



Kansas Hospital Association  
340B Compliance Workshop

June 18, 2019

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*Speaker has nothing to disclose*

Harry C. Norsworthy Jr Rph  
Associate Principle  
340B Services

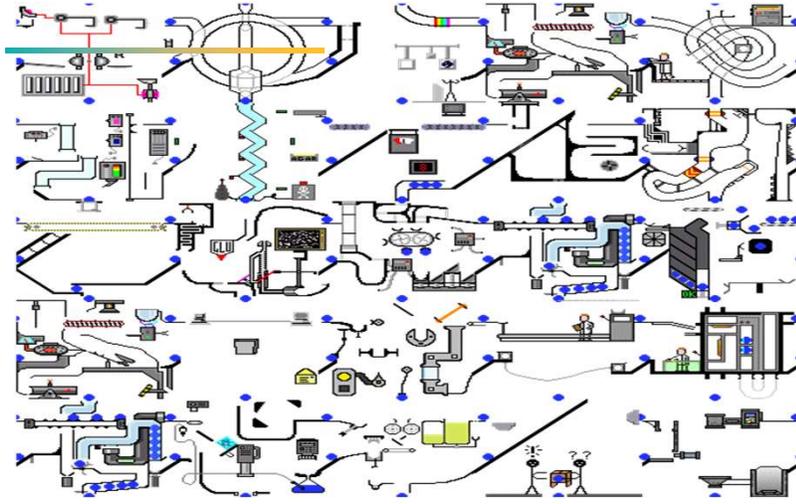
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340B: It's not just one thing, it's a thousand little things



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Rural Hospitals at a  
**CROSSROADS**

## 340B Drug Pricing Program

### 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.

#### Small Program, Big Benefits

- 2.8%** Portion of the United States' \$457 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 reinvest in patient care and health activities to benefit the communities they serve. It also saves money for state and federal governments.
- 1,084 PROVIDERS, INCLUDING 48 HOSPITALS IN PENNSYLVANIA PARTICIPATE IN THE 340B DRUG PRICING PROGRAM**  
340B increases access to care for our most vulnerable populations; participating hospitals provided \$324.8 million in uncompensated care in fiscal year 2016.

#### Who are 340B Hospitals?

- About **half** are urban; half are rural
- 80%** of PA critical access hospitals (CAH) participate in 340B (12 out of 15)
- 45%** of Pennsylvania hospitals (in 30 counties) participate in 340B

#### 340B Hospitals Meet Rigorous Requirements

**340B Eligibility**  
Hospitals must:

- Be designated as a not-for-profit hospital.
- Be classified as a Children's Hospital, Cancer Hospital, Sole Community Hospital, Rural Referral Center, Critical Access Hospital or a Medicare Disproportionate Share Hospital.
- Serve a large proportion of uninsured and low-income patients.
- Undergo random audits by the federal government and pharmaceutical manufacturers.
- Recertify annually as an eligible 340B provider.
- Maintain auditable inventories for 340B and non-340B prescription drugs.

**HAP**  
The Hospital + Healthsystem Association of Pennsylvania  
*Leading for Better Health*  
www.haponline.org

**PRESERVE THE 340B PROGRAM: PROTECT PENNSYLVANIA'S SAFETY NET**  
Sources: Health Resources and Services Administration, IMS Health, American Hospital Association, Apexus, 340BHealth, Pennsylvania Health Care Cost Containment Council, HAP

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**\$\$Expansion → Increased oversight/compliance**

### The 340B Program Continues to Expand

340B Hospital Participation	340B Sales Volume	For-Profit Retail Pharmacy Participation
1992: 51	2004: \$2.65B	2002: 279
2002: 151	2016: \$16.1B	2010: 6,293
2017: 2,357		2017: 51,963

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

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## 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

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## 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

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HEARING: #SubOversight to Continue Review of 340B Drug Pricing Program

10.04.17

**Overhaul of 340B program could happen this spring, key Republican says**

By ERIN MERSHON *Guest Contributor* / JANUARY 11, 2016

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

By DAVID PITTMAN | 11/09/2017 08:30 AM EST

**Heated And Deep-Pocketed Battle Erupts Over 340B Drug Discount Program**

NOV 01, 2017 | MORE ON REIMBURSEMENT

**UPDATED: Hospital groups to sue CMS over \$1.6 billion cut to 340B payments**

The final rule will also allow for higher payment when Medicare beneficiaries receive certain procedures in outpatient departments.

