Kansas Hospital Association
340B Compliance Workshop

June 18, 2019

Speaker has nothing to disclose

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340B: It's not just one thing, it's a thousand little things
340B Drug Pricing Program

Small Program, Big Benefits

- 2.8% Protocol of the United States' $407 billion in annual drug purchases made through the 340B program in 2015.
- $3.5 BILLION in community benefit for fiscal year 2015.

340B creates valuable savings on outpatient drug expenditures to 100+ equivalent care and health activities to better the communities they serve. It also saves money for state and federal governments.

1,084 PROVIDERS IN PENNSYLVANIA PARTICIPATE IN THE 340B DRUG PRICING PROGRAM

340B increases access to care for over 1,000 vulnerable populations; participating hospitals prevented $2.6 billion in uncompensated care in Fiscal year 2016.

PROTECTING PENNSYLVANIA’S SAFETY NET
For more than 25 years, Congress has provided relief from high prescription drug costs through the 340B Drug Pricing Program. The program requires participating pharmaceutical companies to sell covered outpatient drugs at a discount to eligible health care organizations. To be eligible, hospitals must serve a disproportionate share of uninsured and low-income patients. This program gives patients better access to drugs they need and helps hospitals enhance care capabilities by stretching scarce federal resources.

Who are 340B Hospitals?

About half are urban, half are rural.
80% of PA Critical Access Hospitals (CAHs) participated in 340B.
65% of Pennsylvania hospitals (in 15 counties) participated in 340B.

340B Hospitals Meet Rigorous Requirements

- Eligibility
- 340B Drug Pricing Program

The 340B Program Continues to Expand

The 340B Program will effectively surpass today’s spending on drugs in the Part B program.

By 2021, the 340B program will effectively surpass today’s spending on drugs in the Part B program.

EXPANSION → Increased oversight/compliance

The Hospital and Healthcare Association of Pennsylvania
Aging for Better Health
www.aging4better.org

Vizient

Vizient presentation │January 2017 | Confidential Information
Critical Access Hospitals

Critical access hospitals (CAHs) are vital for maintaining access to high-quality health care services in rural communities. CAHs represent a quarter of all U.S. and more than two-thirds of all rural community hospitals. Access to care in vulnerable communities.

Compliance Observations from the field

- Registration inaccuracies
- Emphasis on Policies and Procedures
- Prevention of Duplicate Discounts
- Patient definition
- Healthcare Providers and eligibility based on policies
  - Correctional/Contracted/NP/PA’s
  - Referral
- Program terminations due to failure to recertify (small and rural CE)
- Tracking and tracing accumulations and repurchase methodology
Overhaul of 340B program could happen this spring, key Republican says

Hospitals and PhRMA face off over drug prices and 340B program

Deeper Than the Headlines: Lookout for Compliance Issues with the 340B Drug Pricing Program

Hospitals defend 340B drug program amid scrutiny

2019 MEDICARE CUTS TO 340B HOSPITALS VIOLATE LAW, JUDGE RULES

A federal judge has ruled that Medicare payment cuts imposed this year on many hospitals participating in the 340B program are in violation of federal law. The court is requiring administration officials to determine a remedy for hospitals affected by the cuts, as well as for hospitals affected by 2018 pay reductions that the court had ruled against in December.

Judge Rudolph Contreras, with the U.S. District Court for the District of Columbia, yesterday granted a permanent injunction against the Part B pay reductions of nearly 30 percent that Medicare imposed on many 340B hospitals at the beginning of 2019. The judge in December 2018 had ruled that similar cuts imposed for 2018 were in violation of federal law, but he had not yet weighed in on the 2019 reductions because a hospital plaintiff first needed to file a Part B claim under the reduced rates for the new year.

In issuing the newest injunction, the court is sending the issue back to the Dept. of Health and Human Services (HHS) for the department to come up with a proper remedy for both the 2018 and 2019 cuts. Contreras is directing HHS to give a status report by Aug. 5 on its progress toward implementing that remedy.

340B Health President and CEO Maureen Testoni issued a statement applauding the ruling. “The cuts made in 2018 and again in 2019 have reduced hospitals’ ability to care for those in need,” Testoni said. “The sooner this policy is reversed, the better hospitals will be able to serve the needs of patients with low incomes and those in rural communities. HHS must act quickly, as any further delay will only harm patients and the hospitals they rely on for care.”
340B Health President and CEO Maureen Testoni issued a statement applauding the ruling. “The cuts made in 2018 and again in 2019 have reduced hospitals’ ability to care for those in need,” Testoni said. “The sooner this policy is reversed, the better hospitals will be able to serve the needs of patients with low incomes and those in rural communities. HHS must act quickly, as any further delay will only harm patients and the hospitals they rely on for care.”

