THORN RUN PARTNERS
GOVERNMENT RELATIONS

Background Brief: 340B

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SUBJECT: 340B Program Issue Brief Companion to Omnibus Guidance

I. EXECUTIVE SUMMARY

This memorandum provides background on the 340B Drug Pricing Program to assist with your review of the Health Resources and Services Administration (HRSA) omnibus guidance[1] on key program parameters, released August 27. Congress has demonstrated sustained interest in the program, raising the possibility that HRSA's highly anticipated guidance may not be the final word on these key issues. The Medicare Payment Advisory Commission (MedPAC) also continues to examine Medicare Part B drug spending at 340B hospitals, opening another front of potential 340B scrutiny and reform.

II. BACKGROUND ON 340B PROGRAM GROWTH

A key dimension of the debate is the appropriate bounds of a program envisioned as a means of "stretch[ing] scarce federal resources as far as possible" amid steep escalation in both the number of providers benefiting from the program (covered entities or CEs) and overall 340B outpatient drug discounts. In fiscal year (FY) 2013, CEs received an estimated $3.8 billion in 340B discounts.[2]

340B-participating hospitals reached 1,365 in 2014, a 134% increase from 2005. The increase reflects the ACA's addition of certain children's hospitals, free-standing cancer hospitals, critical access hospitals, rural referral centers (RRCs) and sole community hospitals.[3] Participating disproportionate share hospitals (DSH) also increased substantially (583 to 1,001) and currently account for 78% of CEs' 340B spending on covered outpatient drugs. Through a Medicare-specific lens, MedPAC finds that 340B hospitals accounted for 22% of Medicare Part B hospital spending in 2005, reaching 41% in 2010 and 48% in 2013, with most growth stemming from facilities that were eligible both before and after the ACA's expansion of hospital eligibility.

Manufacturers furnish 340B discounts at least to the level of statutory ceiling prices as a condition of having their drugs covered by Medicaid, a make-or-break incentive that drives near-universal participation. Hospitals cite the program as an enabler of charity care and other value-added services they furnish to patients. While ceiling prices are proprietary, 340B discounts are at least 22.5% less than the average sales price (ASP) of drugs paid under the Medicare hospital

[1] https://www.federalregister.gov/articles/2015/08/28/2015-21246/340b-drug-pricing-program-omnibus-guidance
[2] Apexus (HRSA contractor) FAQs, available here.
[3] ACA Section 7101; summarized at Healthcare Lighthouse here.

outpatient prospective payment system, MedPAC estimates. Most (82%) CEs participate in HRSA's Pharmaceutical Prime Vendor program, through which average discounts of 10% underneath the ceiling price are negotiated for 7,000 drugs.[4]

III. HEIGHTENED SCRUTINY IN A NUTSHELL

Third-party oversight has intensified in recent years. Key developments include:

- In 2011, the **Government Accountability Office (GAO) called[5] for greater oversight of 340B eligibility and enrollment** by HRSA's Office of Pharmacy Affairs (OPA). It noted that "other than relying on self-policing, HRSA engages in few activities to oversee the 340B program." HRSA's OPA began annual auditing in 2012[6] and now requires annual recertification of CEs.[7]

- The **Department of Health and Human Services' Office of Inspector General (HHS OIG)[8] cited rapid growth both in the percentage of CEs using contract pharmacy arrangements** (10% to 22% between 2010 and 2014) as well as the unique number of such pharmacies (a 770% increase). It found that contract pharmacy arrangements – the expansion of which followed 2010 HRSA guidance permitting their broader use (see section IV) – "create complications" in preventing drug diversion in the 340B program, stemming duplicate discounts for Medicaid beneficiaries, and applying HRSA-recommended oversight practices. While it did not make recommendations, the OIG said it planned to continue reviewing such arrangements.

- **Sen. Charles Grassley (R-IA) has repeatedly called for enhanced 340B program oversight**. On March 27, 2013, he wrote to HRSA urging transparency regarding the payer mix for patients receiving 340B drugs. He has followed up with repeated calls for greater scrutiny, including over contract pharmacy arrangements.[9] In June 2015, he called for the Senate Finance Committee to convene a hearing to further examine 340B oversight with an eye toward devising specific legislation.[10] He cited GAO's June 2015 findings[11] on 340B-participating DSH hospitals' prescribing behavior and **GAO's recommendation that "Congress should consider eliminating the incentive to prescribe more drugs or more expensive drugs** than necessary to treat Medicare Part B beneficiaries at 340B hospitals."