Susan Morse, Senior Editor



Testimony Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

**DRUG DISCOUNT PROGRAM**

Update on Agency Efforts to Improve 340B Program Oversight

Statement of Debra A. Draper, Director, Health Care

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

Posted by CJ Wolf  
Aug 7, 2017 1:39:25 PM

**Hospitals defend 340B drug program amid scrutiny**



**FEDERAL REGISTER**  
The Daily Journal of the United States Government

340B Drug Pricing Program Omnibus Guidance



**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 latest development does not immediately affect Medicare Part B payment rates for hospitals who received reduced rates in 2018 or who are receiving reduced rates this year.

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."



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Topic

**POLICY & REGULATION NEWS**

**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 to ensure

**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 these 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.

Ensure compliance through keeping price accuracy

Communicate with 340B leadership for changes to cost report or locations

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# New Pricing Tool released April 2019

**HRSA** Office of Pharmacy Affairs  
Health Resources & Services Administration  
340B OPAIS

Welcome to 340B OPAIS

What would you like to do?

- My Entries
- Register Covered Entity
- Search
- Reports/Files
- Pricing** (circled in red)

Have questions? Contact the 340B Prime Vendor

www.340b.org | 1-888-485-2727 | 646-6767-340B-FX | AgencyAccount@HHS.gov

You are entering an official US Government computer network (NCPDS) using your user ID or password when accessing this system (especially on un-governed computers). Please note: You are entering an official United States government system, which may be used only for authorized purposes. This system may contain unpublic HRSA information when for receipt of 12 CFR 4.530b that is subject to use and disclosure restrictions specified at 41 CFR 1.01. The construction or use of computers, HRSA information or the unauthorized modification of any information stored on the system may result in criminal prosecution or administrative proceedings.

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

Apr 01 | Reach: 1,590

Share article :

**American Hospital Association - The Health Resources and Services Administration** today launched a new website that organizations participating in the 340B Drug Pricing Program can use to determine the maximum prices drug companies can charge them for medications sold under the program. [Read More](#)

### Related Stories:

[HHS Website Now Lists Ceiling Prices for 340B Drugs](#)

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**HRSA** Office of Pharmacy Affairs  
Health Resources & Services Administration  
340B OPAIS

National Drug Code	Product Name	Manufacturer Name	Market Date	Ceiling Price	Flag
00002751001	HERMALOG 100 UNITSML VIAL	ELI LILLY AND COMPANY	07/19/1996	\$0.01	
00002751017	HERMALOG 100 UNITSML VIAL	ELI LILLY AND COMPANY	07/19/1996	\$0.01	
00002751101	HERMALOG MK 75-25 VIAL	ELI LILLY AND COMPANY	12/29/1999	\$0.01	
00002751201	HERMALOG MK 60-50 VIAL	ELI LILLY AND COMPANY	11/13/2006	\$0.01	
00002751011	HERMALOG 100 UNITSML CARTRIDGE	ELI LILLY AND COMPANY	06/02/2000	\$0.01	
00002751059	HERMALOG 100 UNITSML CARTRIDGE	ELI LILLY AND COMPANY	06/02/2000	\$0.01	
00002771201	HERMALOG 200 UNITSML KWKPEN	ELI LILLY AND COMPANY	07/17/2015	\$11.72	
00002771227	HERMALOG 200 UNITSML KWKPEN	ELI LILLY AND COMPANY	07/17/2015	\$11.72	
00002771401	HERMALOG JR 100 UNITSML KWKPEN	ELI LILLY AND COMPANY	07/19/1996	\$0.01	
00002771409	HERMALOG JR 100 UNITSML KWKPEN	ELI LILLY AND COMPANY	07/19/1996	\$0.01	

**HRSA** Office of Pharmacy Affairs  
Health Resources & Services Administration  
340B OPAIS

Manufacturer Contact Information

Manufacturer Name: ELI LILLY AND COMPANY  
Contact Name: LISA HARRIS  
City, State Zip Code: INDIANAPOLIS, IN 46205

Product Information

NDC: 00002751001  
Market Date: 7/19/1996 12:00:00 AM  
Brand Name: HERMALOG 100 UNITSML VIAL  
Termination Date:  
Drug Category: Single Source  
FDB Line Type: Mandatory (Required)  
Drug Type: Prescription (RX)  
CMS Line Type: Manual

Ceiling Price Chart

2015-2

National Drug Code	Effective Year	Effective Quarter	Ceiling Price	Flag
00002751001	2015	2	\$0.01	

(\*) The 340B ceiling price for this product was calculated by HRSA using data submitted by the manufacturer.  
(\*\*) The 340B ceiling price for this product was calculated using data submitted by the manufacturer.  
(\*\*\*) The 340B Ceiling Price was updated by HRSA after review/adjustment of all available data.

