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HSCA FILES COMMENTS ON HRSA 340B DISCOUNT DRUG PROGRAM PROPOSED RULE

Comments Focus on Easing Burdens on Providers by Expanding GPO Prohibition Exemptions and Clarifying Violations While Maintaining Integrity of 340B Program

Washington, DC (October 26, 2015) – The Healthcare Supply Chain Association (HSCA) today filed comments in response to the U.S. Department of Health and Human Services (HHS) Health Resources and Services Administration’s (HRSA) proposed draft guidance “340B Drug Pricing Program Omnibus Guidelines.” The comments focus on easing burdens on healthcare providers under the proposed guidance’s group purchasing organization (GPO) prohibition provision in a manner consistent with the program’s purpose – to enable covered entities to stretch scarce federal resources and reach more eligible patients.

“We are grateful for HRSA’s dedication to providing access to affordable healthcare services to eligible patients, and for HRSA’s formal recognition of exceptions to the GPO Prohibition in the 340B Drug Pricing Program.” Said HSCA President and CEO Todd Ebert, R.Ph., in the filing. “We support the exceptions that HRSA has identified, which acknowledge challenges created by the GPO Prohibition and demonstrate HRSA’s flexibility in interpreting the GPO Prohibition in ways that benefit both patients and providers.”

“HSCA supports the 340B program and the value it offers to providers and the patients they serve. We believe HRSA should amend 340B’s GPO prohibition to reasonably expand exceptions to the prohibition, clarify violations to the prohibition, and clarify the time period for which covered entities must make repayments to manufacturers. Doing so will further enable covered healthcare providers to effectively serve eligible patients without undue difficulties,” added Ebert.

In its comments, HSCA advocated that:

- Off-site outpatient facilities not be required to use separate purchasing accounts to meet GPO exemption.
- Entire hospitals or systems not be removed from GPO exemption if a GPO prohibition violation is limited to just one participating child site, unless the child site has separate purchasing accounts.
- Exceptions to the GPO Prohibition expand to include outpatient services that are “within the four walls” of a hospital-covered entity subject the GPO prohibition, but that are ineligible to participate in the 340B program or are voluntarily excluded from the program by the hospital.

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- GPO-purchased drugs be permitted to be dispensed to an inpatient who is later deemed an outpatient for payment purposes; this exception should extend to status changes arising from hospitals' internal review processes, as well as from third party reviews.
- A GPO exception be made for instances in which applicable hospitals can only access a specific drug through a GPO contract; additional clarity is needed to determine the standard against which "access" to a drug is measured for the purposes of this exception.
- Penalties for isolated non-compliance not be overly punitive and/or inconsistent with the public policy rationale underlying the recognition of isolated non-compliance.
- There be a *de minimus* purchase threshold, below which GPO purchases would not be deemed non-compliant, to exclude GPO purchases of drugs that would have been eligible for 340B pricing – and to reflect a less severe repayment penalty for isolated incidents of non-compliance.
- The appropriate period for non-compliance be limited to the actual dates on which erroneous GPO purchases were made.
- Clear guidance as to what would constitute an isolated instance of non-compliance, and what non-compliance would be considered systemic, be provided.

HSCA's full comments are [available here](#).

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About the Healthcare Supply Chain Association (HSCA) The Healthcare Supply Chain Association (HSCA) represents the nation's leading healthcare group purchasing organizations (GPOs), which are critical cost-savings partners to America's hospitals, nursing homes, nursing home pharmacies, clinics, home healthcare providers and surgery centers. GPOs deliver billions in savings annually to healthcare providers, Medicare and Medicaid, and taxpayers. HSCA and its member GPOs are committed to delivering the best products at the best value to healthcare providers, to increasing competition and innovation in the market, and to being supply chain leaders in transparency and accountability. For more information, visit www.supplychainassociation.org. Follow HSCA on Twitter @HSCA.