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[4] http://www.medpac.gov/documents/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0
[5] http://www.gao.gov/products/GAO-11-836
[6] http://www.hrsa.gov/opa/programintegrity/auditresults/fy15auditresults.html
[7] http://www.hrsa.gov/opa/programrequirements/recertification/index.html
[8] http://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf
[9] http://www.grassley.senate.gov/news/news-releases/report-shows-weak-oversight-drug-discount-program-uninsured
[10] http://www.grassley.senate.gov/news/news-releases/grassley-requests-hearing-340b-prescription-drug-pricing-program-light-gao-report
[11] http://www.gao.gov/assets/680/670676.pdf

The recommendation stemmed from GAO's findings that average per-beneficiary spending at 340B DSH hospitals was higher than at non-340B DSH and other non-340B hospitals. Average per beneficiary spending on oncology drugs also was highest at 340B DSH hospitals. GAO suggested that the difference may reflect a current incentive system that allows 340B DSH hospitals to pay a lower 340B price for cancer drugs and then receive a premium via statutorily-set Medicare reimbursement. The report also observes that "this incentive to prescribe these drugs raises potential concerns about the appropriateness of the health care provided to Medicare Part B beneficiaries." HHS and stakeholders such as 340B Health both raised concern related to GAO's methodology, which GAO disputes.

- In its June 2015 Report to Congress, **MedPAC similarly expresses concern about 340B incentives but stops short of making formal recommendations**. In a chapter on Medicare Part B payment policy,[12] the Commission says hospitals' 340B discounts have implications "for Medicare program expenditures and beneficiary out-of-pocket costs." It indicates, for instance, that an "important policy question [for consideration] is **whether Medicare should pay less than ASP+6%** for Part B drugs purchased by 340B hospitals since they are able to purchase outpatient drugs at a price that is, on average, at least 22.5% below ASP." At a December 2014 E&C Health Subcommittee hearing discussion with Chairman Joe Pitts (R-PA) and John Shimkus (R-IL), MedPAC Executive Director Mark Miller raised this notion in the context of "sharing savings" between the hospital and CMS when the facility receives 340B discounts on Medicare-covered outpatient drugs. MedPAC's June 2015 report elaborates that it "could be argued that, even if Medicare's program payment does not change, **Medicare beneficiaries should pay lower cost sharing for drugs provided by 340B hospitals."**

IV. KEY REGULATORY ISSUES

HRSA has repeatedly recognized that broader efforts are needed to amplify and clarify 340B guidance. But through successive and legally fraught attempts at rulemaking, HRSA has faced questions on the extent of its statutory authority to issue sweeping new 340B regulations. In November 2014, HRSA withdrew[13] a highly anticipated proposed rule – originally slated for June 2014 release – that was expected to propose eligible patient criteria and address hospital eligibility and contract pharmacy oversight. The agency confirmed that it would refocus its rulemaking efforts on areas in which it had explicit rulemaking authority, such as administrative dispute resolution between manufacturers and CEs and certain civil monetary penalties, both of which are specified in Affordable Care Act (ACA) 340B program integrity provisions.

[12] http://www.medpac.gov/documents/reports/chapter-3-part-b-drug-payment-policy-issues-(june-2015-report).pdf?sfvrsn=0
[13] http://www.reginfo.gov/public/do/eoDetails?rrid=123970

Concurrently, HRSA recast higher-profile regulatory issues – originally destined for the proposed rule – as "omnibus guidance," which was released on Aug. 27. The omnibus guidance marks the first proposed attempt to revisit 340B program administration since 2007, when HRSA proposed but did not finalize a more restrictive definition of an eligible patient.[14]

V. KEY ISSUES IN OMNIBUS GUIDANCE

As stakeholders digest HRSA's recently released proposed guidance, following is a brief chart highlighting salient proposals. Comments are due by Oct. 27. Please refer to TRP's August 27 summary for more detail.

