



## On the Subject

### HHS Releases Long-Awaited 340B Proposed Guidance

David Ivill, Emily Cook and Joseph Parise

On August 27, 2015, the U.S. Department of Health and Human Services (HHS) released the long-awaited and much-anticipated proposed 340B Drug Pricing Program (340B Program) Omnibus Guidance (Proposed Guidance). The Proposed Guidance addresses most 340B Program eligibility and compliance requirements that are not subject to HHS rulemaking authority. Of particular interest to entities participating in the 340B Program, the Proposed Guidance includes significantly revised definitions of drugs eligible for discounted 340B pricing and patients eligible to receive such discounted drugs. In addition, the Proposed Guidance would change current requirements related to compliance with the Group Purchasing Organization (GPO) prohibition, contracts with governmental entities to support eligibility, auditable record requirements, dispensing of 340B drugs to Medicaid managed care enrollees, and contract pharmacy oversight, among other topics. The Proposed Guidance is open for public comment until October 27, 2015.

This article highlights key takeaways of the Proposed Guidance and provides an outline of all provisions included in the Proposed Guidance. While portions of the Proposed Guidance reflects current published 340B Program guidance, many elements of the Proposed Guidance appear to articulate new interpretations of existing 340B Program requirements or written guidance consistent with HHS positions previously shared informally, through “frequently asked questions” and through audits of 340B entities. Notably, although not unexpectedly, the Proposed Guidance focuses heavily on

eligibility and compliance obligations for 340B covered entities, with limited attention to new proposed requirements for manufacturers participating in the 340B Program.

#### Key Takeaways: Eligible Drugs and Eligible Patients

The most significant changes to 340B Program policies contained in the Proposed Guidance are the proposed definitions of (i) “covered outpatient drug” and (ii) an eligible “patient.” The Proposed Guidance includes changes to both definitions that, if implemented, would likely reduce overall volume of drugs eligible for 340B pricing and would require implementation of costly and administratively burdensome dispensing and inventory tracking systems.

#### COVERED OUTPATIENT DRUG

Only those drugs classified as “covered outpatient drugs” are eligible to be purchased at discounted 340B prices. The 340B statute defines “covered outpatient drug” by reference to the Medicaid rebate statute. The Medicaid rebate statute’s definition of covered outpatient drug incorporates a “limiting definition” that specifically excludes drugs that are part of a bundled payment for Medicaid reimbursement purposes. Discounts under the 340B Program apply to all “covered outpatient drugs,” regardless of who pays for such drugs; as such, this “limiting definition” has resulted in challenges in applying the statutory definition of covered outpatient drug to the 340B Program. HHS has historically resisted providing guidance regarding the application of the statutory definition in connection with the 340B Program.

In the Proposed Guidance, however, HHS proposes to apply the limiting definition—but only to 340B drugs paid for by

Medicaid. Therefore, when billed to Medicaid, a drug that is bundled for payment purposes would not be considered a covered outpatient drug and would not be eligible for 340B pricing. For those 340B entities subject to the prohibition on the purchase of covered outpatient drugs through a GPO, drugs bundled for payment purposes and billed to Medicaid could presumably be purchased through a GPO. However, if the same drug was billed to any other payor (not Medicaid), such drug would be considered a covered outpatient drug, eligible for 340B pricing and subject to the GPO prohibition.

If implemented as proposed, this provision could create significant administrative challenges. Covered entities could no longer categorically classify certain drugs as “covered outpatient drugs,” because the status of such drugs may vary by payor. As a result, covered entities might be unable to determine the appropriate drug purchasing account to use in purchasing such drugs until after the payor is determined—which in some cases could occur well after the drug is dispensed.

#### ELIGIBLE PATIENTS

Drugs purchased at the 340B price may only be dispensed to eligible “patients” of the 340B entity. The existing definition of an eligible patient was finalized in 1996 and was intended to accommodate the wide range of entities participating in the 340B Program as well as the disparate care delivery models utilized by those entities. Over time, it has become apparent that the current definition of “patient” lacks clarity and creates challenges for covered entities in complying with HHS expectations of which individual patients are considered eligible for 340B drugs. Under the existing definition, an individual may receive a 340B drug if he or she meets the following criteria:

