



# AMERICA'S ESSENTIAL HOSPITALS

## **340B Mega Guidance: Implications for Essential Hospitals**

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*September 10, 2015*



# TODAY'S AGENDA

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- Background
- Major Provisions of the Guidance
  - » Program Scope
  - » Covered Entity Eligibility
  - » Oversight and Compliance
  - » Manufacturers' Obligations
- Next Steps
- Q&A

# Background



## HOW DID WE GET HERE?

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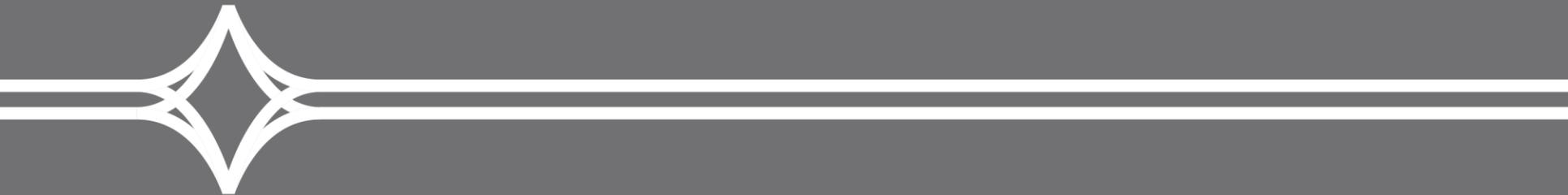
- Veterans Health Care Act of 1992 establishes Section 340B of the Public Health Service Act
- Health Resources Services Administration (HRSA) charged with implementation
- Program implemented informally...letters to individuals and certain covered entities, notices published without notice and comment...
- Under pressure to formalize and clarify, HRSA develops a “mega reg” covering major program requirements and submits for OMB review (April 2014)
- After PhRMA lawsuit calls into question HRSA’s authority to regulate, HRSA withdraws the proposed rule before release (Nov. 2014)
- August 27, 2015: HRSA releases “Mega-Guidance”

# ABOUT THE MEGA-GUIDANCE

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- **Proposed** guidance only – not currently effective
  - » *But* where requirements in proposed guidance are pre-existing, they may currently apply.
    - *How to know which is which?????*
- HHS is soliciting comments – due October 27
- America's Essential Hospitals is soliciting your input to help inform our comments
  - » *Real life impact information is key*

**Major Provisions of the  
Mega-Guidance:  
*Program Scope***



# 340B DRUGS FOR COVERED ENTITY “PATIENTS” ONLY

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- Under the statute, a covered entity may not “resell or otherwise transfer the drug to a person who is not a patient of the entity”
- No further elaboration, restrictions or limitations on what it means to be a “patient”
- 1996 guidance defines a patient
- 2007 proposed rule narrows the definition
  - » But the proposed rule was never finalized

## DEFINITION OF A PATIENT: 1996 VERSION

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1. Covered entity has an established relationship with the individual, such that the covered entity maintains records of the individual's health care;
- and
2. The individual receives health care services from a professional employed by covered entity, or under contractual or other arrangements (e.g. referral) such that responsibility for the care provided remains with the covered entity

# NEW PROPOSED DEFINITION OF A PATIENT

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- “Patient” defined on a *prescription-by-prescription/order-by-order* basis.
  - » Mr. Smith might be your patient for one of his prescriptions, but not another.
  - » Ms. Jones might be your patient for one order of her prescription but not when it is renewed.
  - » Patient status de-linked from the actual patient
- Each prescription/order must meet a 6-part test

## PATIENT DEFINITION: THE SIX PRONGS

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1. Individual receives services received at a registered covered entity site
2. Services received from a provider who is employed or an independent contractor such that the covered entity “may bill” on behalf of the provider
3. Drug is prescribed as a result of the service from said provider
4. Care provided is consistent with federal grant (not applicable to hospitals)
5. The services received are outpatient services
6. Patient records are accessible to the covered entity and demonstrate covered entity responsibility for the care.