The court’s order states that HHS “patently violated the Medicare Act’s text” when it used the administrative process to impose the pay cuts. However, the judge also noted that striking down the rules entirely would be “highly disruptive” because the cuts to 340B hospitals were redistributed among all hospitals under Part B. Thus, repaying affected 340B hospitals under budget-neutrality requirements would involve recouping payments already made to other hospitals, a process the judge described as “an expensive and time-consuming prospect.”

In deciding against vacating the 2018 and 2019 rules immediately, Contreras declined to grant the injunctive relief requested by the American Hospital Association, Association of American Medical Colleges, America’s Essential Hospitals, and three hospital plaintiffs, whose lawsuit against HHS resulted in the injunctions. These plaintiffs had argued that Medicare could fully reimburse affected hospitals using supplemental payments without being required to use a budget-neutral process. The judge said he instead was following the HHS recommendation to give the department “the first crack” at coming up with a workable solution, but he noted that the court “may reconsider the remedy if the agency fails to fulfill its responsibilities in a prompt manner.”

Ensure compliance through keeping price accuracy
Communicate with 340B leadership for changes to cost report or locations

CEILING PRICE DATABASE WILL PROVIDE ADDITIONAL INFORMATION
Starting on July 1, 340B covered entities will be able to access important new information about drug prices through the federal ceiling price website.

The Health Resources & Services Administration (HRSA) announced the changes to the pricing component of the 340B Office of Pharmacy Affairs Information System (OPAIS) in a May program update. The new data coming in July will include the raw ceiling price, package size, case pack size, and package adjusted price.

Since HRSA launched the ceiling price website on April 1, the agency has published a unit ceiling price rounded to two decimal places. Publishing the raw ceiling price will provide hospitals with the average manufacturer price minus the unit rebate amount before it is rounded to two decimal places.

Starting in July, hospitals also will be able to view a drug’s package adjusted price. That price is equal to the raw ceiling price times the package size and case package size. The additional information will allow covered entities to understand the price that is paid in the market.

HRSA said an exception to the package adjusted price will be made when the ceiling price is less than $0.01. In those cases, the 340B ceiling price will be rounded to two decimal places (i.e., one penny) before being multiplied by the package size and case pack size to determine the package adjusted price.

Safety-Net Hospitals Can Now Check 340B Drug Ceiling Prices Online
HRSA launched a website that will allow safety-net hospitals to view 340B drug ceiling prices online.
New Pricing Tool released April 2019

As Urged by AHA, HRSA Launches Website for Checking 340B Maximum Prices

As Urged by AHA, HRSA Launches Website for Checking 340B Maximum Prices

Related Stories:
HHS Website Now Lists Ceiling Prices for 340B Drugs
GAO Conducting Interviews on prevention of Duplicate Discount

1. Please provide a brief overview of your entity, including how long you have been participating in the Medicaid program, the number of enrollees in your entity, whether and how you participate in a multiple state pharmacy program to distribute 340B drugs, and if so, the number of contract pharmacies it uses and the number of Medicaid managed care plans it participates with.

2. Please describe your state’s policy as it relates to:
   i. Drugs dispensed by your in-house pharmacy
   ii. Drugs dispensed by contract pharmacies
   iii. Provider-administered drugs

3. If your state allows or requires name-in for Medicaid managed care, has the state or your entity’s managed care plans provided you with instructions on how you are to identify 340B drugs provided to Medicaid managed care patients so they can exclude them from rebates? If so, what are those instructions, and how, if at all, do they differ among the dispensing methods?

4. Does the state have a covered entity that is responsible for making the same decision regarding the use of 340B drugs in your state’s Medicaid program?

5. Does your state have a covered entity that is responsible for making the same decision regarding the use of 340B drugs in your state’s Medicaid program?

6. Does your entity have a policy related to covering or carve-out of 340B drugs for Medicaid managed care plans that is different from commercial insurance policies?

7. Does your entity have a policy related to covering or carve-out of 340B drugs for Medicaid managed care plans that is different from commercial insurance policies?

8. Does your entity cover or carve-out of 340B drugs for Medicaid fee-for-service patients?
GAO Interviews underway on Duplicate Discount

Effective immediately, Covered Entity pharmacies (excludes physician-administered drugs and contracting pharmacies) that are listed on the Health Resources and Services Administration (HRSA) Medicaid Exclusion File (MEF) and fill Medicaid managed care organization (MCO) member prescriptions with drugs purchased at the prices authorized under Section 1340B of the Public Health Service Act are no longer required to use a claim modifier to identify 340B claims and are no longer required to summate actual acquisition cost.