- The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual’s health care.
  - 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 (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity.
  - The individual receives a health care service or range of services from the covered entity that is consistent with the service or range of services for which grant funding or federally qualified health center lookalike status has been provided to the entity (This provision does not apply to hospitals).
- Under the Proposed Guidance, HHS would require a tighter nexus between each prescription filled with a 340B drug and the care provided by the 340B entity. The Proposed Guidance states that the eligibility determination would be on a per-prescription (or per-order) basis and must meet all of the following criteria:
1. The individual receives a health care service at a covered entity site that is registered for the 340B Program and listed on the public 340B Database.
  2. The individual receives a health care service from a health care provider who (i) is employed by the covered entity or (ii) is an independent contractor of the covered entity such that the covered entity may bill for services on behalf of the provider.
  3. An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in (2). An individual will not be considered a patient of the covered entity if the only health care received by the individual from the covered entity is the infusion of a drug or the dispensing of a drug.
  4. The individual receives a health care service that is consistent with the covered entity’s scope of grant, project or contract.
  5. The individual is classified as an outpatient when the drug is ordered or prescribed. The patient’s classification status is determined by how the services for the patient are billed to the insurer (e.g., Medicare, Medicaid, private insurance). An individual who is self-pay, uninsured, or whose cost of care is covered by the covered entity will be considered a patient if the covered entity has clearly defined policies and procedures that it follows to classify such individuals consistently.
  6. The individual has a relationship with the covered entity such that the covered entity maintains access to auditable

health care records which demonstrate that the covered entity has a provider-to-patient relationship, that the responsibility for care is with the covered entity, and that each element of this patient definition in this section is met for each 340B drug.

It appears that this proposed definition of “patient” is intended to address a concern on the part of HHS that, in certain circumstances, the current definition of patient permitted dispensing of 340B drugs to individuals whose relationship with the 340B entity was too attenuated for such individuals to be considered “patients” of the entity. Of note in the proposed definition is the removal of the maintenance of records of the individual’s care as an element of eligibility and the removal of the reference to arrangements with practitioners beyond employment or independent contractor status. Further, the proposed definition ties the eligibility of a prescription to a service for which the 340B entity could bill the patient or a payor as an outpatient service. Among current common arrangements that would appear not to qualify for 340B eligibility under the proposed guidance are (i) arrangements under which a 340B entity contracts with a community provider to furnish services to a patient where the care is provided outside of the 340B entity and must be billed by the contracted provider, and (ii) arrangements for infusion services where the prescription or order for the infused drug is written by a community practitioner who is not employed by or under contract with the 340B entity.

In addition to changes in the relationship between the practitioner writing the prescription and the covered entity, the Proposed Guidance makes a notable change to the scope of drugs eligible for 340B pricing. The Proposed Guidance would limit 340B pricing to drugs that are ordered or prescribed while the patient is classified as an outpatient, as determined by payor billing rules. Currently, HHS permits each 340B entity to establish guidelines for determining patient status at the time a drug is dispensed; therefore, if the entity determines that a patient is an outpatient at the time of dispensing, but the patient is later admitted as an inpatient, the entity can dispense a 340B drug to the patient while in outpatient status as long as the entity retains documentation to support the patient’s outpatient status at the time of dispensing. Under the Proposed Guidance, if a patient were treated as an outpatient and later admitted as an inpatient, and if the patient’s payor

required the combined service to be billed as an inpatient service (e.g., the Medicare “three-day payment window,” which can result in certain outpatient services furnished as much as three days prior to an inpatient admission being bundled into the inpatient bill and payment), the drugs dispensed while the patient was considered an outpatient by the entity would appear to no longer be eligible for 340B pricing. This element of the patient definition in the Proposed Guidance appears to prevent hospitals from classifying as 340B-eligible discharge prescriptions written in the course of a patient discharge from an inpatient service, to be filled at a retail pharmacy post-discharge.

The proposed changes to the patient definition are likely to create challenges for most hospital covered entities, because it makes it impossible to determine patient eligibility for 340B drugs at the time of dispensing in certain locations. Further, many hospitals that operate outpatient clinics and currently stock only 340B drugs would be required to implement new inventory systems, because it would not be possible to determine with certainty that all services furnished at the location would ultimately be billed to all payors as outpatient services. The patient definition also appears to be inconsistent with HHS Medicare policies, which differentiate between patient status and payment provisions. Under Medicare program guidance, a patient is considered an inpatient as of the time the inpatient admission occurs and, although certain services furnished while the patient was an outpatient may be bundled into the inpatient payment, the admission does not result in classification of the patient as an inpatient prior to the time of the inpatient admission.