Topic	HRSA Proposals
Eligible Patients	• Replaces the governing three-pronged 1996 definition of an eligible patient with a proposed six-point revised definition. Key changes include: o Clarifying that services provided by providers who have privileges or credentials at the CE are insufficient to demonstrate patient eligibility; o Delineating that seeing a physician in private practice not listed in the 340B database (or any other non-340B site, even as a follow-up to a CE visit) does not carry eligibility for 340B drugs for services provided at the non-340B site; o Requiring that a drug be ordered/prescribed as a result of the applicable service by a CE provider and specifying that the service for which 340B drugs are ordered/prescribed must explicitly be classified as outpatient; o Modifying requirement from records being "maintained" to "accessible" to the CE, though records still must demonstrate responsibility for care.
Drugs Eligible for Purchase	• Clarifies the statutory "limiting definition" of a covered outpatient drug
Contract Pharmacy Arrangements	• Sustains CE ability to contract with one or more contract pharmacies • Creates a presumption that contract pharmacies will not distribute 340B drugs to Medicaid beneficiaries; requires a plan if CEs seek to do so and requires repayment if duplicate discounts are identified • Codifies registration requirements, including specified contractual elements and facets of statutory compliance (e.g., routine audits, corrective action)
Hospital Eligibility	• Delineates registration requirements for eligible hospital and non-hospital entities for inclusion on the public 340B database • Stipulates immediate HHS notification requirements for parent or child site loss of eligibility, as well as registration and annual recertification requirements • Clarifies the standing prohibition against obtaining covered outpatient drugs via GPO
CE Responsibilities	• Stipulates that CEs notify HHS of carve-in vs. carve-out purchasing of drugs for Medicaid beneficiaries to facilitate avoidance of duplicate discounts (different determinations are permitted for MCO beneficiaries) • Codifies statutory requirements for auditable records available to HHS and manufacturers with a five-year retention requirement • Delineates penalty of 340B exclusion for failures to maintain auditable records, though "non-systemic" violations may carry less stringent penalties; terminated entities may reenroll during next regular registration
Manufacturer Responsibilities	• Codifies obligation to honor ceiling prices for outpatient drugs via pharmaceutical pricing agreements if drugs are subject to Medicaid rebates; notes expectations for timeliness of adding new drugs and maintenance of auditable records • Requires pre-implementation notification to HHS of manufacturers' limited distribution plans for a covered outpatient drug (e.g., amid supply issue) • Clarifies refund/credit procedures in the event of overcharging • Proposes manufacturer recertification and listing in a public database

[14] http://www.hrsa.gov/opa/programrequirements/federalregisternotices/definitionofpatient011207.pdf

Program Integrity	• Describes HHS authority for auditing CEs • Proposes a notice and hearing process for CE response to adverse audit findings • Delineates corrective action plan parameters

VI. PROSPECTS FOR LEGISLATIVE ACTION

Prior to a House Committee on Energy and Commerce (E&C) markup of 21st Century Cures legislation, language was placed into a draft version of the bill that affected the 340B program. The language was ultimately not included in the final version of the bill advanced by the Full Committee and overwhelmingly passed by the House. Hospital stakeholders expressed concern about the floated 340B provisions, saying the 21st Century Cures bill was an inappropriate context for making such changes and that they would make 340B program implementation more burdensome. The draft language restricted the definition of an eligible patient, imposed extensive internal oversight and reporting requirements on hospitals and pharmacies and required written agreements between hospitals and contract pharmacies. The un-adopted provisions would also have imposed a small user fee on hospitals in order to pay for the additional government oversight and auditing, driven by the new reporting requirements. Furthermore, the draft would have imposed severe penalties for non-compliance, like a five-year exclusion for hospitals.

At this point, it is unclear whether Congress may try to intervene before finalization of HRSA's omnibus guidance, though efforts among stakeholders to secure certain specifications trumping the guidance are probable. The immediate response from hospital stakeholders to the draft 340B provisions and their prompt removal from the legislative docket signal hospitals' expectation for enfranchisement in any draft legislation. Furthermore, Congress faces several high-stakes deadlines – including a Sept. 30 government funding lapse and fall debt ceiling limit – that will place floor time at a premium. However, the vigor of the HRSA omnibus guidance's comment period could portend the emergence of subsequent legislation, especially if select program integrity issues are seen as unresolved by a final rule.

The E&C Committee reportedly was motivated to pursue the draft language during the 21st Century Cures markup in part by lingering questions about HRSA's statutory authority to accomplish needed clarifications and reforms. While limited statutory authority is driving HRSA's use of guidance rather than rulemaking, the agency may nonetheless find itself constrained by the statute and result in redirected focus to Congress on providing clear statutory direction. That task opens the door to potentially broader reforms, such as GAO and MedPAC ideas on changing incentives to prescribe 340B-acquired drugs in Medicare Part B or E&C ideas on requiring hospital disclosure of how 340B discounts are used.

VII. CONCLUSION

We hope this is a helpful overview of key issues facing the 340B program. We will continue to keep you apprised of further developments via real-time updates on regulatory releases and congressional action. Please let us know if you would like assistance in preparing any comments on the proposed guidance.