# 1. SERVICES RECEIVED AT REGISTERED COVERED ENTITY SITE

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- Individual must receive services at the hospital or a registered outpatient clinic
- Excludes affiliated clinics
  - » E.g. freestanding clinics run by faculty group practice
  - » E.g. specialist referrals outside of the hospital
  - » E.g. community partners providing follow-up care
- This prong is new

## 2. PROVIDER RELATIONSHIP

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- Services received from a provider ***employed*** by or an ***independent contractor*** of covered entity such that entity “***may bill***” on behalf of the provider
  - » *Includes* faculty practice arrangements, established residency, internship, locum tenens and volunteer provider programs
  - » *Excludes* providers with referral or other arrangements
  - » *Excludes* providers with only privileges or credentials
- “May bill” requirement is unclear
  - » Under what circumstances may a hospital bill for a provider? Is assignment required? Must the provider only be eligible to assign payments to hospital? Under whose rules? Medicaid? Medicare? Other?
- **Prior guidance allowed referral/other arrangements and did not include billing requirement**

### 3. DRUG PRESCRIBED AS A RESULT OF THE PROVIDER'S SERVICE

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- Not only requires patient to receive a service from the covered entity but must also receive the prescription at the covered entity by the covered entity's provider
- Dispensing or infusing the drug, by itself, is not enough
- Covered entity may use telemedicine, telepharmacy or other remote arrangements (e.g. medication management)
  - » Must involve the issuance of a prescription by the covered entity
- This prong is new

## 5. SERVICE MUST BE OUTPATIENT

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- *Excludes* discharge prescriptions
  - » Discharge prescriptions have long been eligible for 340B pricing
  - » On-site post-discharge fulfillment of prescription critical to preventing readmissions
- May include outpatient services later reclassified as inpatient
- **This prong is new**

## 6. ACCESSIBLE PATIENT RECORDS DEMONSTRATING RESPONSIBILITY FOR CARE

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- Patient must have an “established relationship” such that the covered entity maintains auditable health care records
- Preamble states that records must demonstrate that covered entity “retains responsibility for care that results in every 340B drug ordered, dispensed, or prescribed to an individual”
  - » What about multiple providers with responsibility for care?
  - » Integrated medical records?
- This prong is not new

## PhRMA PROPOSALS FOR PATIENT DEFINITION, 2013

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- Individual receives outpatient medical care from the covered entity
- Care is provided on an ongoing basis
  - » Not just dispensing drugs or case management
- Care is provided and drugs prescribed by an employee or an independent contractor of the covered entity
  - » Independent contractor is one who can reassign right to bill to the covered entity
  - » Excludes drugs provided by an outside physician as a result of a referral from the covered entity
- Care must be provided at covered entity facilities

*(Letter to OPA, June 28, 2013)*

# CONCERNS ABOUT THE PATIENT DEFINITION

- Dramatically restricts drugs eligible for discount
- Undermines the purpose of the program
- Discourages integration
- Drives up costs—eg promotes provision of care in hospital-based settings
- Erects regulatory barriers to appropriate referrals
- Logistical nightmare in tracking and categorizing each prescription for each patient
- Minefields of legal risk for covered entities
- Other issues? Let us know!



# COVERED ENTITY EMPLOYEES

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- 340B may not be used for covered entity employees unless the employee received care from the covered entity that meets the 6-part patient definition
- Financial relationship between covered entity and employee is not enough

# COVERED OUTPATIENT DRUG DEFINITION

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- 340B statutory definition linked to Medicaid drug rebate statute
- Medicaid rebate definition *excludes* drugs that are:
  - » Provided as part of, incident to and in the same setting as another service
  - » Paid for by Medicaid as part of such service, not separately
- HRSA prior guidance not specific/inconsistent on whether “limiting definition” applies
- Proposed rule now says yes, exclusion does apply
- Result: fewer drugs subject to 340B discount
- Perverse incentive for Medicaid programs to unbundle drugs
- **Bundled payment exclusion is new**