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# GAO Conducting Interviews on prevention of Duplicate Discount

**GAO** U.S. GOVERNMENT ACCOUNTABILITY OFFICE  
 441 G St. N.W.  
 Washington, DC 20548

Interview Questions for Pinnacle Health Hospitals (Pennsylvania RRC390067-00)

**Background**

1. Please provide a brief overview of your entity, including how long you have been participating in the 340B program, the number of child sites your entity has, whether and how many in-house pharmacies your entity has; whether your entity uses contract pharmacies 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.

**State policy on use of 340B for Medicaid patients**

Note: This section of questions asks about the Pennsylvania Medicaid Program's policy related to 340B drugs. Not about the practices of your covered entity.

2. Please describe your state's policy with regard to whether covered entities can or must use 340B drugs for Medicaid fee-for-service patients (i.e. carve-in 340B drugs for Medicaid fee-for-service).
  - a. Please describe the 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
  - b. If your state allows or requires carve-in for Medicaid fee-for-service, has the state provided your entity with instructions on how you are to identify 340B drugs provided to Medicaid fee-for-service 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?
3. Please describe your state's policy with regard to whether covered entities can or must use 340B drugs for Medicaid managed care patients (i.e. carve-in 340B drugs for Medicaid managed care).
  - a. Please describe the 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
  - b. To what extent, if at all, does this policy vary by Medicaid managed care plan?

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**GAO** U.S. GOVERNMENT ACCOUNTABILITY OFFICE  
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 Washington, DC 20548

- c. If your state allows or requires carve-in for Medicaid managed care, has the state and/or managed care plans provided your entity 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?
    - d. Do the Medicaid managed care plans in your state have unique BIN/PCN/Group combinations to distinguish Medicaid enrollees from commercial enrollees?
  4. Does the state require a covered entity to make the same decision regarding the use of 340B drugs (i.e. carving-in or carving-out) for Medicaid managed care patients and Medicaid fee-for-service patients?
  5. How does your entity learn about your state(s) policy(ies) related to 340B, and changes made to it? For example, are they posted on the state's website, sent out as policy notifications or alerts, etc.?
    - a. What about managed care plans' 340B related-policies?

**Covered entity policy on use of 340B for Medicaid patients**

6. Does your entity carve-in or carve-out 340B drugs for Medicaid fee-for-service patients?
  - a. In your response, please discuss your policy for:
    - i. Drugs dispensed by your in-house pharmacy
    - ii. Drugs dispensed by contract pharmacies
    - iii. Provider-administered drugs
  - b. How, if at all, does your entity's decision regarding carving-in or carving-out Medicaid fee-for-service differ by child site? That is, do all of your child sites follow the same practice or do different child sites have different practices?
7. Does your entity carve-in or carve-out 340B drugs for Medicaid managed care patients?
  - a. In your response, please discuss your policy for:
    - i. Drugs dispensed by covered entities' in-house pharmacy
    - ii. Drugs dispensed by contract pharmacies
    - iii. Provider-administered drugs
  - b. Is your entity's policy related to carving-in or carving-out the same for all Medicaid managed care plans with which you participate?

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GAO Interviews underway on Duplicate Discount



441 G St. N.W.  
Washington, DC 20548

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**Background**

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**State policy on use of 340B for Medicaid patients**

*Note: This section of questions asks about the Pennsylvania Medicaid Program's policy related to 340B drugs. Not about the practices of your covered entity.*

2. Please describe your state's policy with regard to whether covered entities can or must use 340B drugs for Medicaid fee-for-service patients (i.e. carve-in 340B drugs for Medicaid fee-for-service).