## Other Significant Proposed Changes

### GROUP PURCHASING ORGANIZATION PROHIBITION

Hospitals participating in the 340B Program as disproportionate share hospitals, children’s hospitals or cancer hospitals are prohibited by statute from purchasing covered outpatient drugs through a GPO. As discussed previously, the proposed changes to the definition of covered outpatient drug may result in challenges in identifying those drugs eligible for purchase at 340B pricing and those eligible for purchase through a GPO. In addition, the Proposed Guidance contains discussion of consequences for non-compliance with the GPO Prohibition, as well as exceptions to the GPO Prohibition. As

previously articulated in HHS guidance materials, compliance with the GPO Prohibition is a requirement for eligibility in the 340B Program. Non-compliance may result in removal from the 340B Program and renders covered entities liable to manufacturers for 340B discounts received during periods of non-compliance. HHS had previously provided for an exception to the GPO Prohibition for off-site outpatient locations of a hospital that were explicitly excluded from participation in the 340B Program. HHS again articulated that exception and formally proposed two additional exceptions. The additional exceptions apply (i) to the dispensing of GPO drugs to individuals originally classified and billed as inpatients, but where the stay was later converted to outpatient following review by a third party (e.g., Recovery Audit Contractor), and (ii) to the dispensing of GPO drugs to outpatients where clinical needs require a drug that is only available through a GPO.

#### **CONTRACTS WITH GOVERNMENTAL ENTITIES TO SUPPORT ELIGIBILITY**

Hospitals participating in the 340B Program must meet one of three criteria related to the hospital's relationship with a governmental entity, as follows:

- Government ownership/control
- Grant of governmental powers
- Contract with state or local government for the provision of health care services to low-income individuals not eligible for Medicare or Medicaid

In the Proposed Guidance, HHS includes language related to the contract requirement, stating that the contract must "create enforceable expectations for the hospital for the provision of health care services." Prior HHS guidance regarding the contract requirement did not include this language, and the Proposed Guidance does not provide further clarity regarding this requirement. Without additional detail, this proposed new requirement is difficult to interpret and apply. It is not apparent what types of enforcement action HHS expects state and/or local governments to take. Further, it is not clear whether HHS would require entities with long-standing contracts in place to enter into new contracts if the current contracts do not include language addressing enforcement.

#### **AUDITABLE RECORDS REQUIREMENTS**

The Proposed Guidance includes several provisions related to the creation, maintenance and retention of auditable records. While the expectation to create and maintain auditable records is not new, the Proposed Guidance's emphasis on this requirement suggests that HHS has concerns regarding current compliance. The particular attention to auditable records in connection with replenishment inventory models and contract pharmacies suggests that these are particular areas of increased attention also. Although historically there has been an understanding that the 340B Program required retention of records for at least three years, the Proposed Guidance creates an explicit five-year record retention requirement. It also states that HHS could look back further than five years in the event of an audit. The Proposed Guidance does not, however, provide for a specific look-back period for non-compliance.

#### **MEDICAID MANAGED CARE AND DUPLICATE DISCOUNTS**

Duplicate discounts occur when a drug manufacturer provides both a 340B discount and a Medicaid rebate on the same drug. HHS has previously released guidance materials regarding prevention of duplicate discounts, but indicated that Medicaid managed care patients were outside of the scope of such guidance. The Proposed Guidance provides some limited instruction regarding prevention of duplicate discounts as to Medicaid managed care patients. The Proposed Guidance would establish an expectation that 340B drugs would not be dispensed to Medicaid managed care patients through contract pharmacy arrangements, and would permit 340B entities to establish different approaches to addressing duplicate discounts for Medicaid fee-for-service and Medicaid managed care patients. Regarding the specifics of how a 340B entity would identify Medicaid managed care patients and 340B drug claims for such patients, the Proposed Guidance encourages 340B entities, state Medicaid programs and Medicaid managed care entities to engage in further discussions. Historically, it has been challenging to obtain guidance and coordination on 340B duplicate discount issues between the state Medicaid programs and Medicaid managed care entities. As a result, the Proposed Guidance may create more challenges for compliance with duplicate discounts than if HHS had proposed more clear and uniform expectations for 340B entities and Medicaid managed care organizations.

## CONTRACT PHARMACY OVERSIGHT

Despite recent attention to the growth in 340B contract pharmacy arrangements and associated compliance concerns, the Proposed Guidance does not include provisions to limit the number of contract pharmacy arrangements. The Proposed Guidance approach to addressing contract pharmacy concerns is generally limited to restatement of certain existing compliance expectations, removing the ability of contract pharmacies to submit registrations of contract pharmacy arrangements and a proposal for increased monitoring. While not explicitly stated, the Proposed Guidance also appears to replace current guidance regarding inclusion of specific contract provisions in 340B contract pharmacy agreements with a more general statement indicating that the written agreement “should also set forth the requirements contained in [the Proposed Guidance].”

