340B Health Preliminary Analysis of Mega-Guidance
Discussion of Part B – Drugs Eligible for Purchase Under 340B
August 31, 2015

I. The guidance proposes a definition of the term “covered outpatient drug” that makes bundled Medicaid drugs ineligible for 340B pricing.

- The guidance states that a drug is eligible for 340B if it is a covered outpatient drug, as defined in section 1927(k)(2) and (3) of the Social Security Act. For purposes of the 340B program, a drug will be excluded from the definition of a covered outpatient drug only when a drug is “bundled for and receiving such reimbursement under [Medicaid].”

- The preamble to the guidance provides more detail on when drugs “will not qualify” as covered outpatient drugs and therefore will not be eligible for 340B. For the 340B program, a drug will not be considered a covered outpatient drug if the drug:
  o (1) is “provided as part of, or as incident to and in the same setting as” the following services:
    - (A) Inpatient hospital services;
    - (B) Hospice services;
    - (C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs;
    - (D) Physicians’ services;
    - (E) Outpatient hospital services;
    - (F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded;
    - (G) Other laboratory and x-ray services; and
    - (H) Renal dialysis;

  and

  o (2) receives a bundled payment by Medicaid and does not receive direct reimbursement for the drug.

- The guidance makes clear that, under the proposal, drugs would not be considered “covered outpatient drugs” only when they receive bundled payments under Medicaid. Drugs would be considered covered outpatient drugs if they receive bundled payments from other payors or a direct payment from Medicaid. This would require hospitals to use group purchasing organization (GPO) or other non-340B pricing for any drug that is not separately paid by Medicaid, but use 340B for drugs that are separately paid.

- This standard would require hospitals to develop new tracking systems. Such systems would also need to take into consideration provisions in Part C of the proposed guidance that require hospitals to use GPO or other non-340B pricing for drugs furnished to outpatients that are ultimately bundled into an inpatient bill, such as through Medicare’s 72-hour rule or observation stays. These provisions taken together would require hospitals to have tracking systems to identify how a drug is billed, as well as, for Medicaid purposes, how a drug is paid.

  o Part C of the guidance says that for an individual to be eligible to receive a 340B drug, the health care services the individual receives at the hospital or a registered child site must be billed to a payor as outpatient. Therefore, drugs paid under Medicare’s 72-hour rule or a similar policy for any other payor would not be eligible for 340B under this proposal.
Under Medicare’s 72-hour rule, if a Medicare beneficiary receives services in an outpatient setting and is then admitted as an inpatient, the hospital must bill Medicare for any services provided within 72-hours of the patient’s admission, including drugs, as part of the inpatient stay. (Note that the 72-hour rule does not apply to critical access hospitals). Other payors may have similar billing policies. Under the proposed guidance, drugs would not be eligible for 340B if they are billed to a payor as inpatient.

II. The guidance creates confusion around HRSA’s current policy on which drugs are eligible for 340B.

- Historically, hospitals have understood that 340B pricing is available for drugs used in outpatient settings, regardless of how drugs are paid by any payor, and this position has been supported by written guidance. For example, an FAQ on the Apexus website suggests that hospitals could treat bundled drugs as not eligible for 340B, although they are not required to do so. The FAQ says hospitals may interpret the definition of covered outpatient drug and determine whether drugs meet the definition, so long as the decision is “defensible, consistently applied in all areas of the entity, documented in policy/procedures, and auditable.” HRSA also published guidance in the Federal Register in 1993 (and referenced it again in 2000) that specifically states that drugs may be purchased at 340B prices when they are billed to Medicaid as part of all-inclusive rates. This guidance, combined with the Apexus FAQ, has provided a basis for hospitals to conclude that 340B pricing is available for bundled drugs. For hospitals that are currently using 340B for bundled drugs, HRSA’s proposed definition of the term could make a significant number of drugs ineligible for 340B.

- It is unclear what implications, if any, this has for HRSA’s current policy on which drugs are eligible for 340B and the agency’s current expectations. The preamble states that “remedies for violations [of the provision] would be imposed,” suggesting that HRSA is not currently enforcing its proposed definition.

- The preamble to the guidance reviews some of HRSA’s past guidance in this area but omits other guidance that states the opposite position.

  - The preamble reviews 1993 HRSA guidance that said the term covered outpatient drug does not include drugs that are “provided as part of, or incident to and in the same setting as” any one of a number of services, which include inpatient and outpatient hospital services. The preamble also references 1994 HRSA guidance that said a drug will not be eligible for 340B if is “included in the per diem rate (i.e., bundled with other payments in an all-inclusive, a per visit, or an encounter rate)....”

  - The proposed guidance does not reference HRSA’s 1993 guidance (that it referenced again in 2000) that appears to take the opposite position, specifically stating that drugs may be purchased at 340B prices when they are billed to Medicaid as part of all-inclusive rates.

- Although the guidance does not clearly state HRSA’s current position on the definition of “covered outpatient drug,” it is clear that HRSA is proposing a policy not previously enforced since there is nothing in prior guidance or audit results to suggest this connection between bundling of drugs and Medicaid. The preamble’s discussion of this standard suggests that the new standard is not the same as HRSA’s current view of the term.

III. The preamble to the guidance discusses how the term “covered outpatient drug” impacts the obligations of hospitals subject to the GPO exclusion

- Hospitals subject to the GPO exclusion, including DSH and free-standing children’s and cancer hospitals, may not purchase covered outpatient drugs through a GPO or other group purchasing arrangement. Though not explicitly stated, this presumably means that drugs that do not meet the definition of covered outpatient drug may be purchased through a GPO.

- It is unclear, however, how the GPO exclusion would apply to drugs that would not eligible for 340B under the proposed guidance because they were billed as inpatient. For example, it is unclear whether
these drugs would be considered covered outpatient drugs and, therefore, whether hospitals subject to the GPO exclusion would be permitted to use GPO pricing for those drugs. It would not appear to be HRSA’s intention to require WAC pricing for those purchases, but it is an area of concern.

- The preamble notes that hospitals subject to the GPO exclusion “must ensure” that purchases of drugs that meet the covered outpatient drug definition in section 1927(k) of the Social Security Act comply with the GPO exclusion. These hospitals must maintain auditable records showing compliance. This is consistent with HRSA’s current policy on the GPO exclusion, although it is unclear, based on the guidance, what HRSA’s current position is on the definition of covered outpatient drug in section 1927(k).