**Per PA Policy, covered entities have the option to either carve-in or carve-out 340B drugs.**

a. Please describe the 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

The PA Department of Public Welfare issued a Medical Assistance bulletin in May 2013, specifying the following three (3) requirements for 340B covered entities that bill for and dispense drugs to MA FFS and MA MCO recipients. The bulletin does not distinguish amongst the different service areas where 340B drugs may be dispensed. The guidance provided by the state are as follows:

- 1) Report to HRSA if they are billing MA for drugs purchased under the 340B program (carve in/carve out status)
- 2) Be listed on the HRSA Medicaid Exclusion File (MEF) if they are billing MA for 340B drugs
- 3) Ensure information on the HRSA MEF is accurate, complete, and verifiable

b. If your state allows or requires carve-in for Medicaid fee-for-service, has the state provided your entity with instructions on how you are to identify 340B drugs provided to Medicaid fee-for-service patients so they can exclude them from rebates? If so,



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what are those instructions, and how, if at all, do they differ among the dispensing methods?

"When submitting a claim for a 340B-purchased drug dispensed by a covered entity to a MA recipient in the FFS program, the covered entity must enter the lowest net charge a non-Medicaid 340B-eligible patient would pay for the prescription in the Usual and Customary Charge field. For example:

- The charge to a non-Medicaid 340B-eligible patient for a 30 day supply of Drug A, purchased under the 340B program is \$4.00.
- The entry in the Usual and Customary Charge field on a claim for the same prescription (a 30 day supply of Drug A, purchased under the 340B program) for a MA recipient would be \$4.00."

3. Please describe your state's policy with regard to whether covered entities can or must use 340B drugs for Medicaid managed care patients (i.e. carve-in 340B drugs for Medicaid managed care).

**Same response as Question #2 (PA guidance applies to both MA FFS and MA-MCO).**

a. Please describe the 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

b. To what extent, if at all, does this policy vary by Medicaid managed care plan?

There is no difference based on MA-MCO plan

c. If your state allows or requires carve-in for Medicaid managed care, has the state and/or managed care plans provided your entity 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?

Yes (see above re: use of the MEF)

d. Do the Medicaid managed care plans in your state have unique BIN/PCN/Group combinations to distinguish Medicaid enrollees from commercial enrollees?

No -- not all MCO MA plans utilize unique BIN/PCN/Group codes. Some plans utilize codes that cannot be distinguished between a MCO MA plan and an MCO commercial plan.

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JANUARY 2018

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**MCO PHARMACY BULLETIN 18013**

**MCO 340B Policy Update**

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 340B of the Public Health Services Act are **no longer required to use a claim modifier to identify 340B claims and are no longer required to submit 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 [Bulletins](#) 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.

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## Kansas Medicaid Carve In Percentages

Select State/Territory from the drop down

State/Territory Kansas ▼

### Medicaid Carve In Percentages for Q2, 2019

Kansas	Current Quarter			Prior Quarter	
	% Carve-IN	Number of 340B CEs	Change from Prior Quarter	% Carve-IN	Number of 340B CEs
<b>All Types</b>	48%	118	1%	48%	117
<b>All Grantees</b>	59%	98	1%	59%	97
<b>All Hospitals</b>	26%	20	0%	25%	20
CAH	19%	13	8%	18%	12
DSH	67%	2	-33%	75%	3
PED	100%	1	0%	100%	1
RRC	100%	1	0%	100%	1
SCH	50%	3	0%	50%	3



### Kansas Medicaid State Details

(as of 27-MAY-17)

#### Retail

**Drug Ingredient Cost**  
340B AAC Invoice

**Professional Dispensing Fee**  
10.5

**Required Claim Identifiers**  
Unable to locate information

**Professional Dispensing Fee (Max Range)**

#### 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

**Kansas Medicaid Contacts**

Technical Contact	Rebate Contact	Policy Contact
CINDY HEMMINGER <a href="mailto:KSDRUGREBATE@DXC.COM">KSDRUGREBATE@DXC.COM</a> PO BOX 19287, 6511 SE FORBES AVE, BLDG 283 TOPEKA, KS 66619 (785) 379 2116	CINDY HEMMINGER <a href="mailto:KSDRUGREBATE@DXC.COM">KSDRUGREBATE@DXC.COM</a> PO BOX 19287, 6511 SE FORBES AVE, BLDG 283 TOPEKA, KS 66619 (800) 937 6231	ANNETTE M. GRANT <a href="mailto:ANNETTE.GRANT@KS.GOV">ANNETTE.GRANT@KS.GOV</a> 6511 SW FORBES AVE, BLDG 283, P.O. BOX 19287 TOPEKA, KS 666190287 (785) 296 8406

**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

**Compliance**

The diagram consists of seven overlapping circles arranged in two rows. The top row contains four circles: Eligibility, Diversion, Contract Pharmacy, and Orphan Drugs. The bottom row contains three circles: Registration, Duplicate Discounts, and Group Purchasing Organization. The circles overlap significantly, with some overlapping three or four circles.

