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HRSA PROPOSES OMNIBUS GUIDANCE FOR THE 340B PROGRAM

The Health Resources and Services Administration (HRSA) recently issued [proposed omnibus guidance](#) (Omnibus Guidance) interpreting various provisions of the 340B Drug Pricing Program (340B Program). The 340B Program allows certain eligible “covered entities” to purchase outpatient prescription drugs at discounted rates from participating drug manufacturers. The purpose of the Omnibus Guidance is to assist covered entities and drug manufacturers in complying with the 340B Program’s requirements. Since implementation of the 340B Program, HRSA and its prime vendor for the 340B Program, Apexus, have issued several guidance documents and FAQs regarding various aspects of the 340B Program; however, ambiguities from this guidance still exist. The Omnibus Guidance proposes to clarify and revise certain aspects of the current guidance. Highlights of the proposals in the Omnibus Guidance are summarized below. Public comments on the Omnibus Guidance are due to the HRSA by October 27, 2015.

Eligible Patients

To receive a 340B Program drug from a covered entity, an individual must qualify as a “patient” of that covered entity. Currently, an individual is generally considered to be a patient of a covered entity if (1) the covered entity maintains records of the individual’s health care at the covered entity; (2) the individual receives health care from an employee or contractor of the covered entity, with the covered entity maintaining ultimate responsibility for the individual’s care; and (3) the individual receives a range of health care services from the covered entity consistent with the range of services for which the covered entity receives federal funding.

The Omnibus Guidance proposes several important changes to the definition of patient. Under the guidance, an individual is required to satisfy a six-part test (described below) on a “prescription-by-prescription or order-by-order basis.” This means that the determination of whether an individual is a 340B Program patient is made each time a prescription or order is written. The six-part patient eligibility test is as follows:

1. *The individual must receive a health care service at an eligible covered entity, and the covered entity must be registered for the 340B Program and listed in the 340B public database. The Omnibus Guidance states that prescriptions issued after a telemedicine visit with a covered entity satisfies this requirement to the extent permitted by federal and state law; however, care*

provided by a health care organization that has an affiliation with a covered entity does not qualify the individual as a patient of the covered entity for 340B Program purposes.

2. *The individual must receive a health care service from a provider that is either employed by or a contractor of the covered entity “such that the covered entity may bill for services on behalf of the provider.”* Relationships that satisfy this requirement include *locum tenens* arrangements and faculty practice arrangements. According to the Omnibus Guidance, “having privileges or credentials at a covered entity is not sufficient to demonstrate that an individual treated by that privileged provider is a patient of the covered entity for 340B Program purposes.”
3. *The covered entity must order or prescribe a drug as a result of the health care service provided in 2. above.* Under the Omnibus Guidance, covered entities are able to use telemedicine, telepharmacy, remote, and other health care service arrangements to provide the services and prescriptions to the extent otherwise permitted by federal and state law. If, however, the covered entity’s only relationship to the individual is through dispensing or infusing the drug, the individual does not qualify as a 340B Program patient.
4. *The health care service provided to the individual must be within the scope of the covered entity’s federal grant, project, designation, or contract.* This requirement applies only to covered entities whose 340B Program eligibility is based on receipt of a federal grant, project, designation, or contract.
5. *The individual’s drug must be prescribed or ordered as a result of an outpatient health care service.* Under the proposed Omnibus Guidance, outpatient status is determined by how the services are billed. To be eligible, the covered entity must bill the service as an outpatient service to a third-party payor. In the case of self-pay or uninsured individuals, the covered entity determines whether the service is an outpatient service based on the covered entity’s written policies and procedures regarding outpatient classification.
6. *The individual and covered entity must have a provider-patient relationship, and the covered entity must maintain access to the individual’s medical records sufficient to demonstrate that the covered entity is responsible for the individual’s care.* The Omnibus Guidance requires that all such medical records be auditable.

