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No Summer Vacation for 340B Program Stakeholders

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Summary

After an already active first half of 2018 for 340B Program developments, 340B Program stakeholders are not getting a summer respite. In just the past week, the US Government Accounting Office (GAO) released its much-anticipated report on 340B contract pharmacy arrangements, the Health Resources and Services Administration (HRSA) released two new policy updates, two new 340B-related bills have been introduced in the US House of Representatives, and the House Committee on Energy and Commerce Subcommittee on Health announced that it would be holding a hearing on July 11 to discuss seven previously introduced House bills covering 340B issues and discussion drafts of an additional eight 340B bills.

In Depth

Many 340B Program stakeholders had expected 2018 to be the year that significant changes were made to the 340B Program. While the likelihood for significant change during 2018 has decreased, developments in the last week of June and first week of July suggest that 2018 may be laying the groundwork for changes that could fundamentally alter the 340B Program in 2019.

Meanwhile, 340B covered entities should ensure that they do not lose track of the “now” in the midst of the potential for future program changes and should remain actively engaged in continued monitoring and oversight of compliance with current 340B Program requirements and guidance. Despite the uncertain future of the 340B Program, HRSA appears to be ramping up its oversight of covered entity compliance and covered entities that become complacent about on-going compliance monitoring could become subject to unwanted (and unexpected) scrutiny.

GAO Report on Federal Oversight of 340B Contract Pharmacy Arrangements

On June 21, 2018, the GAO released its long-awaited report on 340B contract pharmacy arrangements. The GAO reviewed: the extent of 340B covered entities’ arrangements with contract pharmacies; the financial arrangements between covered entities, contract pharmacies and contract pharmacy vendors; the provision of discounts on 340B drugs dispensed through contract pharmacy arrangements; and, HRSA’s oversight of 340B contract pharmacy compliance. The GAO found that

contract pharmacy arrangements offer opportunities for 340B covered entities to increase 340B revenue and create challenges for compliance with 340B Program requirements. Further, the GAO found that HRSA's current oversight of 340B contract pharmacy arrangements does not allow HRSA to adequately ensure contract pharmacy compliance with 340B Program requirements. The GAO was particularly critical of HRSA's contract pharmacy guidance to covered entities, which the GAO criticized for lack of specificity, and the infrequency of HRSA review of contract pharmacy compliance.

A summary of the GAO recommendations and HRSA responses is provided below. HRSA's responses appear to reflect frustrations with its lack of regulatory authority and challenges of working with CMS to address Medicaid managed care duplicate discount prevention. The HRSA responses indicate that in the short term, HRSA's only policy or process change in response to the GAO recommendations will be a change in the HRSA audit selection criteria to better target audits to covered entities with large numbers of child sites utilizing contract pharmacy arrangements. Therefore, covered entities with large numbers of child sites and contract pharmacy arrangements should expect stepped up HRSA audit activity and, notwithstanding HRSA's disagreement with GAO's recommendations to require additional documentation of post-audit corrective actions, all covered entities should anticipate increased corrective action plan documentation review and oversight in all areas of compliance (not just contract pharmacy) following a HRSA audit.

GAO Recommendation	HRSA Response
Require covered entities to register contract pharmacies for each child site within the scope of the contract	HRSA will assume that contract pharmacy arrangements apply to all registered locations of a covered entity
Issue guidance on prevention of duplicate discounts under Medicaid managed care	HRSA and CMS must work together to develop guidance and that work is on-going
Incorporate review of duplicate discounts under Medicaid managed care into HRSA audits	HRSA cannot review compliance until guidance has been issued
Issue guidance on post-audit corrective action look-back period	HRSA is working to determine next steps, but is challenged by the issuing of guidance versus regulations
Require that corrective action plans include a description of covered entity's methodology for identifying the full scope of non-compliance and HRSA review of such methodology	HRSA does not concur with this recommendation and believes it will create significant burden for covered entities
Require evidence of successful implementation of corrective action prior to closing audit	HRSA does not concur with this recommendation and believes it will create significant burden for covered entities and extend the time period to close audits
Provide more specific guidance on covered entity oversight of contract pharmacy arrangements, including scope and frequency	HRSA is working to determine next steps, but is challenged by the issuing of guidance versus regulations

June and July 340B Program Policy Updates

After a several month hiatus, HRSA re-initiated its release of monthly 340B Program policy updates in May 2018. The June and July updates were released in close proximity to one another and both address compliance requirements for contract pharmacy arrangements. These updates are summarized below. In light of the June update, covered entities should review their contract pharmacy arrangements for provisions that involve repayments to manufacturers by the contract

pharmacy or any third party administrator (TPA), ensure that they understand the repayment mechanism and the risks associated with the arrangement and, if necessary, contact the contract pharmacy or TPA to renegotiate the agreement to mitigate risks of non-compliance.