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## 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**

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## 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**

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## Diversion

### 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

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## 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**

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## 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?

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## 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**

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## Wholesaler Account Setup

### -DSH/PED/CAN with GPO Prohibition

Inpatient	Outpatient (not 340B eligible)	Outpatient (340B eligible)
GPO	Non-GPO/WAC	340B
<ul style="list-style-type: none"> <li>GPO Contract</li> <li>DSH Inpatient GPO Contracts (DSH only)</li> <li>GPO or Wholesaler Generic Source Program</li> <li>Individual Hospital Agreement</li> </ul> <p style="text-align: center; color: #1a3d54; font-weight: bold; margin-top: 20px;">Account #1</p>	<ul style="list-style-type: none"> <li>WAC Pricing</li> <li>PVP Sub-WAC (if enrolled in PVP)</li> <li>Apexus Generic Portfolio (AGP) (if enrolled in PVP)</li> <li>Individual Hospital Agreement (single entity only)</li> </ul> <p style="text-align: center; color: #1a3d54; font-weight: bold; margin-top: 20px;">Account #3</p>	<ul style="list-style-type: none"> <li>PHS/340B</li> <li>PVP Sub-340B (if enrolled in PVP)</li> <li>Apexus Generic Portfolio (AGP) (if enrolled in PVP)</li> <li>Individual Hospital Agreement (single entity only)</li> </ul> <p style="text-align: center; color: #1a3d54; font-weight: bold; margin-top: 20px;">Account #2</p>

29 CONFIDENTIAL: DO NOT FORWARD: MNP RxNetwork Contracting Xray/CT Contrast Media | NOV 2018

## Orphan Drugs/Voluntary Pricing

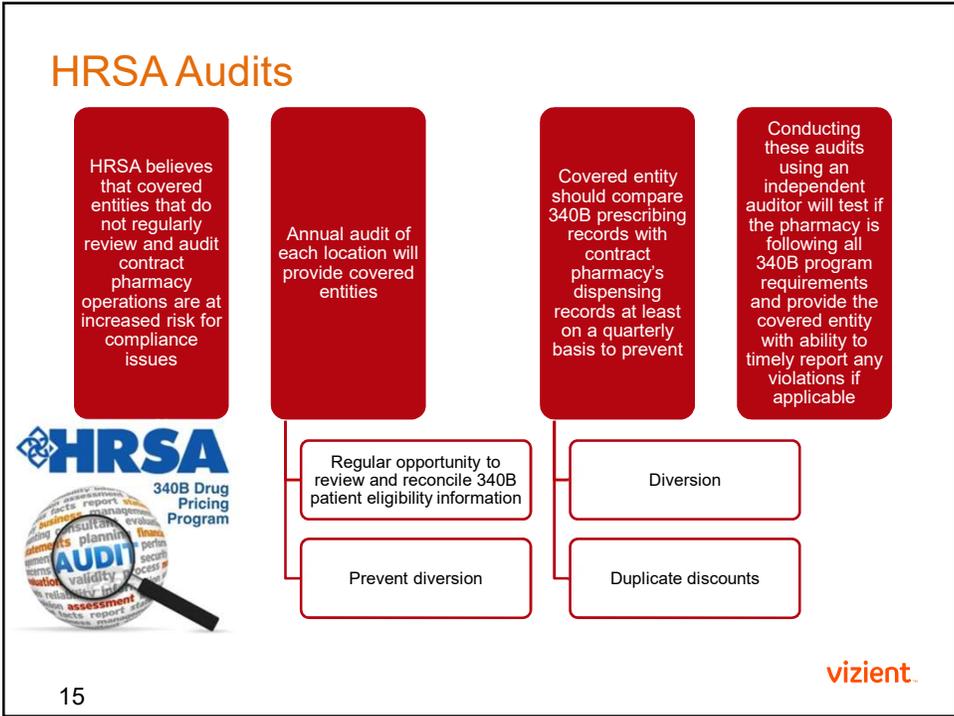
**These covered entity types must purchase all orphan drugs at non-340B pricing**