Covered Entity pharmacy MCO claims will be reimbursed as a standard retail pharmacy claim, using the NADAC lesser of methodology.

MCO Pharmacy Bulletin 17244 has been rescinded on the Bulletin page of the Kansas Medical Assistance Program (KMAP) website.

The current policy for fee-for-service 340B claims is not changed by this MCO 340B policy. Reference the Pharmacy Fee-for-Service Provider Manual on the Provider Manuals page of the KMAP website.
Kansas Medicaid Carve In Percentages

Select State/Territory from the drop down

State/Territory: Kansas

Medicaid Carve In Percentages for Q2, 2019

<table>
<thead>
<tr>
<th>Kansas</th>
<th>% Carve-IN</th>
<th>Number of 340B CEs</th>
<th>Change from Prior Quarter</th>
<th>% Carve-IN</th>
<th>Number of 340B CEs</th>
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<td>12</td>
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<tr>
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<td>13</td>
<td>-6%</td>
<td>19%</td>
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<td>SCH</td>
<td>50%</td>
<td>3</td>
<td>0%</td>
<td>50%</td>
<td>3</td>
</tr>
</tbody>
</table>

Kansas Medicaid State Details
(as of 27-MAY-17)

Retail
Drug Ingredient Cost 340B AOC Invoice
Required Claim Identifiers Unable to locate information

Provider or Facility Administered Drugs
Drug Ingredient Cost ASP + 6%
Required Claim Identifiers Unable to locate information

Can Contract Pharmacies Dispense 340B Drugs
No - explicitly prohibited by state

Comments/Notes
The Medicaid State Details Table Shows:

Retail Prescriptions
- Drug Ingredient Cost – cost to submit to Medicaid for reimbursement
- Required Claim Identifiers – any identifiers required by the state to accompany the claim
- Professional Dispensing Fee (PDF) – amount Medicaid will pay for dispensing service
- Professional Dispensing Fee (Max Range) – if the PDF varies, this is the max amount

Provider or Facility Administered Drugs
- Drug Ingredient Cost – cost to submit to Medicaid for reimbursement
- Required Claim Identifiers – any identifiers required by the state to accompany the claim

Can Contract Pharmacies Dispense 340B Drugs
- Does the state permit dispensing 340B drugs through contract pharmacies. NOTE: Entities who want to dispense 340B drugs through contract pharmacies must have established an arrangement among the covered entity, the contract pharmacy, and the state Medicaid agency to prevent duplicate discounts, and reported this arrangement to HRSA
Registration

4 registration periods annually
New 340B OPAIS went live on September 18, 2017
Authorizing Official and Primary Contact must be different individuals and neither can be consultant
Both are required to create logins
2 step authentication
Only Authorizing Official can attest to changes, registrations, terminations and recertification
Government Official
340B OPAIS will house the statutorily mandated secure website to make 340B ceiling pricings available to providers

Recertification

340B covered entities must annually recertify their 340B eligibility
Notifications are sent to Primary Contact and Authorizing Official
Once recertification period begins the Authorizing Official only has access via their user accounts to attest their covered entity’s compliance with 340B requirements and complete recertification
Contacts listed in the 340B database must be accurate at all times to receive all notifications
Diversion

Drugs can only be used on an outpatient basis for covered entity’s patients as defined by HRSA
Use for other individuals constitutes prohibited diversion
Focus on defining “patient” & “covered entity”

What is “covered entity”?

Where services are provided
Physicians must be employed or under a contractual or other arrangement
Entity should maintain a listing of approved 340B physicians

Medicaid Duplicate Discounts

340B laws prohibit application of both 340B price discount on front end and payment of pharmacy rebate to state Medicaid on back end for same drug claim

General options for covered entities
   Carve-out Medicaid - from 340B drug purchases
   Carve-in Medicaid - requires verifying Medicaid exclusion file is accurate in 340B OPAIS

Some states have been slow to establish and communicate Medicaid billing requirements and potential modifiers
Transition to Medicaid managed care has created confusion
Covered entities should have mechanisms in place to identify Medicaid MCO patients
Contract pharmacies should not “Carve-in” Medicaid FFS or MCO
Contract Pharmacy

HRSA allows providers to enter into arrangements with multiple contract pharmacies to dispense 340B drugs to qualifying patients of providers
Covered entity is responsible for compliance and must monitor contract pharmacies
HRSA recommends independent audits
Child sites, outpatient clinics
Retail pharmacy split-billing software
Brand vs. generic
Do you periodically review your contract pharmacy arrangements?