The June update focuses exclusively on resolving contract pharmacy-related non-compliance. The June update reminds covered entities that responsibility for 340B Program compliance remains with the covered entity and that the covered entity is responsible for addressing instances of diversion and duplicate discounts. Notably, the June update explicitly references a particular corrective action practice that HRSA believes is undertaken by some contract pharmacies and TPA whereby the contract pharmacy or TPA makes repayments to manufacturers to correct non-compliance – at times without the prior knowledge or "engagement" of the covered entity. HRSA states in the June update that such repayments do not comply with 340B Program requirements.

The July update focuses more on 340B Program integrity efforts undertaken at the time of registration of a hospital or child site. HRSA advises that random lists are generated during the registration process to identify entities for additional review. As part of these reviews, HRSA may request documentation to support a hospital's 340B eligibility or the written and signed contract between a covered entity and a contract pharmacy.

New and Draft 340B Legislation

Continuing its on-going 340B oversight activities and progress toward expected legislative action, the House Committee on Energy and Commerce Subcommittee on Health announced that it will hold its next 340B hearing on July 11, 2018. During the hearing, the Subcommittee will discuss 15 separate bills related to the 340B Program, including seven previously-introduced bills and eight new and not yet introduced discussion drafts (some without current sponsors).

Many of the bills, particularly the discussion drafts, cover discrete issues that had not previously been identified as likely candidates for 340B-related legislation (*e.g.*, adding services for victims of sexual assaults as a 340B Program eligibility requirement for certain hospitals or creating a new position for a Presidentially-appointed, Senate confirmed 340B Program Administrator), while others have been previously identified as likely subjects of 340B legislation and will generate significant debate from all corners of the 340B stakeholder community (*e.g.*, significantly narrowing the definition of patients eligible to receive 340B drugs from certain hospitals).

A chart identifying and summarizing the bills to be discussed during the July 11 hearing is below.

Bill Number	Brief Summary
H.R. 2889	Expand scope of orphan drug purchasin and cancer hospitals participating i
H.R. 4392	Prevent CMS from implementing, admin payment cut to 340B drugs under the Prospective Payment
H.R. 4710	• Two-year moratorium on new Dis Hospitals (DSH) and child sites • Public data reporting for DSH, ch hospitals of:

	◦ Patients receiving 340B d ◦ Charity care provided at c ◦ Aggregate costs and gros 340B drugs ◦ Names of 340B vendors ◦ For non-profits, copies of government Additional summary and a
H.R. 5598	Establish reporting requirements related of outpatient hospital s
H.R. 6071	• Repeal the cut to 340B drugs und Prospective Payment System (O • Clearly establish that the Congre Program is to “enable[] covered e resources as far as possible, rea providing more comprehensive s program” • Codify in statute the current defin the 340B Program, as set forth in Federal Register • Expand 340B eligibility to Commu Services Block Grants and Subst and Treatment Block Grants • Prohibit third-party payors from d covered entities or contract pharm terms of reimbursement due to pa Program • Impose additional 340B Program drug manufacturers
H.R. 6240	Impose user fee of 0.1 percent of 340B covered entities, which would be use integrity and oversight activities and pro services at hospital cover
H.R. 6273	Require that DSH covered entities wi

	employ or contract with sexual assault fo availability
H.R. [TBD]	Increase DSH percentage threshold for hospitals to 18 percent and increase th for children's hospitals, cancer hospit hospitals
H.R. [TBD]	Create a new presidentially-appointed position of Administrator for the 340B Dr transfer authority for the 340B Program Administrator to the new 340E
H.R. [TBD]	Define "patient" for DSH, children's and eligibility to individual • Receive health care services at a child site location • Receive outpatient services in-pe is employed by or an independen covered entity, such that the cove services on behalf of the provider • Receives drugs that are prescribe provider as a result of the in-pers • If the covered entity has a contra government, receives services fr pursuant to such contract • Is classified as an outpatient whe prescribed, as based on how the by the applicable payer (or if no r how the service would have been • Has a relationship with the covere covered entity creates and mainta that demonstrate the provider-to- responsibility for care that resulte • Excludes inmates of correctional receiving only administration or in dispensing of drug for subsequen administration in the home; indivi care services provided under an with the covered entity; individual relationship with the covered enti
H.R. [TBD]	Require the US Department of Health an to implement all recommendations to H 2018 GAO report on contract ph

H.R. [TBD]	Require hospital covered entities to s aggregate 340B savings, aggregate 340 uncompensated care
H.R. [TBD]	Require HRSA to conduct covered entity in accordance with the most recent government auditing standards issued by of the United Stat
H.R. [TBD]	Require DSH, children's and cancer h income patients no more than the 340 drugs
H.R. [TBD]	Provide HHS with authority to promulga to carry out the 340B P

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