The Omnibus Guidance affirms HRSA’s position that employees of a covered entity are not considered patients of the covered entity as a result of their employee status and must satisfy the definition of a patient to be eligible to receive 340B drugs. The Omnibus Guidance preserves the current exception that allows individuals enrolled in a Ryan White HIV/AIDS drug program to receive 340B Program drugs without satisfying the definition of a patient, described above.

Covered Entity Designation of Child Sites

Only certain types of hospitals and nonhospital providers are eligible to become covered entities under the 340B Program. A hospital that is a covered entity may register off-site outpatient locations that are not located at the same physical address as an eligible 340B Program location (each referred to as a “child site”). To become a child site, the location must be listed as reimbursable on the hospital’s cost report, and the services provided at that location must have outpatient Medicare costs. Through the Omnibus Guidance, HRSA seeks comments on other methods for demonstrating that an off-site outpatient facility is an eligible child site.

Eligible Drugs

The 340B Program requires drug manufacturers to offer covered entities outpatient drugs at a price that is below the ceiling price set by HRSA. The 340B Program statute and prior guidance issued by HRSA and Apexus provides that certain outpatient drugs are not eligible for purchase under the 340B Program if included in a bundled payment rate. This restriction is applied regardless of whether the payment is made by Medicaid or another third-party payor. The Omnibus Guidance proposes to modify

this restriction so that a drug is ineligible only if it is part of a bundled payment paid by Medicaid.

Contract Pharmacy Arrangements

The 340B Program permits covered entities to contract with one or more licensed pharmacies (contract pharmacies) to dispense 340B Program drugs, provided the arrangement satisfies other 340B Program requirements and is otherwise in compliance with applicable law (including the Anti-Kickback Statute). The Omnibus Guidance requires covered entities to conduct quarterly reviews and annual independent audits of each contract pharmacy and to disclose any violations to the Department of Health and Human Services (HHS).

Record Keeping and Audit Response

Under the Omnibus Guidance, HRSA proposes a five-year minimum record retention period for covered entities. The five-year term is calculated from the date the particular drug is ordered or prescribed or, in the case of a covered entity's termination from the 340B Program, from the date of termination. This record retention requirement also applies to all child sites and contract pharmacies. Throughout the Omnibus Guidance, HRSA emphasizes that covered entities must keep auditable records relating to compliance with the 340B Program requirements. The failure to keep appropriate records could result in the ineligibility of a covered entity and corresponding repayments, as well as potential removal from the 340B Program.

The statutes governing the 340B Program permit both HHS and participating drug manufacturers to audit covered entities for compliance with the 340B Program requirements. Under the Omnibus Guidance, if HHS's audit reveals any adverse findings, the covered entity is given notice of such findings and an opportunity to respond.

Registration, Recertification, and Termination

Currently, a covered entity that becomes ineligible to participate in the 340B Program is removed from the program and must immediately notify HHS and stop purchasing 340B drugs. In the Omnibus Guidance, HHS proposes to clarify when a covered entity may reenroll in the 340B Program after becoming ineligible. Specifically, the Omnibus Guidance proposes that a covered entity may reenroll in the 340B Program during the next enrollment period after the covered entity satisfactorily demonstrates to HHS that it will comply with all 340B Program requirements and, if necessary, has repaid, or is in the process of offering repayment to, drug manufacturers.

Prohibition on Duplicate Discounts

The Social Security Act requires drug manufacturers to provide rebates to states for certain outpatient drugs provided to Medicaid fee-for-service (FFS) beneficiaries. The Affordable Care Act extended this rebate program to apply to certain outpatient drugs provided to patients of Medicaid managed care organizations (MCOs). The 340B Program prohibits "duplicate discounts," meaning that a drug provided at the discounted 340B price is not eligible for an FFS or MCO rebate. Upon enrolling in the 340B Program, a covered entity must notify HHS whether it will purchase drugs for Medicaid FFS and MCO patients through the 340B Program (carve-in) or through other means (carve-out). Currently, if a covered entity is carved-in, then all drugs billed under the covered entity's provider number for Medicaid patients must be purchased under the 340B Program. If a covered entity is carved-out, then all drugs billed under the entity's provider number must be purchased outside the 340B Program. Under the Omnibus Guidance, a covered entity is permitted to vary its carve-in/carve-out election with respect to purchases for MCOs by site and by particular MCO, provided the covered entity informs HHS of such elections and meets other 340B Program requirements.

