

# 340B Expansion and Diversion Issues



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CONGRESS AND BEST PRACTICES FORUM*

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# Overview



- GAO report
- Diversion
- SNHPA's position
- Audits
- Upcoming events

# GAO Report: Key Findings for Covered Entities



- 340B program supports and expands access to services
- Covered entities use savings in ways consistent with purpose of program
- 340B pricing does not affect provider access with two exceptions
  - IVIG
  - Penny pricing
- 340B providers concerned over drug pricing overcharges

# GAO Report: What Report *Didn't* Say



- Program is not being used as Congress intended
- Program should not be expanded
- Program creates a problem for non-340B purchasers seeking access to needed medications
- There is rampant diversion in the program

# Diversion



- SNHPA supports GAO recommendation that HRSA finalize new and more specific guidance on patient definition
- There is not rampant diversion in 340B program but there is rampant disagreement over what constitutes diversion
- Lessons from HRSA's proposed changes in 2007
- Allegations of diversion are weak in the absence of concrete evidence based on audits

# SNHPA's Position



- Available on SNHPA's website for both members and non-members are a set of "Principles" that SNHPA developed to assist with complying with patient definition requirements
- According to SNHPA's Principles, 340B can be used to fill prescriptions written within the walls of the hospital
- Prescriptions written outside the walls of the hospital should not be filled with 340B drugs unless they fall within two limited exceptions:
  1. follow-up care
  2. contractual care

# SNHPA's Position (cont'd)



- Regarding contractual care, the costs associated with the care must be reimbursable on hospital's Medicare cost report
- This limitation prevents abuses because the cost report provides documentation of compliance
- According to SNHPA's Principles, 340B should not be used for physician-administered drugs that are administered outside the walls of the hospital

# Audits



- SNHPA supports GAO recommendation that HRSA perform audits
- Audits will advance the integrity of the program
- Audits should extend to both manufacturers and covered entities
- Scope of an audit must be limited to documentation relevant to diversion and duplicate discounts
- How to audit for diversion prior to clarification of patient definition?



# Upcoming Events



## 8<sup>th</sup> Annual 340B Coalition Conference

Co-Hosted with Apexus

Feb. 29-Mar. 2, 2012

Hotel del Coronado

San Diego, CA

[www.340bcoalition.org](http://www.340bcoalition.org)

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