## OFF-SITE OUTPATIENT FACILITY – CHILD SITE

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- To be considered part of the Covered Entity, the offsite clinic must—
  1. Be listed as reimbursable on most recently filed Medicare cost report, AND
  2. Provide services that have associated outpatient Medicare cost and charges
- Concern about delayed participation if tied to filed cost report
  - » HRSA exception for children’s hospitals – attestation suffices
  - » **This requirement is not new**, but AEH has long objected to it
- Requirement for Medicare costs/charges will exclude special population clinics
  - » Clinics targeted to indigent, Medicaid/uninsured, pediatric, OB/GYN, prisoners, etc. unlikely to qualify
  - » Unclear why it’s necessary to serve Medicare patients to be part of the hospital
  - » **This requirement is new**

# CONTRACT PHARMACIES

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- Covered entities may continue to use multiple contract pharmacies
  - » 2010 contract pharmacy guidance permitted this
- Must ensure compliance with prohibition on diversion and duplicate discounts and have auditable compliance records
  - » More (much more) on this later....
- Scope could have been but was not narrowed

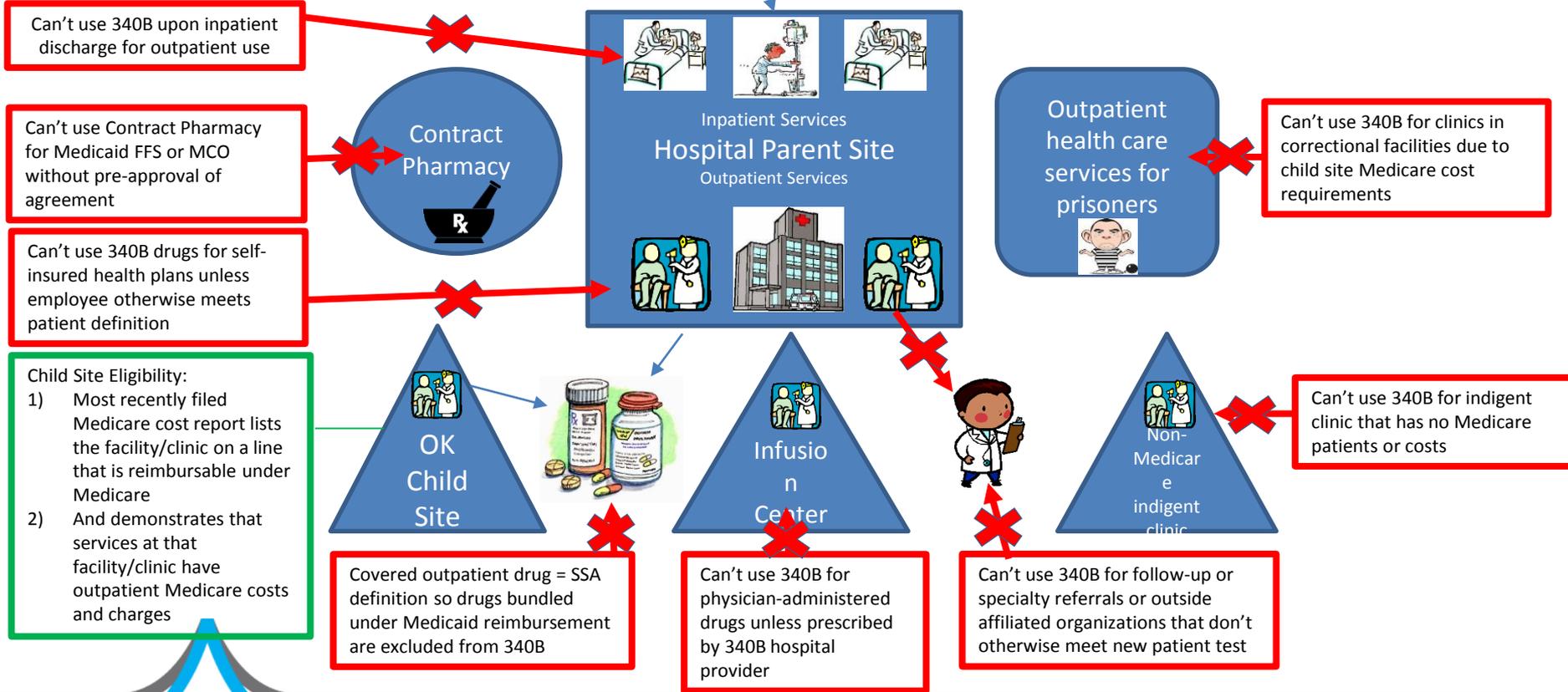
# 340B Mega-Guidance Reduction in 340B Drugs for Hospitals