HHS currently expects 340B entities to engage in annual compliance review of contract pharmacy arrangements. The Proposed Guidance also includes a new provision for quarterly reviews by covered entities of 340B prescribing records and contract pharmacy 340B dispensing records. The Proposed Guidance indicates that both the quarterly and annual reviews should be undertaken for each contract pharmacy location. While 340B entities should ensure compliance with 340B Program requirements as to 340B drugs dispensed to their patients through contract pharmacy arrangements, the Proposed Guidance recommendations for quarterly and annual reviews at each contract pharmacy location may be sufficiently burdensome, both administratively and financially, that 340B entities opt to remove certain contract pharmacy arrangements with low dispensing volumes. It appears that HHS may have anticipated such a reaction, as the Proposed Guidance encourages 340B entities to evaluate the costs and benefits of contract pharmacy dispensing arrangements, and to ensure that the benefit of such arrangements is accruing to the covered entity.

## Additional Provisions and Outline

In addition to the proposals discussed above, the Proposed Guidance includes many other provisions related to 340B Program compliance and participation for 340B entities and manufacturers. These items are detailed in the outline below. While interested stakeholders should submit comments

regarding any provision of the Proposed Guidance for which they wish to express support or disagreement and an alternative approach, there are several provisions for which HHS explicitly has requested comments:

- Alternatives to Medicare cost reports for demonstrating eligibility of an off-site hospital outpatient facility or clinic
- Information that could be used to demonstrate compliance sufficient to re-enroll in the 340B Program following involuntary termination for non-compliance
- Use of and format of information regarding dispensing of 340B drugs to Medicaid fee-for-service and Medicaid managed care patients
- Information regarding approaches, including existing state approaches, to addressing dispensing of 340B drugs to Medicaid fee-for-service and Medicaid managed care patients
- Responses to proposed data submission in connection with requests for AIDS drug assistance program (ADAP) rebate requests
- Impact of proposed policy regarding ADAP purchase of insurance coverage and payment of cost-sharing on existing ADAP insurance purchase practices

## Outline: 340B Drug Pricing Program Omnibus Guidance

### I. 340B PROGRAM ELIGIBILITY AND REGISTRATION

Certain hospitals, and certain non-hospital entities, are eligible to participate as covered entities (CEs) in the 340B Program. The guidance sets forth eligibility requirements for both hospital and non-hospital CEs.

#### *Eligibility*

- A non-hospital CE must register on the 340B database and must establish the qualifying federal grant, contract, designation or project through which such entity is eligible for the 340B Program.
- A hospital CE must also register on the 340B database and must qualify (i) as either government owned or operated, (ii) through a formal grant of governmental powers, or (iii) through a contract with state or local government.

**Child Sites** – Both non-hospital and hospital CEs may register so-called “child sites” on the 340B database.

- A non-hospital CE may register “associated sites” as child sites. An associated site is defined as “a health care delivery site which is not located at the same physical address as a non-hospital CE, but is part of and delivers outpatient services for the non-hospital CE.”
- A hospital CE may list an off-site outpatient facility or clinic in the 340B database as a “child site” if the clinic or facility is listed as reimbursable on the hospital’s most recently filed Medicare cost report, and the hospital demonstrates that services provided at the facility or clinic have associated Medicare outpatient costs and charges. Eligible children’s hospitals (which do not file Medicare cost reports) may register off-site outpatient facilities or clinics upon submission of a signed statement that provides that:
  - The facility or clinic is an integral part of the children’s hospital whose patients meet 340B Program eligibility requirements.
  - The facility or clinic would be correctly included on a reimbursable line, with associated Medicare outpatient costs and charges, on a Medicare cost report if filed.

**DSH Percentage** – For a hospital seeking to qualify for 340B Program participation through its disproportionate share hospital (DSH) percentage, HHS will review such hospital’s most recently filed Medicare cost report to ensure that the hospital meets the required DSH percentage. A children’s hospital (which does not file a Medicare cost report) may provide a statement from a qualified independent auditor of the DSH percentage.

**Loss of Eligibility**

- A non-hospital CE will be immediately terminated from participation in the 340B Program in the event that such entity loses its grant or contract, or closes.
  - A non-hospital CE’s child site can lose eligibility separately from its parent if the child site no longer qualifies under the parent’s grant.
- A hospital CE, along with all its child sites, is immediately ineligible upon the closing of the hospital or upon a change of ownership or contract status that results in the hospital’s failure to qualify for the 340B Program.