GPO Exclusion

The GPO Prohibition pertains to DSH, Pediatric Hospitals and Free-Standing Cancer Hospitals
Drug Purchases through GPO contracts cannot be used for outpatients covered by 340B
If covered entity is unable to track 340B and GPO use, required to purchase on WAC account
All outpatient drugs not purchased on 340B account must be purchased on WAC account
Orphan Drugs/Voluntary Pricing

These covered entity types must purchase all orphan drugs at non-340B pricing
- Critical Access Hospitals
- Sole Community Hospitals
- Rural Referral Centers
- Free-Standing Cancer Hospitals

Manufacturers are not required to provide these covered entities orphan drugs under the 340B Program. A manufacturer may, at its sole discretion, offer discounts on orphan drugs to these hospitals.

October 14, 2015 – U.S. District Court for District of Columbia ruled on Orphan Drug Interpretation

HRSA lacks the authority to allow 340B pricing for orphan drugs used for common indications
HRSA Audits

HRSA believes that covered entities that do not regularly review and audit contract pharmacy operations are at increased risk for compliance issues.

Annual audit of each location will provide covered entities with a regular opportunity to review and reconcile 340B patient eligibility information, prevent diversion, and ensure the contract pharmacy’s dispensing records are accurate.

Covered entity should compare 340B prescribing records with contract pharmacy’s dispensing records at least on a quarterly basis to prevent diversion and duplicate discounts.

Conducting these audits using an independent auditor will test if the pharmacy is following all 340B program requirements and provide the covered entity with the ability to timely report any violations if applicable.

2017 Audit Results

HRSA has conducted approximately 200 audits annually since 2015

146 publically available for 2017

Audits initially had a collaborative/educational tone but the tone has changed when HRSA began instituting punitive penalties to ensure compliance

HRSA’s budget will remain the same for FY 2018

340B program has grown to 22 FTEs in 2017 from 4 FTEs in 2014

HRSA will continue to focus on contract pharmacy arrangements, diversion, duplicate discounts and 340B database records.
Audit Finding Overview

- More than 1,000 audit results posted since 2012: 78% are of hospitals
- Majority of findings involve diversion
- Results for hospitals posted on HRSA website: 61% require repayment
- Another 200 expected in 2019

HRSA Focus on DSH Hospitals

- Over half (52%) of HRSA audits have been of DSH hospitals (548 DSH audits/1052 covered entity audits)
- Two thirds of HRSA hospital audits have been of DSH hospitals (548 DSH audits/824 hospital audits), even though they account for less than half of enrolled hospitals
- Approximately 49% of all DSH hospitals in the 340B program have been audited (548 DSH audits/1,124 DSH hospitals enrolled in 340B as of 1/17/19)
## Hospital Audit Findings Over Time

<table>
<thead>
<tr>
<th></th>
<th>FY12</th>
<th>FY13</th>
<th>FY14</th>
<th>FY15</th>
<th>FY16</th>
<th>FY17</th>
<th>FY18*</th>
<th>FY19**</th>
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<td>21%</td>
<td>18%</td>
<td>20%</td>
<td>27%</td>
<td>34%</td>
<td>32%</td>
<td>75%</td>
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<tr>
<td>Findings</td>
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<td>79%</td>
<td>82%</td>
<td>80%</td>
<td>73%</td>
<td>66%</td>
<td>68%</td>
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<td>Total Hospital Audits</td>
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<td>79</td>
<td>158</td>
<td>155</td>
<td>160</td>
<td>155</td>
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</table>

*4 additional covered entity audits expected  
**187 additional covered entity audits expected

## Specific Hospital Audit Findings

<table>
<thead>
<tr>
<th></th>
<th>FY12</th>
<th>FY13</th>
<th>FY14</th>
<th>FY15</th>
<th>FY16</th>
<th>FY17</th>
<th>FY18*</th>
<th>FY19**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diversion</td>
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<td>58%</td>
<td>61%</td>
<td>50%</td>
<td>53%</td>
<td>51%</td>
<td>39%</td>
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<tr>
<td>Duplicate Discount</td>
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<td>21%</td>
<td>23%</td>
<td>23%</td>
<td>22%</td>
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<td>28%</td>
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<td>8%</td>
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<tr>
<td>Inaccurate Database</td>
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<td>4%</td>
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</table>