- 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**



## 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**

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## 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

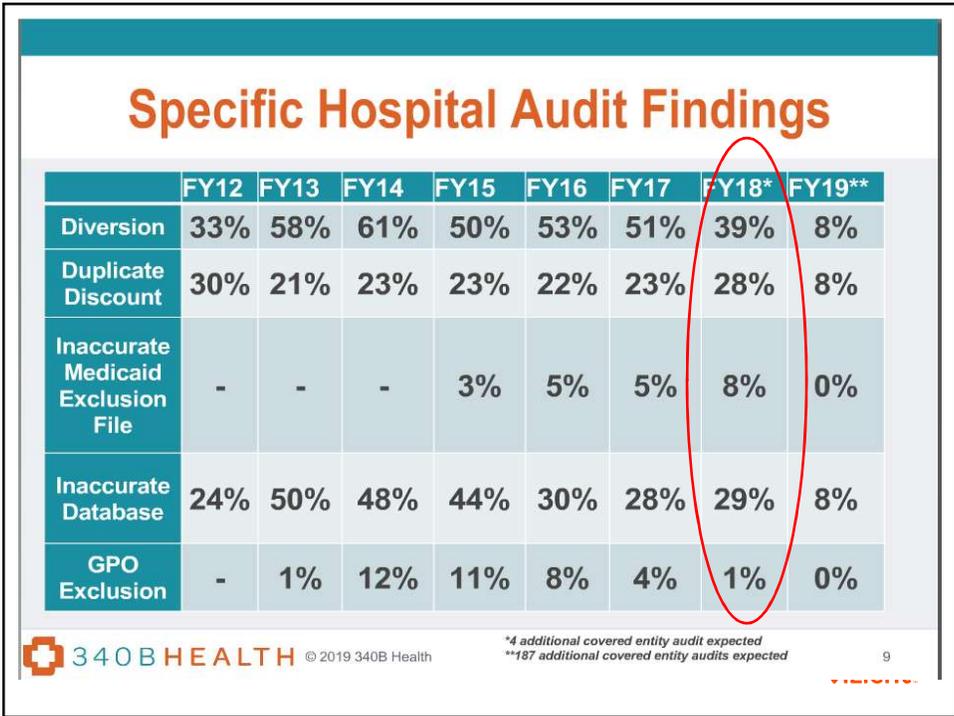
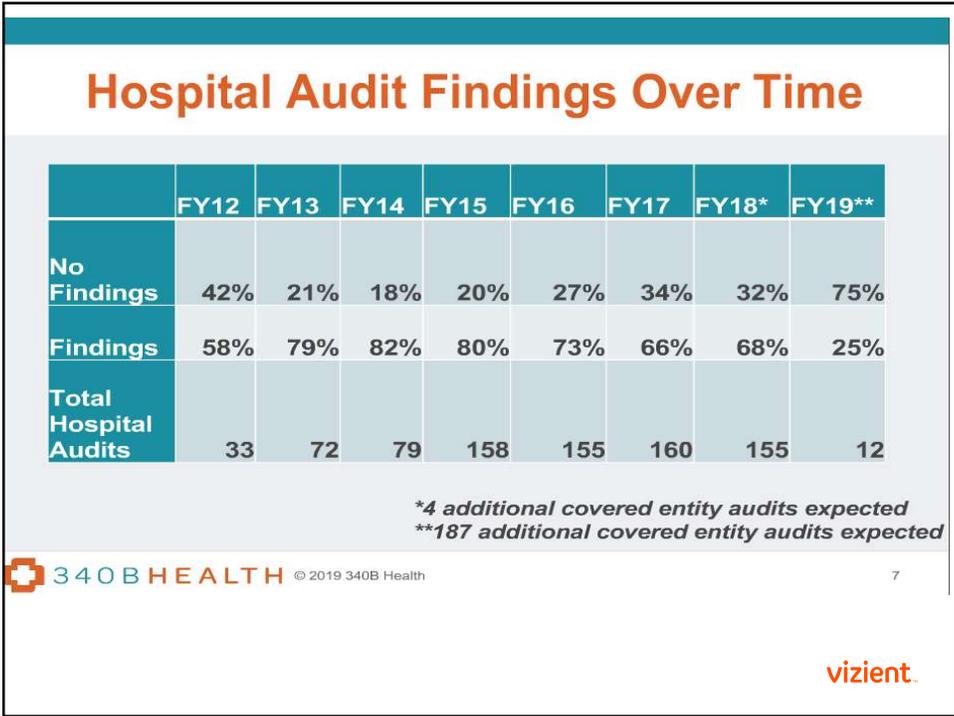
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## HRSA Focus on DSH Hospitals

- 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)



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## Manufacturer Audits



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## Consequences of non-compliance



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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

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



03-18 FORM CMS-2552-10 4090 (Cont.)