- DSHs will be disqualified upon the filing of a Medicare cost report where the DSH percentage falls below requisite threshold. Eligible children’s hospitals will be immediately disqualified from 340B Program participation upon an independent audit showing a DSH percentage less than 11.75 percent.
- Hospital child sites lose eligibility in the following circumstances:
  - Immediately upon the closing of the clinic or facility, or when the clinic or facility is sold or transferred to any entity
  - Upon the filing of a Medicare cost report showing that the site is not listed as reimbursable or no longer has associated outpatient costs
  - For hospitals subject to the GPO Prohibition, immediately upon the use of a GPO for covered outpatient drugs
- **Termination** – Upon loss of eligibility, a CE must immediately notify HHS and stop purchasing and using 340B drugs. A CE will be liable to affected manufacturers for repayment of the 340B discounts on any drugs purchased for itself, any child site or any contract pharmacy when the CE was ineligible for the 340B Program for any reason.
- **Re-Enrollment** – A CE removed from the 340B Program is eligible to re-enroll during the next regular enrollment period after it has “satisfactorily demonstrated to HHS that it will comply with all statutory requirements moving forward and is in the process of offering repayments to affected manufacturers, if necessary.”
- **Annual Recertification** – A CE must annually re-certify that it, its child sites and its contract pharmacy arrangements meet all 340B eligibility and compliance requirements. If it cannot do so, it must cease all applicable 340B purchasing and usage and terminate its listing(s).
- **GPO Prohibition** – CEs subject to the GPO prohibition must not obtain any covered outpatient drugs through a GPO or other group purchasing arrangement after enrollment into the 340B Program. Inclusion of off-site outpatient facilities and clinics in the 340B database record of the CE that is

subject to the GPO prohibition demonstrates that such facilities and clinics are also subject to GPO prohibition.

- *Exceptions* – A GPO may be used to obtain covered outpatient drugs in the following scenarios, and such uses will not be considered a violation of the statutory GPO prohibition:
  - An off-site outpatient clinic of a 340B hospital CE, if the clinic is located at a separate physical address, is not participating in the 340B Program or listed on the 340B database, and purchases drugs through a separate account from the 340B parent CE
  - A GPO-purchased drug provided to an inpatient that, upon subsequent review, results in the designation of that patient as an outpatient for payment purposes
  - A hospital that can only access a covered outpatient drug through a GPO, in which case the hospital is expected to document its attempts to purchase the drug at 340B and wholesale acquisition cost prices and report the circumstances to HHS
- *Drug Replenishment Models* – If using a drug replenishment model, a CE must clearly demonstrate through auditable records that the replenishment model and any associated software is used in a manner compliant with the statute.
- *Use of Previously Purchased GPO Drugs* – A CE may use drugs acquired through a GPO prior to the first day the CE is listed on the 340B database, until such drugs are expended.
- *Violations of Statutory Prohibition on Use of GPOs* – Compliance with the GPO prohibition is a condition of eligibility for those CEs that are subject to such prohibition. If found in violation of the GPO prohibition, a CE will be considered ineligible and removed from the 340B Program after a notice and hearing process. If a CE can demonstrate that it was an “isolated error,” then HHS may allow that CE to continue participation. A CE must offer to repay affected manufactures for any 340B drug purchase made after the date of the first GPO violation.
  - If a CE parent site is terminated from the program because of a GPO violation, then all child sites of that CE are also terminated. If the GPO prohibition violation is limited to one or more child sites, then only the child site(s) will be removed, but the CE must offer repayment to affected manufacturers for the period of ineligibility. GPO violations may only be limited to a child site if the child site has auditable records that show the following:
    - The child site is located in a separate building from the parent site and other child sites.
    - All drug purchasing for the child site occurs using separate purchase accounts from the parent site and other child sites.
  - *Re-Enrollment in the 340B Program* – If removed from the 340B Program for a GPO prohibition violation, a CE will be able to re-enroll in the program during the next regular registration period after it satisfactorily demonstrates to HHS that it will comply with the GPO prohibition going forward and that it is in the process of offering repayment to affected manufacturers.

## II. DRUGS ELIGIBLE FOR PURCHASE UNDER THE 340B PROGRAM

Covered outpatient drugs, as defined in Section 1927(k)(2) and (3), are eligible for purchase under the 340B Program. Only drugs bundled for and receiving such bundled reimbursement under Title XIX of the Social Security Act described in Section 1927(k)(3) will be considered excluded from the covered outpatient drug definition.