*4 additional covered entity audits expected  
**187 additional covered entity audits expected
## Manufacturer Audits

### Manufacturer Audit Guidelines

| May only conduct after showing of “reasonable cause” | Manufacturer inquiries to covered entity may help support “reasonable cause” | Important for covered entities to respond to manufacturer inquiries, failure to respond could result in audit | Details are not publicly available |

## Consequences of non-compliance

- **Repayment of discount to manufacturer**
- **Removal from 340B Program**
- **Possible Civil Monetary Penalties for knowing & intentional violations**
- **Potentially false claim liability (ripe for qui tam actions?)**
Develop a crosswalk from MCR to EMR and HRSA registration

Understanding the Medicare Cost Report

**Purpose:** This tool is intended to help hospitals understand the key areas of the Medicare Cost Report that HRSA reviews when determining 340B eligibility.

**Background:** HRSA uses a hospital's Medicare Cost Report (MCR) when validating eligibility information for hospitals, both during registration and also during audits. This tool helps identify areas of the MCR that are important for determining:
- Eligibility type and status
- CE information (address, provider number, etc)
- Eligibility of child sites and service lines

**Medicare Cost Report Worksheets**

<table>
<thead>
<tr>
<th>Worksheet</th>
<th>Information used by HRSA</th>
<th>Conveys Parent Site Information</th>
<th>Conveys Child Site Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>Important information about cost report filing (dates, provider number, signature)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>S-2</td>
<td>Parent address; control type</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>E, Part A</td>
<td>DISH %</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>A</td>
<td>Net expenses for eligible service/clinics</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>C</td>
<td>Outpatient charges for eligible service/clinics</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

The hospital's reporting period should correspond to the filing date below. Reporting dates and filing dates should be the same on all worksheets.

CAH and PED hospitals are identified based on the third and forth digit of the CON (13 and 33 respectively).

Only sites billing using this provider number are eligible under this parent hospital.

Needs to be signed and dated (electronic time stamp).
| CONCEPT/DESCRIPTION | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # | ITEM # |
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|                     |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |

Clinics/reasons must be reimbursable on the most recently filed cost report to be considered 340B eligible. Any with a separate physical address must also be separately registered on DPAIS.

We will also verify that the line has a net response in order to be eligible.

Typically, lines 50 - 118 are potentially reimbursable.

Remunerable clinics must show outpatient charges in columns 7.
Organized 340B - Advantages to System Thinking

- Understanding your 340B Program’s Profitability,
- Providing meaningful program financial and community benefit through dashboards for C-Suite as a organization
- Compliance solution for the organization
- Peer to Peer Quarterly experiences / Education
- Consider the power of total spend for KHA as it relates to negotiation for greater expansion of voluntary pricing
- Create system Patient Assistance Programs to include retail and hospital participation
- Expand clinical pharmacy services to improve medication management for all patients through In-house Rx Solutions
- Contract pharmacy relationships between hospitals to provide infusions services that decreases patient travel inconvenience
- Implement Meds to Bed Program (discharge Rx)
- Improve prescription identification and capture
- Employee/dependent benefit when self insured
- Losses in Slow movers / Winners only models / Pending claims / Near misses
- Integrated Pharmacy Solutions
- Strategic focus on Specialty products
Maintenance of Auditable Records

Section 340B(a)(5)(C) of the PHS Act requires a covered entity to permit the Secretary and certain manufacturers to audit covered entity records that pertain to the entity’s compliance with 340B Program requirements. Documentation of compliance would include records of contract pharmacies used by covered entities to dispense 340B drugs. Failure to maintain the records necessary to permit such auditing is failure to meet the requirements of section 340B(a)(5) of the PHS Act. A covered entity’s failure to maintain auditable records is grounds for losing eligibility to participate in the 340B Program.

Covered Entities should be aware of self-protection by maintaining auditable records for a period of 5 years per federal regulations. Covered Entities should insist on custody of all records and archive as appropriate when converting split billing or Third Party Administrators. Standard applies to records pertaining to all child sites and contract pharmacies in the case of termination. Manufacturers may investigate records back to CE date of eligibility.

Documentation of auditable records

- Covered Entities should be aware of self-protection by maintaining auditable records for a period of 5 year retention per federal regulations.
- Covered Entities should insist on custody of all records and archive as appropriate when converting split billing or Third Party Administrators.
- Standard applies to records pertaining to all child sites and contract pharmacies in the case of termination.
- Manufacturers may investigate records back to CE date of eligibility.
Covered Entities should create a crosswalk from their MCR to EMR to HRSA registration