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OMB Number: 0906-NEW
Information Collection Request Title: *340B Rebate Model Pilot Program Application, Implementation, and Evaluation*
Federal Register Document Number: 2026-11989

The Craneware Group appreciates the opportunity to comment on the proposed Information Collection Request (ICR) associated with HRSA's consideration of a pilot 340B Program rebate model. These comments focus specifically on the operational feasibility of the proposed claims-level reporting requirements.

The Craneware Group has intentionally limited its comments to the operational and technical considerations within its area of expertise. Even within that limited scope, however, the estimated burden of five hours per respondent is not grounded in the operational realities of healthcare organizations. The activities described in this letter represent only a portion of the work necessary to support recurring claims-level reporting. When the full range of organizational functions required to implement, govern, and sustain such reporting is considered, the actual burden would be substantially greater than the estimate presented in the ICR.

The sections that follow describe representative operational activities required to support claims-level reporting. While not exhaustive, they demonstrate that the proposed burden estimate significantly understates the operational effort required to produce accurate, compliant, and recurring claims-level reporting within hospital environments.

I. The Operational Reality of Hospital Claims

The proposed claims-level reporting requirement assumes that covered entities can produce a complete, validated, and reportable claims record within the reporting timeframe established by the proposed rebate model.

For many hospital-administered drugs, that assumption is inconsistent with the operational reality of hospital claims processing. The complete claims record required to support rebate validation often does not exist until the drug administration has progressed through documentation, charge capture, coding, billing, payor adjudication, and financial reconciliation.

Unlike retail pharmacy claims, hospital-administered drugs move through a revenue cycle that continues well beyond the patient encounter. Clinical documentation, charge capture, coding, billing, payer adjudication, claim correction, and financial reconciliation occur over time, often extending well beyond the initial patient encounter.

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The complete claims record is not created at a single point in time. It matures as the hospital revenue cycle progresses.

This distinction is central to evaluating the feasibility of the proposed reporting requirement.

The proposed reporting requirement does not simply require hospitals to report information they already possess. *It requires covered entities to report a record before the claims processing cycle has produced a complete and validated record suitable for rebate determination.*

II. A Complete Claims Record Is Produced Through Reconciliation, Not Extraction

The requested claims record does not exist within a single system. It is assembled through reconciliation across multiple operational systems, vendors, and stakeholders. Relevant information frequently resides across electronic health records, pharmacy systems, charge capture applications, split-billing platforms, wholesaler records, revenue cycle systems, manufacturer reporting platforms, and state Medicaid reporting processes.

The operational challenge is not only data collection. *The operational challenges include determining when the claims record has matured sufficiently to support accurate rebate determination.*

For this reason, the central question presented by this Information Collection Request is not how long it takes a covered entity to submit information. It is whether the proposed reporting timeframe reflects the operational realities of hospital claims processing.

III. The Need for Additional Claims-Level Reporting Has Not Been Established

The proposed reporting requirement is premised on the need for additional claims-level reporting to address duplicate discount concerns. **Yet, HRSA does not explain why existing safeguards and reporting mechanisms are insufficient** to achieve that objective, nor does it demonstrate that the proposed reporting requirements are proportional to the significant operational burden they would impose on covered entities.

In addition, the proposal does not explain how the Rebate Pilot's reporting requirements relate to existing manufacturer-established reporting platforms, including ESP and Beacon. Those platforms already require covered entities to submit claims-level information to support duplicate discount prevention, yet the proposed Rebate Pilot would not replace or eliminate those reporting obligations.

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As a result, covered entities could be required to maintain multiple reporting workflows for substantially similar purposes without a corresponding reduction in administrative burden. HRSA should explain why additional claims-level reporting is necessary in light of these existing requirements and how the proposed approach avoids creating duplicative reporting obligations.

Summary

The principal operational challenge is not the absence of information. It is producing a complete and validated claims record within the reporting timeframe contemplated by the proposed rebate model.

That challenge reflects the operational realities of hospital claims processing — not a lack of available data. Additional reporting requirements alone do not resolve those underlying operational realities.

While The Craneware Group appreciates the opportunity to provide these comments and welcomes continued dialogue regarding the operational realities of hospital claims processing, healthcare data reconciliation, and 340B program administration, we urge HRSA to fully consider the more than 5,000 comments already submitted on this issue before instituting additional reporting requirements that would further increase the administrative burden on the nation's healthcare safety-net providers. We encourage HRSA to ensure that any future reporting framework is supported by a clearly demonstrated need, avoids duplicative reporting obligations, and appropriately balances program integrity with the operational realities facing covered entities.

Respectfully submitted,

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