### III. INDIVIDUALS ELIGIBLE TO RECEIVE 340B DRUGS

A CE cannot resell or transfer 340B drugs to a person who is not an eligible patient of the CE. To be considered “eligible,” a patient must meet the following criteria:

1. The individual receives a health care service at a covered entity site that is registered for the 340B Program and listed on the public 340B Database.
2. The individual receives a health care service from a health care provider who (i) is employed by the covered entity or (ii) is an independent contractor of the covered entity such that the covered entity may bill for services on behalf of the provider.
3. An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in (2). An individual will not be considered a patient of the covered entity if the only health care received by the individual from the covered entity is the infusion of a drug or the dispensing of a drug.
4. The individual receives a health care service that is consistent with the covered entity’s scope of grant, project or contract.
5. The individual is classified as an outpatient when the drug is ordered or prescribed. The patient’s classification status is determined by how the services for the patient are billed to the insurer (e.g., Medicare, Medicaid, private insurance). An individual who is self-pay, uninsured, or whose cost of care is covered by the covered entity will be considered a patient if the covered entity has clearly defined policies and procedures that it follows to classify such individuals consistently.
6. The individual has a relationship with the covered entity such that the covered entity maintains access to auditable health care records which demonstrate that the covered entity has a provider-to-patient relationship, that the responsibility for care is with the covered entity, and that each element of this patient definition in this section is met for each 340B drug.

In addition, individuals enrolled in the Ryan White HIV/AIDS Program AIDS Drug Assistance Program funded by Title XXVI

of the Public Health Service Act will be considered patients of the CE for purposes of this definition.

If 340B drugs are diverted to an individual who does not meet the above definition of eligible patient, then the CE is responsible for offering repayment to all affected manufacturers for any such diverted drugs. The CE is also responsible for repayment for 340B drugs diverted from a child site or through a contract pharmacy arrangement. A CE should notify HHS of any corrective actions on diversion, including manufacturer agreement on repayments.

### IV. COVERED ENTITY REQUIREMENTS (DUPLICATE DISCOUNTS)

HHS has established a Medicaid Exclusion File (MEF) as a way to prevent duplicate discounts. The MEF is posted on the HHS website to allow 340B CEs, states and manufacturers to determine whether or not a CE purchases 340B drugs for Medicaid patients.

- *Medicaid Fee for Service (FFS)* – HHS lists the Medicaid provider number and/or NPI number of a CE or its child sites used to purchase 340B drugs for its Medicaid FFS patients on the MEF. If a CE’s Medicaid/NPI number is listed, that means that all drugs billed to Medicaid FFS under those numbers are purchased through the 340B Program. If such numbers are not listed, then Medicaid drugs are purchased outside of the 340B Program.
- *Medicaid Managed Care (MMC)* – A CE may choose whether or not to use 340B drugs for Medicaid Managed Care patients. CEs may make differing decisions for each CE site and for each managed care organization as long as the distinction is made available to HHS and the information may be made available publicly. CEs should have mechanisms in place to identify MMC patients.

A CE may change its use of 340B drugs for Medicaid FFS/MMC patients after initial registration (for itself or child sites) during HHS-specified timeframes. A CE must inform HHS of any change prior to implementing such change.

Unless otherwise noted on the 340B database, contract pharmacies will not dispense 340B drugs to Medicaid patients (either FFS or MMC). If a CE wishes to “carve in” and use 340B Medicaid drugs for dispensing to patients through



contract pharmacies, then the CE has to provide HHS with a written agreement for HHS approval.

If the information provided to HHS does not reflect a CE's actual billing practices, then the CE may be found in violation of the duplicate discount prohibition and would be required to repay rebate amounts to manufacturers if duplicate discounts have actually occurred.

- *Maintenance of Auditable Records* – A CE must maintain auditable records demonstrating compliance with 340B Program requirements for itself, its child sites and its contract pharmacies for at least five years from the date the 340B drug was ordered or prescribed (even after termination of program participation), and for five years following termination of participation in the 340B Program.
- *Failure to Maintain Records* – If a CE cannot produce records for a specific requirement, then the CE might be presumed to be out of compliance with that requirement and subject to the applicable penalty. If the CE demonstrates systematic failure to maintain records (statutory eligibility requirement) or fails to provide records as requested by HHS or manufacturers authorized to conduct an audit, then the CE will be removed from the 340B Program following a notice and hearing process. A CE removed for such reason would be liable for repayment to manufacturers for the periods of ineligibility.
- *Re-Enrollment in the 340B Program* – A CE removed from 340B Program because of failure to maintain auditable records may re-enroll for the 340B Program during the next regular registration period following its demonstration to HHS of its ability to comply with all 340B Program requirements, including record retention requirements.

