes the scope of patients who are eligible for 340B drug prescriptions and will create significant issues for hospitals. The first issue relates to the new standard regarding the prescribing or ordering provider's relationship with the covered entity. Hospitals will need to significantly revise their list of providers who may prescribe 340B drugs to hospital outpatients. This may seem relatively straightforward given that OPA attempted to simplify the standard for provider affiliation with a covered entity. However, through the simplification, OPA will cause certain hospitals to be unable to meet the patient definition at all. Specifically, it does not appear that physicians and other providers who are employed by or contracted with a covered entity hospital affiliate will meet the standard set forth above. If not, many hospitals will have no qualifying providers because they are part of a health system that employs or contracts with physicians through a subsidiary or affiliate entity that is separate from the 340B covered entity. This could result in a scenario in which the hospital is unable to ever meet element (ii) of the new proposed "patient" definition, thereby effectively preventing the hospital from participating in the Program.

Another area of concern relates to a potential compliance risk due to a lack of clarity as to whether the proposed patient definition allows follow-up prescriptions or refills related to conditions diagnosed and treated with prescriptions from the original outpatient visit described in element (ii) of the proposed standard. Is a patient required to visit the hospital outpatient department for each prescription in order to be deemed a "patient" for purposes of the Program or are refills relating back to the original visit acceptable? This is not clear from the Guidance. This issue and others will create significant compliance risk for hospitals that will inevitably lead to additional costs and use of scarce resources.

In order to rectify these potential issues, we recommend the following. First, the OPA should retain element (ii) of the 1996 patient definition in lieu of utilizing element (ii) of the proposed patient definition. This would allow hospital covered entities to maintain their current practices and standards and eliminate the possibility of effectively disqualifying certain

hospitals from participating in the Program if they do not directly contract with providers. Second, we recommend that the OPA clarify that refill prescriptions arising out of a qualifying outpatient visit would meet the criteria in the proposed patient definition. This would provide clear guidance to the covered entity and establish a bright line regarding which prescriptions qualify for 340B Program treatment.

Contract Pharmacy Audits and Quarterly Reviews

OPA has proposed new standards for oversight of contract pharmacies by covered entities. Specifically, OPA has proposed that each covered entity undertake annual audits of each contract pharmacy with which it contracts under the Program. This annual audit must be conducted by an independent entity. OPA has also proposed that covered entities review the contract pharmacy's dispensing data on at least a quarterly basis to ensure that no diversion has occurred or duplicate discounts have been provided. 80 Fed. Reg. 52321. These new requirements impose a significant administrative and cost burden on the covered entity hospitals. Hospitals do not need this increased oversight, given that each has already determined the optimal level of oversight through its current contract with the contract pharmacy. Each covered entity is aware that it is responsible for compliance with the Program's requirements. Thus, each covered entity has ensured that its contracts with its contract pharmacies include specific mechanisms to allow the covered entity to review the contract pharmacy's actions and to ensure compliance with the Program's requirements. The new proposed audit and quarterly review requirements are unnecessary and duplicative given the existing oversight that each covered entity hospital has imposed on its contract pharmacies through its contracts. It is an unnecessary expense and one that will reduce the hospital's financial and administrative resources. We recommend that the proposed annual audit and quarterly review requirements be eliminated and that the covered entity hospitals be allowed to independently determine the adequate audit and oversight of each contract pharmacy. OPA still has the ultimate authority to sanction covered entities for non-compliance, which should be adequate incentive to oversee and monitor contract pharmacies.

Medicaid Managed Care Organizations

The Guidance indicates that a covered entity may determine whether to carve-in or carve-out for Medicaid managed care organization ("MCO") patients separately from such determination for Medicaid fee for service patients. In addition, the covered entity may make such a determination independently for each covered entity site, but must provide HRSA with the details of such decision, including information regarding the site and the applicable MCO. 80 Fed. Reg. 52309. Further, OPA has indicated that it will presume that a contract pharmacy will not dispense 340B drugs to Medicaid MCO patients. In order to rebut the presumption and dispense 340B drugs to Medicaid MCO patients through a contract pharmacy, the covered entity will be required to provide HHS a written agreement with its contract pharmacy and the MCO that describes a system to prevent duplicate discounts. *See id.* HHS must approve the arrangement.

We agree with the OPA's general proposed guidance on this issue, but recommend that OPA provide more specific guidance regarding the content of the written agreement to prevent duplicate discounts. Kentucky currently has five Medicaid MCOs operating in the Commonwealth. Each MCO has its own processes and systems, each of which presents

unique challenges to hospitals in the Commonwealth. If OPA could provide specific, bright line guidance regarding the content of the written agreements and a standardized system to prevent duplicate discounts, it would simplify a complicated process for the hospital covered entities and MCOs. As OPA is aware, the cooperation of the MCOs is necessary in this process, and any assistance OPA could provide the hospitals would ease the burden in contracting with the MCOs, particularly in a state with five separate MCOs with which the hospitals are contracting.

WTC appreciates the opportunity to express our concerns with the Guidance and we hope our recommendations will be reflected in the final guidance.

Please contact me should you have any questions.

Sincerely,

WYATT, TARRANT & COMBS, LLP

Daniel C. Soldato
P 859-288-7631
dsoldato@wyattfirm.com