

September 11, 2019

Valerie Smith
Rules and Publications Program Manager
Washington State Health Care Authority
P.O. Box 42716
Olympia, WA 98501

Re: OTS-1525.3 ER: Proposed Amendments to WAC 182-530-7900, Drugs Purchased Under the Public Health Service Act

Dear Ms. Smith:

On behalf of our 103 hospital and health system members, the Washington State Hospital Association (WSHA) values the opportunity to comment on the stakeholder rule amending WAC 182-530-7900, Drugs Purchased Under the Public Health Service Act. We appreciate the Health Care Authority's (HCA) concern with compliance and the state's responsibility to ensure accurate information regarding 340B participation and avoid inappropriate payment of manufacturer rebates in cases where the drugs were purchased at 340B discounted rates. We believe HCA's intent for the attestation approach is to ensure and demonstrate the state's compliance. **However, we do not support this approach unless hospitals know what is in the attestation form before the rule becomes effective. If HCA adopts this approach, it should be used as an opportunity to maximize clarity and understanding of the various federal and state-specific regulations for the 340B program.**

Form needs to be available during rulemaking process. WSHA was informed by HCA staff that a copy of the attestation form (HCA 13-0047) would not be available for review before the rule is finalized. The purpose of the rule is to promote and ensure understanding and compliance regarding 340B regulations. While we understand that rulemaking and form creation often occurs concurrently, we cannot provide meaningful comment on the impact of the rule without reviewing the specifics of the regulations as understood by HCA. We request that the development of form HCA 13-0047 be accelerated so that stakeholders can assess and understand potential impacts during this rulemaking period.

Alignment of timing. To aid in this evaluation process and reduce burden of separate timeframes, we recommend that the timing of the attestation be consistent with the time the entity receives its recertification for participation in the 340B program by the federal Health Resources and Services Administration.

Confusion within the current WAC language. 340B regulations are by their nature complex and confusing as they include both the federal regulations, as well as state-specific policies HCA has adopted to ensure compliance with the federal regulations. It would be helpful to have a greater understanding of which rules are federally required versus those that reflect state-specific policies to aid and ensure our state's compliance. Some specific federal requirements apply the same for both fee-for-service Medicaid and Medicaid managed care, but other requirements apply differently within the program. For example, the requirement that drugs be billed and paid at actual acquisition cost does not apply to Medicaid managed care. We are concerned that the phrase "all claims for Washington apple health

clients in fee-for-service and managed care, are subject to 340B rules” may be interpreted as connoting greater uniformity between the rules for two components of the program than actually exists. The ability to review HCA’s understanding of “340B rules” and intent as expressed in the attestation would help 340B entities evaluate their participation and operation of the program.

We strongly support changes to the draft rule language to promote clarity. We recommend:

(3) As part of participation in the 340B program, providers must submit a completed annual attestation form (HCA 13-0047) to the agency acknowledging that all claims for Washington apple health clients in **both** fee-for-service and managed care, are subject to **their respective** 340B rules. Providers who fail to submit a completed attestation form to the agency may receive a compliance audit.

(4) With the exception of claim types identified in subsection (5) of this section, all 340B purchased drugs **under the Medicaid fee for service program** must be billed to the medicaid agency at the 340B actual acquisition cost (340B AAC).

While the agency may believe the subsection (4) is clear. WSHA continually hears confusion from our members. We would appreciate the opportunity to clarify the language.

If you have questions, please contact Andrew Busz, WSHA Policy Director, Finance at (206) 216-2533 or andrewb@wsha.org.



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