## V. CONTRACT PHARMACY ARRANGEMENTS

A CE may contract with one or more licensed pharmacies to dispense 340B drugs to eligible patients, regardless of in-house pharmacy availability, provided that the arrangement is in accordance with applicable laws.

- *Registration* – HHS lists a contract pharmacy on the 340B database if a written agreement exists between the CE and the pharmacy that lists all locations of the pharmacy and all child sites that will use the contract pharmacy. A CE is responsible for registration of the arrangement and for the

contract pharmacy's compliance. HHS may remove a contract pharmacy if it finds that the contract pharmacy is not complying with 340B Program requirements. A CE would be responsible for offering repayment in the amount of the 340B discount to a manufacturer for 340B drugs dispensed by a contract pharmacy that has not adhered to 340B Program requirements.

- *Prevention of Diversion* – A CE must have a system in place to verify patient eligibility for each 340B drug dispensed by the contract pharmacy and must prevent diversion.
- *Prevention of Duplicate Discounts* – A contract pharmacy may not dispense 340B drugs to a CE's Medicaid patients unless the CE has submitted information to HHS regarding the arrangement and has systems in place with the Medicaid agency and the contract pharmacy to ensure that duplicate discounts do not occur.
- *Contract Pharmacy Oversight* – A CE is expected to conduct quarterly reviews and annual independent audits of each contract pharmacy location. Results are included in record retention requirements. Any violation identified through the reviews or audit should be disclosed to HHS. CEs are subject to applicable penalties for instances of duplicate discounts and diversion.

## VI. MANUFACTURER RESPONSIBILITIES

A manufacturer that has entered into a Medicaid Drug Rebate Agreement (MDRA) must enter into a pharmaceutical pricing agreement (PPA). Under a PPA, a manufacturer must offer all covered outpatient drugs to CEs at no more than the statutory 340B ceiling price and must abide by 340B Program requirements. A manufacturer may choose to sell covered outpatient drugs below 340B ceiling price. Such pricing is voluntary and need not be applied to all 340B CEs. A participating manufacturer should review and update 340B database information on an annual basis.

- *No Conditioning of Sales* – A manufacturer is required to offer 340B drugs to each CE if the drugs are available to any other purchaser at any price. A manufacturer may not condition the offer of the 340B ceiling price on a CE's assurance of compliance with 340B Program requirements.

- *Limited Distribution Plan* – A manufacturer that uses a specialty pharmacy or a restricted distribution network, or that needs to limit distribution because of potential or actual shortages, is expected to notify HHS in writing prior to implementation of a limited distribution plan, which plan HHS may make public. Limited distribution plans must adhere to certain requirements, as set forth in the guidance.
- *Procedures for Issuance of Refunds and Credits* – A manufacturer must refund or credit a CE when the manufacturer overcharges the CE, in an amount equal to the difference between the sale price and correct 340B price for the drug, multiplied by number of units. A refund or credit is expected to occur within 90 days of determination by the manufacturer or HHS that overcharge occurred.
- *Required Information* – A manufacturer must submit to HHS the 340B ceiling price recalculation information, an explanation of why overcharge occurred, how refunds will be calculated, and to which CEs refunds or credits will be issued.
- *Waiver* – Unless the refund amount is subject to dispute, if the CE receiving a direct repayment fails to take action to accept or execute repayment within 90 days of receipt of repayment, the CE has waived its right to repayment.

## VII. REBATE OPTION FOR AIDS DRUG ASSISTANCE PROGRAMS

A state ADAP may register and participate in the 340B Program through a rebate option or hybrid option. ADAPs must be listed on the 340B database to participate in the rebate or hybrid option. ADAPs are expected to make certain qualified payments (direct purchases of covered outpatient drugs or payments of health insurance premiums that cover those covered outpatient drugs) for an eligible patient. ADAPs are also expected to submit claims-level data to manufacturers to show that a qualified payment was made.

An ADAP participating in the 340B Program via the rebate option or hybrid option may not request a 340B rebate for a covered outpatient drug that was already purchased by another CE at or below the 340B ceiling price. ADAPs participating via the rebate option or hybrid option are subject to audit by HHS.

A manufacturer must pay a rebate for a covered outpatient drug to an ADAP that has registered under the rebate or hybrid option and has made a qualified payment for such covered outpatient drug. The rebate owed to an ADAP for a qualified payment for a covered outpatient drug is equal to the rebate described in section 1927(c) of the Social Security Act, multiplied by the units of drug included in the rebate claim.