## DSH Hospital eligibility:

- 1) government owned or operated, documented delegation of governmental powers, or contract with state or local government with "enforceable expectations....., including provision of direct medical care"
- 2) 11.75 DSH % in most recently filed Medicare cost report
- 3) Prohibition of GPO for covered outpatient drugs

## Hospital ineligibility:

- 1) Effective immediately re low DSH % upon filed cost report or first GPO violation if systemic
- 2) CE must notify OPA
- 3) CE liable to manufacturers from date of ineligibility



**Major Provisions of the  
Mega-Guidance:  
*Covered Entity Eligibility***



# HOSPITAL ELIGIBILITY

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Statute specifies 3 criteria for hospital eligibility:

1. DSH adjustment percentage of 11.75% or more
  - » As demonstrated on latest filed cost report (no change)
2. Governmental Relationship
3. GPO Exclusion

# REQUIRED GOVERNMENTAL RELATIONSHIP

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1. Governmentally owned or operated
  - » Ownership demonstrated in IRS filings or other federal documentation (new requirement)
  - » Or state/local government is the “sole operating authority”
2. Delegated governmental powers
  - » Must provide certification of formal delegation of a power “usually exercised” by state/local government
  - » E.g. power to tax, issue government bonds, act on behalf of the government
  - » Excludes powers generally granted to private persons or corporations
  - » Delegation may be through statute, regulation, contract, creation of a public corporation, development of a hospital authority or district

## REQUIRED GOVERNMENTAL RELATIONSHIP (cont'd)

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3. Under contract with a state/local government to provide care to low income persons not eligible for Medicaid or Medicare
  - » Need signed certification from hospital and government officials
  - » Must create “enforceable expectations” for the provision of care, including “direct medical care” (new requirements)

# GPO EXCLUSION

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- Group Purchasing Organizations may not be used to purchase covered outpatient drugs
  - » Exceptions:
    1. Offsite facilities not enrolled in 340B (*not new*)
    2. Drugs for inpatients reclassified as outpatient (*new*)
    3. Drugs unavailable at 340B price needed to prevent disruptions in care (*new*)
- GPO purchases for *non-340B* drugs is permitted
- “Drug replenishment model” permitted if non-GPO account is used, but:
  - » Must demonstrate compliance through auditable records

***Violations of GPO exclusion are grounds for termination from the program – beware!***

# GAINING AND LOSING ELIGIBILITY

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- Eligibility gained on date all eligibility criteria are satisfied and lost on date any criterion no longer met
- Covered entity and all offsite locations (child sites) must be registered and listed in 340B database
  - » Annual recertification continues
- Must notify HRSA of any loss of eligibility for any site
- 340B purchasing must cease on date of loss of eligibility.
- GPO purchasing must cease on date eligibility is gained.
- Covered entity liable for repayment to manufacturers for all 340B purchases retroactive to loss of eligibility



**Major Provisions of the  
Mega-Guidance:  
*Oversight and Compliance***



# MAINTENANCE OF RECORDS

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- Covered entities must retain auditable records for 5-years (**new**)
  - » Failure to meet the standard could lead to termination
  - » HRSA to distinguish between systematic and non-systematic violations
  - » Subject to notice and hearing
- Covered entity declared ***ineligible*** for entire period in which the standard is not met and liable for manufacturer repayment
  - » Repayment could potentially include purchases for which covered entity has complete records.