GPO Prohibition

Under the 340B Program, disproportionate share hospitals (DSHs), children's hospitals, and freestanding cancer hospitals may not purchase from a group purchasing organization (GPO) any drugs covered by the 340B Program. In general, disproportionate share hospitals, children's hospitals, and freestanding cancer hospitals may only use a GPO for inpatient purposes or to purchase drugs not

covered by the 340B Program. The Omnibus Guidance proposes to permit locations of a covered entity, including DSHs, children's hospitals, and freestanding cancer hospitals, that are not 340B Program child sites to purchase outpatient drugs through a GPO as long as such purchase is made through a separate GPO account from the covered entity's 340B Program-enrolled sites and the covered entity prevents drugs purchased through the GPO from being provided to outpatients of sites enrolled in the 340B Program. The Omnibus Guidance clarifies that a covered entity does not become ineligible for the 340B Program by providing GPO drugs to an inpatient whose status is later reclassified as an outpatient as long as such change in status is appropriately documented. The Omnibus Guidance proposes to exempt hospitals from the GPO prohibition in situations where they cannot access a drug at a 340B Program-approved price. It also proposes to extend the 340B Program's notice and hearing process to a covered entity's violations of the GPO prohibition.

Conclusion

If finalized, the Omnibus Guidance will make several significant changes to the 340B Program, particularly with respect to patient eligibility. Many other proposals in the Omnibus Guidance provide more clarity around previously issued guidance. Public comments on the Omnibus Guidance are due to HRSA by October 27, 2015.

60-DAY RULE LAWSUIT HEADS FOR SETTLEMENT CONFERENCE

The parties in *U.S. ex rel. Kane v. Continuum Health Partners, Inc., et al.* (alternately known as *Kane v. Healthfirst, Inc., et al.*) have begun settlement talks in the wake of the U.S. District Court for the Southern District of New York's (SDNY) ruling rejecting the defendants' motion to dismiss. In a letter from the Department of Justice (DOJ) to the judge in the case, Judge Edgardo Ramos, the DOJ stated that the parties "believe it is in their best interests to explore settlement before engaging in discovery." The case has been referred to a magistrate judge, who will hold a settlement conference between the parties on October 29.

The case, which Robinson+Cole most recently wrote about [here](#), is the first publicly unsealed whistleblower case to interpret the "60-Day Rule" found in the Affordable Care Act. The 60-Day Rule subjects health care providers to potential liability under the federal False Claims Act (FCA) for failing to report and return a Medicare or Medicaid overpayment within 60 days of the date on which such overpayment is identified. The defendants in *Kane* are challenging the interpretation of the term "identified." In his ruling on the defendants' motion to dismiss, Judge Ramos held that an overpayment is identified when a provider is put on notice of a potential overpayment rather than the moment an overpayment is conclusively ascertained.

The case has potentially wide-reaching implications, as it may affect a pending Centers for Medicare and Medicaid Services (CMS) final rule addressing Medicare Part A and Part B overpayments. If the case settles, it may lead to further uncertainty as to the definition of "identify" in the 60-Day Rule, as the Court will not rule on the ultimate issue of when the defendants identified their overpayments. Additional 60-Day Rule guidance is expected by February 1, 2016, when CMS is slated to publish its final rule. Until that time, health care providers would be well served to contact their legal counsel as soon as possible if they have identified potential Medicare or Medicaid overpayments. Robinson+Cole will continue to monitor developments in this case and with the 60-Day Rule.

If you have any questions, please contact a member of Robinson+Cole's [Health Law Group](#):

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