

Run a Regulatory-Compliant 340B Program

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MedImpact 2016 ANNUAL CONFERENCE



Agenda

- Current Patient Definition (1996)
- SUNRx System Set-up and Logic
- HRSA MegaGuidance (2015)—Proposed Changes to Patient Definition, and its Potential Impact on 340B Entities



Current Patient Definition (1996)

1. The covered entity has established a relationship with the individual such that the covered entity maintains records of the individual's health care. (Facility and Medical Record Rules)
2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity (Provider, Responsibility for Care Rules)

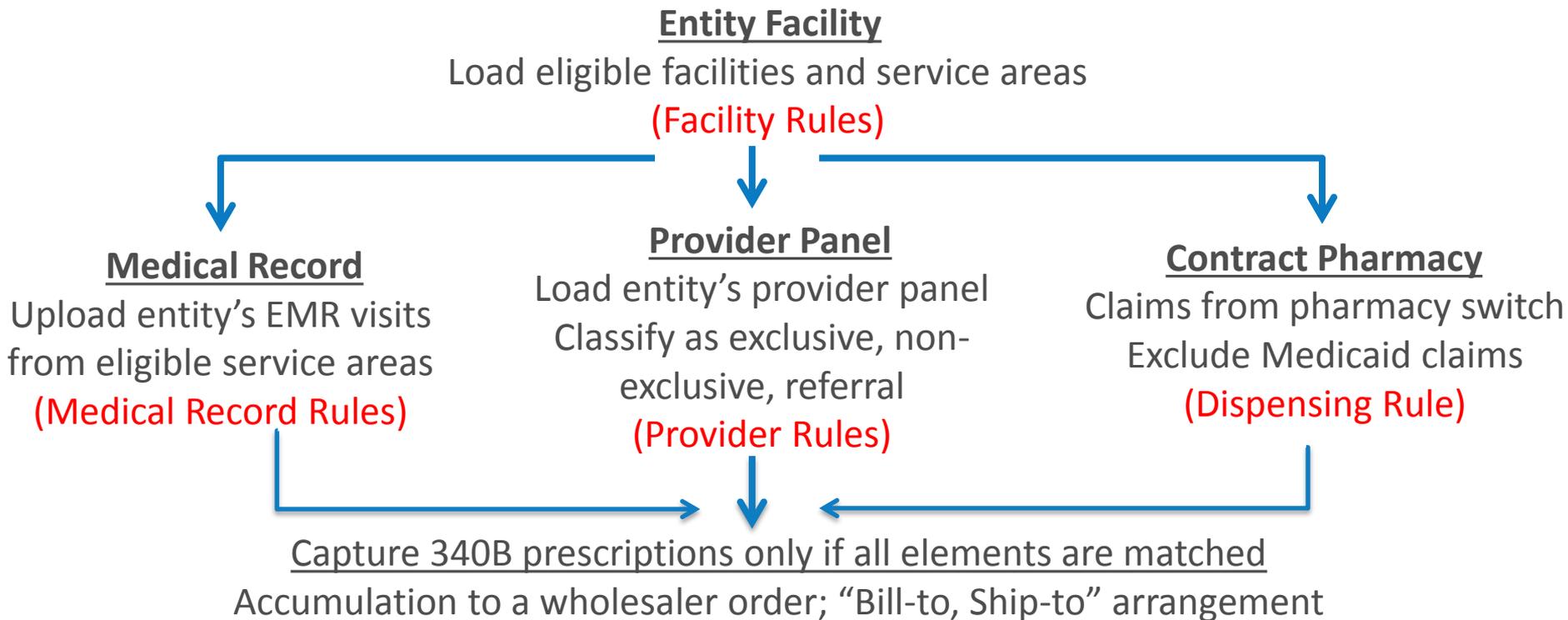


Current Patient Definition (1996)

3. The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement. (Grant Rule)
4. An individual will not be considered a 'patient' of the entity for purposes of 340B if the only health care received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting. (Dispensing Rule)



SUNRx Prescription Capture—Data and Logic



340B MegaGuidance (August 2015)

- Public comment period ended in October 2015—HRSA received 1273 comments (mostly hospitals and FQHCs)
- Guidance was intended to increase regulatory clarity for stakeholders, and strengthen HRSA’s ability to administer the 340B program
- Addressed most major program elements—includes both the current interpretations and new program elements
- Changed the Patient Definition from three to six elements; defined eligibility on a “prescription-by-prescription” basis
- The Guidance is not in final form—the final form may vary significantly from the proposal
- The final form is expected September 2016 (there is no legal deadline—and it may take longer)



What was NOT addressed in MegaGuidance

MegaGuidance did not change the core of the 340B program. It DID NOT:

- Change the 340B “statement of program intent”
- Limit the program to only prescriptions to the uninsured
- Limit on how entities spend their 340B savings
- Change the type or qualifications of 340B eligible entities
- Place limits on contract pharmacy arrangements
- Restrict the financial arrangements between stakeholders
- Change the DSH adjustment % or Medicare Cost Report requirements for hospitals

These elements may be addressed by Congress



340B Patient Definition—Providers

MegaGuidance Eligibility (2015)	Implication to 340B Entities
<ul style="list-style-type: none">The individual receives a health care service from a health care <u>provider who is employed</u> by the covered entity or is an <u>independent contractor</u> of the covered entity such that the covered entity <u>may bill for services</u> on behalf of the provider	<ul style="list-style-type: none">Vague provider definition and billing practices would reduce eligible scripts and overburden hospitalsThe “may bill” wording is unclearMay eliminate scripts written by “privileged” providers <p>“Simply having privileges or credentials at a covered entity is not sufficient to demonstrate that an individual treated by that privileged provider is a patient of the covered entity for 340B Program purposes.”</p>



340B Patient Definition—Off-Site Scripts

MegaGuidance 340B Eligibility (2015)	Implication to Covered Entities
<ul style="list-style-type: none">The individual <u>receives a health care service</u> at a covered entity site which is <u>registered</u> for the 340B Program and listed on the public 340B database	<ul style="list-style-type: none">Eliminates follow-on and referral scripts (greatest detrimental impact to FQHCs and rural hospitals) <p>“An individual who sees a physician in his or her <u>private practice</u> which is not listed on the public 340B database or any other non-340B site of a covered entity, even as <u>follow-up to care</u> at a registered site, would <u>not be eligible to receive 340B drugs</u> for the services provided at these non-340B sites.”</p> <p>“If a patient is <u>referred</u> from the covered entity for care at an outside provider and receives a prescription from that provider, the drug in question would <u>not be eligible for a 340B discount</u> at that covered entity.”</p>



340B Patient Definition—Infused Drugs

MegaGuidance Eligibility (2015)	Implication to 340B Entities
<ul style="list-style-type: none">An individual would not be considered a patient of a covered entity whose only relationship to the individual is the <u>dispensing or infusion of a drug</u>	<ul style="list-style-type: none">Eliminates “infused” drugs that were written by specialists outside the hospital (common practice)Common “reverse referral” arrangementThreatens access to care, especially for rural hospitals and FQHCs with infusion centers, even if the entity is responsible for the infusion care



340B Patient Definition—Discharge Scripts

MegaGuidance Patient Eligibility (2015)	Implication to 340B Entities
<ul style="list-style-type: none">The individual's drug is ordered or prescribed pursuant to a health care <u>service that is classified as outpatient</u>	<ul style="list-style-type: none">Would disallow <u>discharge</u> prescriptions written as part of an inpatient stayReduces access to affordable medications upon discharge. Discharge scripts are an important factor in improving care and reducing re-admissions



340B Patient Definition—Employees

MegaGuidance Patient Eligibility (2015)	Implication to 340B Entities
<ul style="list-style-type: none">The 340B Program does not serve as a general employee pharmacy benefit or self-insured pharmacy benefit.	<ul style="list-style-type: none">No change to existing Regulation—Employee must be an “eligible patient”, <u>meeting all patient definitions</u>



340B Patient Definition—Bundled Payments

MegaGuidance Patient Eligibility (2015)	Implication to 340B Entities
<ul style="list-style-type: none">• Excludes from 340B drugs that are “bundled” into a single payment under Medicaid• Insurance companies are more often requiring hospitals to bundle into a single bill the drugs used for outpatient who were later admitted as an inpatient	<ul style="list-style-type: none">• Commonly affects the ER (outpatient services followed by a later inpatient admission)• The Guidance confuses how a service is billed vs. where the services is delivered• Would add major financial and administrative burdens to hospitals



Medicaid Guidance

340B Medicaid MegaGuidance (2015)	Implication to 340B Entities
<ul style="list-style-type: none">Proposes a new mechanism for entities to separately elect to carve-in/out Fee-for-Service Medicaid from MCO Medicaid, and to select sites and plans	<ul style="list-style-type: none">Positive for entities—provides flexibility to differentiate FFS from Managed Medicaid
<ul style="list-style-type: none">Expects entities to not use 340B for <u>both FFS and MCO Medicaid</u> at contract pharmacies (unless it has a HRSA reported <u>agreement with the State or MCO to prevent duplicate discounts</u>)	<ul style="list-style-type: none">Blocks are required for both FFS and Managed Medicaid, even though the 340B is intended for Managed MedicaidAgreement needed with the State/MCO to prevent duplicate discountsCurrent methods are unworkable



Questions?

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