## DUPLICATE DISCOUNTS

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- Statute prohibits double discount where State obtains rebate on same drug already obtained at 340B price
- Covered entities may choose:
  - » *Carve In*: Will use 340B drugs for Medicaid patients
  - » *Carve Out*: Will not use 340B drugs for Medicaid patients
- Medicaid Exclusion File records carve-in/carve-out choices
  - » FFS: If covered entity not in exclusion file, must purchase Medicaid FFS drugs at non-340B price
  - » Managed care: Covered entity election may vary by MCO and by site,
    - Elections reported to HRSA
    - Work with states/MCOs to prevent duplicate discounts
  - » Contract pharmacy: Contract pharmacies may not be used for Medicaid purchases unless prior HRSA approval of written agreement describing system to prevent duplicate discounts

# DIVERSION

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- Statute prohibits covered entities from diverting 340B drugs to non-340B patients.
- If diversion occurs, covered entities are expected to work with manufacturers to correct (and repay) within 90 days.
- Must report each instance of diversion and associated corrective action to HRSA.

# CONTRACT PHARMACY

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- Contract pharmacy arrangements must be in writing and registered with HRSA
  - » Must list all locations of the pharmacy and covered entity offsite clinics
  - » Check 2010 guidance lists additional required elements of the contract; unclear if these requirements still apply
- Covered entity retain responsibility for compliance
- Expectation of annual independent audits and quarterly reviews
  - » Any discovered violations must be reported to HRSA
  - » Quarterly reviews are new; annual audit requirement strengthened

# HRSA AUDITS OF COVERED ENTITIES

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- Under statute, covered entities must allow HRSA audits and make records available
- Audits followed by “notice and hearing” process
  - » Covered entity may respond to adverse findings in writing within 30 days
  - » HRSA will consider the response and issue a final determination
  - » Action could include termination and/or repayment.
  - » No in-person or telephonic hearing
  - » No guarantee of independent arbiter
- Covered entity must submit corrective action plan and timeline, measures to prevent recurrence, plan to repay manufacturers

# MANUFACTURER AUDITS OF COVERED ENTITIES

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- Under statute, manufacturers have right to audit covered entities for duplicate discounts and drug diversion
- Must document reasonable cause for suspected violations and proposed audit plan
- HHS may limit scope of the audit
- Final audit reports submitted to HRSA
- Must continue offering 340B prices unless/until HRSA makes final determination of a violation



# HRSA AUDITS OF MANUFACTURERS

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- Manufacturers must permit audits and make records available
  - » Also subject to 5-year records retention requirement
- Similar notice and hearing process for adverse findings
- Manufacturers with adverse final determinations may be required to submit corrective action plans and timelines, measures to prevent future occurrences and any applicable refunds to covered entities



**Major Provisions of the  
Mega-Guidance:  
*Manufacturer Responsibility***



# PHARMACEUTICAL PRICING AGREEMENT

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- PPA required as a prerequisite for federal Medicaid funding for manufacturer's products
- PPA requires manufacturers to provide 340B discounts on covered outpatient drugs to covered entities

# OBLIGATION TO OFFER 340B DISCOUNTS

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- Manufacturers must offer *all* covered outpatient drugs at no more than the 340B ceiling price.
- 340B drugs *must* be made available to a covered entity if available to *any other purchase at any other price*.



# LIMITED DISTRIBUTION PLANS

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- If manufacturer distributes drugs only through a specialty pharmacy or if supply is limited, it must submit a Limited Distribution Plan to HRSA
- Plan must include:
  - » Explanation of and rationale for restricted distribution
  - » Assurance that restrictions are equitably imposed
  - » Details of distribution plan
  - » Dates plan will begin and end
  - » Plan for notification of wholesalers and distributors

# Next Steps



# WHAT IS AMERICA'S ESSENTIAL HOSPITALS DOING?

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- Action updates—short version on day of release, longer analysis in your inboxes
- Detailed comments—Draft to be circulated to members in advance of due date; final to be submitted to HRSA 10/27
  - » Member feedback is critical
  - » Action alert to be circulated with specific feedback requests
- Seeking meeting with HRSA (and beyond)
- Educating members of Congress and staff
- All options for response are being considered



## WHAT CAN YOU DO?

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- Work with financial, pharmacy, compliance and legal staff to determine extent of impact on your organization
- Provide detailed and specific feedback to America's Essential Hospitals
- Prepare comments for submission to HRSA
  - » America's Essential Hospitals draft letter can be a template
- Come to the Policy Assembly October 27-28

# Q&A

