Navigating 340B Good-Faith Inquiries (GFIs)

Purpose: This tool is designed to help all 340B stakeholders understand, conduct, or respond to good-faith inquiries (GFIs). It provides practical guidance to support consistent communication, appropriate scope, and compliance with the Health Resources and Services Administration's (HRSA's) expectations.

Background: A GFI is a request for clarification that may be initiated when data suggest potential Medicaid duplicate discounts or diversion in the 340B Program. Though they are intended to ensure program integrity, GFIs may include unclear requests or incomplete data, causing confusion, delays, and added administrative burden for covered entities.

This tool was developed to promote consistent expectations; encourage professional collaboration among covered entities and manufacturers; and support efficient resolution of legitimate concerns while reducing unnecessary workload.

Understanding GFIs: GFIs are limited to medications from a specific manufacturer, not all drug products. GFIs are not audits; however, unresolved or unaddressed inquiries may lead a manufacturer to request a formal audit through HRSA. GFIs may be initiated by pharmaceutical manufacturers or their authorized representatives. Common reasons include:

- Apparent statutory duplicate discounts (Medicaid Drug Rebate Program [MDRP] rebate + 340B purchase)
- Requests for clarification about state Medicaid billing modifiers
- Unusual increases or variances in 340B purchasing for a specific product

Discrepancies can arise as a result of system conversions, changing of carve-in or carve-out decisions, data mismatches, NDC changes, utilization shifts, or the addition of new child or associated sites.

How GFIs Are Communicated: GFIs are typically communicated via letter, email, phone call, or a third-party portal. A valid GFI should include:

- Manufacturer name and contact information
- Drug/NDC(s) in question
- A clearly defined and reasonable time period
- Description of the concern (i.e., duplicate discount, diversion)
- The data source or evidence supporting the concern
- An authorization letter, if a third party is representing the manufacturer

Responding to a GFI: Covered entities should take the following steps when a GFI is received:

1. **Verify the sender** – Confirm that the inquiry originates from a manufacturer or an authorized representative. If unclear, request a letter of authorization.
2. **Clarify the request** – If data is incomplete or ambiguous, ask the manufacturer or representative to specify the exact nature of the concern and scope of the inquiry in writing.
3. **Route internally** – Direct the inquiry to the appropriate 340B contact or department within the organization.

HRSA expects a timely and good-faith effort to respond. Depending on the complexity of the inquiry, the process of responding to and resolving a GFI may take considerable time; the key is for all parties involved to maintain communication and request additional information when needed.

Stakeholder Collaboration:

- **For Covered Entities:**
  - Keep all communications professional and factual.
  - Confirm details before sharing data externally.
  - Respond accurately and in a timely manner.
  - Maintain records of all GFIs and responses.
  - Ensure that GFIs are routed internally to the appropriate 340B program contact.
  - Safeguard patients' protected health information (PHI) and other confidential or proprietary information.

- **For Manufacturers:**
  - Keep all communications professional and factual.
  - Respond accurately and in a timely manner.
  - Limit inquiries to relevant data related to Medicaid duplicate discount or diversion concerns.
  - Provide sufficient context, data source information, and proper authorization.
  - Exclude invalid or zero-quantity transactions.
  - Acknowledge the operational workload and response timelines of covered entities.
  - Ensure that authorized representatives are conducting GFIs only within their scope of authority.
  - If the appropriate 340B program contact is not already identified, direct GFIs to both the authorizing official (AO) and primary contact (PC) listed in 340B OPAIS.
  - Make reasonable, documented attempts to contact the covered entity through multiple outreach efforts before characterizing the entity as unresponsive.

Data Quality and Common Issues:

- Zero-quantity or reversed transactions in manufacturer files
- Portal "yes/no" responses incorrectly assumed to confirm Medicaid duplicate discounts
- Claims missing required state Medicaid identifiers
- Outdated or mismatched identifiers caused by electronic medical record (EMR) or billing transitions

Covered Entity Best Practices:

- Acknowledge receipt of the GFI as soon as reasonably possible (e.g., within 14 business days, unless the request specifies otherwise). If the review is expected to take longer than 30 business days, communicate that expectation in the acknowledgement and provide an estimated timeframe for response.
- Validate all incoming data before responding. Differentiate data from different purchasing accounts and evaluate whether both mixed-use and separate inventories were affected by the potential issue.
- Exclude zero-quantity or invalid transactions.
- Review Medicaid claims for proper state billing modifiers.
- Involve billing, information technology (IT), or third-party administrator (TPA) teams when needed.
- Request additional data from manufacturers or representatives if necessary to ensure accuracy.
- Provide a complete and accurate response after data review.

Tips for Covered Entities to Reduce Future GFIs:

- Monitor for NDC changes and update purchasing records accordingly.
- Verify Medicaid billing modifiers and coding accuracy.
- Engage 340B and compliance teams during EMR, billing, or TPA transitions.
- Run periodic quality assurance reports to confirm correct billing unit setup.
- Maintain and regularly update internal policies and procedures addressing GFI handling and escalation.

When GFIs Lead to Audits or Administrative Dispute Resolution (ADR): If a covered entity fails to respond or provides incomplete information, or if unresolved inconsistencies remain, the manufacturer may request an audit through HRSA.

- Manufacturer audits must be conducted by an independent third party unaffiliated with the covered entity.
- Audits are limited to Medicaid duplicate discounts and diversion for NDCs of that specific manufacturer.
- Covered entities should maintain thorough documentation of all GFIs, responses, and supporting data validation steps.
- A covered entity can be audited by only one manufacturer at a time.

If a dispute cannot be resolved through good-faith communication and an audit, the manufacturer may escalate the matter to HRSA's administrative dispute resolution (ADR) process. The ADR process serves as a formal mechanism for resolving disagreements regarding 340B compliance. One of the purposes of the 340B ADR process is to resolve claims by manufacturers, after a manufacturer has conducted an audit as authorized by section 340B(a)(5)(C) of the Public Health Service (PHS) Act, that a covered entity has violated the prohibition on diversion or Medicaid duplicate discounts.