## VIII. PROGRAM INTEGRITY

A. **HHS Audits** – CEs, including their child sites and contract pharmacies, are subject to audit by HHS for compliance with 340B Program requirements.

- *Provision of Auditable Records* – At HHS’s request, a CE shall provide or arrange for access of all specified auditable records on behalf of the CE, its child sites and its contract pharmacies by a specified deadline. Failure to provide records or respond to the HHS inquiry may result in penalties for failure to maintain auditable records and termination from the 340B Program.
- *Notice and Hearing* – HHS will initiate a notice and hearing process, whereby a CE will have the opportunity to respond to any adverse audit findings and instances of non-compliance, or to respond to a proposed loss of 340B Program eligibility. HHS initiates this process by providing written notice and a 30-day response deadline. Thereafter, the CE will respond in writing to each issue of non-compliance and provide supporting documentation as necessary. Finally, HHS will issue a final written notice with its final determination regarding non-compliance. If HHS’s final notice includes termination, then HHS will include a termination date. The CE would be liable to manufacturers for repayment of claims after such date.
- *Corrective Action Plans* – HHS considers a CE to be in compliance if the CE submitted a corrective action plan that documents the correction of any finding of non-compliance, explains measures taken to prevent future occurrences of non-compliance, includes a plan to offer repayment to affected manufacturers (if applicable) and states a timeline for corrective actions. HHS will review corrective action plans and work with CEs to revised submitted corrective action plans. Failure by a CE to submit a corrective action plan may lead to further penalty, including termination from the 340B Program.

- Public Information – HHS may make final audit results available to the public.

**B. Manufacturer Audit of a CE** – Manufacturers may audit a CE, its child sites and its contract pharmacies regarding compliance with the diversion and duplicate discount prohibitions. Manufacturers may refer any concerns other than duplicate discounts and diversion to HHS. Until HHS makes a determination of non-compliance, a manufacturer must continue to sell covered outpatient drugs to a CE at no more than the 340B ceiling price, and a CE must continue to comply with 340B Program requirements.

- Procedures for Requesting and Conducting an Audit
  - The manufacturer shall notify the CE in writing and engage the CE in good faith to resolve the issues for at least 30 days.
  - If the matter cannot be resolved through good faith negotiation, the manufacturer may submit its grounds for reasonable cause with supporting documentation, evidence of its attempt to resolve the matter and its audit plan to HHS. HHS will review all documentation and the work plan. HHS will notify the manufacturer of any concerns it has with the work plan and may require revision of the work plan.
  - A CE must provide access to records for manufacturer audit (including records for child sites and contract pharmacies).
  - Patient confidentiality must be observed throughout the process.
  - The manufacturer will submit a final audit report to the CE, and the CE shall provide a response within 30 days. Failure to respond by the CE is deemed to be an acceptance of the audit report findings.
  - The manufacturer will submit copies of the audit report and CE responses to HHS. HHS may also refer findings to other federal agencies.

**C. HHS Audit of a Manufacturer and Its Contractors** – HHS may audit a manufacturer to determine whether the manufacturer is complying with 340B Program requirements.

HHS will notify the manufacturer in writing of HHS's intent to audit.

- *Provision of Auditable Records* – Manufacturers shall provide all requested records demonstrating 340B Program compliance. Failure to provide may result in further action by HHS or referral for investigation.
- *Notice and Hearing* – HHS will provide manufacturers with written notice of any proposed audit findings. A manufacturer has 30 days to respond to each proposed finding. Any failure to respond equals acceptance. HHS will review all documentation and make a final determination, and may request a corrective action plan if necessary.
- *Corrective Action Plan* – Manufacturers must submit a corrective action plan within 30 days of receiving HHS's audit findings of non-compliance. Such plan must address each audit finding of non-compliance, document the correction of such findings, institute measures to prevent future occurrences, offer affected CEs repayment for overcharges (if applicable) and state a timeline for corrective action to occur. HHS will determine whether such corrective action is sufficient.
- *Public Information* – HHS may make final audit results available to the public.

#### THE McDERMOTT DIFFERENCE

To augment this article, McDermott will present a webinar in the near future covering the Proposed Guidance. We will distribute further information via e-mail in the coming days.

**AUTHORS**

For more information, please contact your regular McDermott lawyer, or:

**David Ivill**

+1 212 547 5698  
divill@mwe.com

**Emily Cook**

+1 310 284 6113  
ecook@mwe.com

**Joseph Parise**

+1 212 547 5411  
jparise@mwe.com

For more information about McDermott Will & Emery visit  
[www.mwe.com](http://www.mwe.com)

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