This report is required by law (42 USC 1395g, 42 CFR 413.200(b)). Failure to report can result in all future payments made since the beginning of the cost reporting period being deemed overpayments (42 USC 1395g).

FORM APPROVED OMB NO. 0938-0050

HOSPITAL AND HOSPITAL HEALTH CARE COMPLEX COST REPORT CERTIFICATION AND SETTLEMENT SUMMARY

PROVIDER CCN: \_\_\_\_\_ PERIOD FROM: \_\_\_\_\_ TO: \_\_\_\_\_ WORKSHEET'S PARTS I, E & III

**PART I - COST REPORT STATUS**

Provider use only

1. [ ] Electronically filed cost report

2. [ ] Manually submitted cost report

3. [ ] If this is an amended report enter the number of times provider resubmitted this cost report

4. [ ] Medicare Violation. Enter "W" for full or "L" for less.

5. [ ] Cost Report Status

(1) As Submitted

(2) Settled without audit

(3) Settled with audit

(4) Reopened

(5) Amended

6. Date Received: \_\_\_\_\_

7. Contractor No.: \_\_\_\_\_

8. [ ] Limited Remission of the Provider CCN

9. NFR Date: \_\_\_\_\_

10. Contractor's Vendor Code: \_\_\_\_\_

11. [ ] If line 5, column 1, is 4: Enter number of times reported - 0-9.

12. [ ] If line 5, column 1, is 4: Enter number of times reported - 0-9.

**PART II - CERTIFICATION**

MISSREPRESENTATION OR FALSIFICATION OF ACTION, FINE AND/OR IMPRISONMENT UNDER THE PAYMENT DIRECTLY OR INDIRECTLY OF IMPRISONMENT MAY RESULT.

CERTIFICATION BY CHIEF FINANCIAL OFFICER

I HEREBY CERTIFY that I have read the above information submitted and have examined the submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by \_\_\_\_\_ and ending \_\_\_\_\_ and to the best of my knowledge and belief, the information is true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions, laws and regulations regarding the provision of health care services, and that the services identified and regulations.

I have read and agree with the above certification statement. I certify that I intend my electronic signature on this certification statement to be the legal equivalent of my original signature.

(Sign) \_\_\_\_\_  
 Chief Financial Officer or Administrator of Provider  
 Title \_\_\_\_\_  
 Date \_\_\_\_\_

**PART III - SETTLEMENT SUMMARY**

	TITLE V	TITLE XVIII		HIT	TITLE XIX
	1	PART A	PART B		5
1 HOSPITAL					1
2 SUBPROVIDER - IPF					2
3 SUBPROVIDER - IBF					3
4 SUBPROVIDER (OTHER)					4
5 SWING BED - SNF					5
6 SWING BED - NF					6



4090 (Cont.) FORM CMS-2552-10 PROVIDER CCN: FREQID FROM TO WORKSHEET #2 PART I 03-18

HOSPITAL AND HOSPITAL HEALTH CARE COMPLEX IDENTIFICATION DATA

Hospital and Hospital Health Care Complex Address:

City: State: ZIP Code: County:

Hospital (and Hospital Health Care Complex) Information:

Component	Component Name	CRSA Number	CRSA Number	Prevalence Type
1	Hospital			
2	Sub-provider - IPP			
3	Sub-provider - IPF			
4	Sub-provider - Other			
5	Swing Beds - SW			
6	Swing Beds - NP			
7	Hospital-based NP			
8	Hospital-based IPF			
9	Hospital-based IPF			
10	Hospital-based IPF			
11	Hospital-based IPF			
12	Hospital-based IPF			
13	Hospital-based IPF			
14	Hospital-based IPF			
15	Hospital-based IPF			
16	Hospital-based IPF			
17	Hospital-based IPF			
18	Hospital-based IPF			
19	Hospital-based IPF			
20	Hospital-based IPF			
21	Hospital-based IPF			
22	Hospital-based IPF			
23	Hospital-based IPF			
24	Hospital-based IPF			
25	Hospital-based IPF			
26	Hospital-based IPF			
27	Hospital-based IPF			
28	Hospital-based IPF			
29	Hospital-based IPF			
30	Hospital-based IPF			
31	Hospital-based IPF			
32	Hospital-based IPF			
33	Hospital-based IPF			
34	Hospital-based IPF			
35	Hospital-based IPF			
36	Hospital-based IPF			
37	Hospital-based IPF			
38	Hospital-based IPF			
39	Hospital-based IPF			
40	Hospital-based IPF			

Impairment Information:

21 Does this facility qualify and is it currently receiving payments for disproportionate share hospital adjustment, in accordance with 42 CFR 412.106? In column 1, enter "Y" for yes or "N" for no.

22 Is this facility subject to 42 CFR 412.106 (a) (2) (Public emergency hospitals)? In column 2, enter "Y" for yes or "N" for no.

22.01 Does this hospital receive inpatient uncompensated care payments for the cost reporting period? Enter in column 1, "Y" for yes or "N" for no for the portion of the cost reporting period occurring prior to October 1.

22.02 Enter in column 2, "Y" for yes or "N" for no for the portion of the cost reporting period occurring on or after October 1. (see instructions)

22.03 Did this hospital receive a progressive reclassification from urban to rural as a result of the DSH standards for defining statistical areas adopted by CMS in FY2017? Enter in column 1, "Y" for yes or "N" for no for the portion of the cost reporting period prior to October 1. Enter in column 2, "Y" for yes or "N" for no for the portion of the cost reporting period occurring on or after October 1. (see instructions)

22.04 Did this hospital receive a progressive reclassification from urban to rural as a result of the DSH standards for defining statistical areas adopted by CMS in FY2017? Enter in column 1, "Y" for yes or "N" for no for the portion of the cost reporting period prior to October 1. Enter in column 2, "Y" for yes or "N" for no for the portion of the cost reporting period occurring on or after October 1. (see instructions)

23 Which method is used to determine Medicaid days in lines 24 and/or 25 below? In column 1, enter 1 if rate of admissions; 2 if cost charges; or 3 if rate of discharges.

24 Is the method of identifying the data in this cost reporting period different from the method used in the prior cost reporting period? In column 2, enter "Y" for yes or "N" for no.

24 In-State Medicaid paid days in column 1, in-State Medicaid eligible unpaid days in column 2, out-of-state Medicaid paid days in column 3, out-of-state Medicaid eligible unpaid days in column 4, Medicaid IMO paid and eligible but unpaid days in column 5, and other Medicaid days in column 6.

25 If this provider is an IPPS hospital, enter the in-state Medicaid paid days in column 1, in-state Medicaid eligible unpaid days in column 2, out-of-state Medicaid paid days in column 3, out-of-state Medicaid eligible unpaid days in column 4, Medicaid IMO paid and eligible but unpaid days in column 5, and other Medicaid days in column 6.

26 Enter your standard geographic classification (see wage rates at the beginning of the cost reporting period).

27 Enter your standard geographic classification (see wage rates at the beginning of the cost reporting period).

28 If this is a high-cost specialty hospital (HSC), enter the number of persons with status in effect in the cost reporting period.

29 Enter applicable beginning and ending dates of SC 31 status. Subsequent lines for number of persons in excess of 100 are not required.

30 If this is a Medicare dependent hospital (MDH), enter the number of persons with MDH status in effect in the cost reporting period.

31 If the hospital is a Medicare dependent hospital (MDH) that is eligible for the MDH transitional payment in accordance with the 2018 OIG report, enter "Y" for yes or "N" for no. (see instructions)

32 If line 31 is "Y", enter the beginning and ending dates of MDH status. If line 31 is greater than 1, subtract this line for the number of periods in excess of one and enter subsequent dates.

33 Does this facility qualify for the enhanced hospital payment adjustment for low-volume hospitals in accordance with 42 CFR 412.101(b)(2)(ii) or (iii)? Enter in column 1, "Y" for yes or "N" for no. (see instructions)

34 Does the facility meet the mileage requirements in accordance with 42 CFR 412.101(b)(2)(ii) or (iii)? Enter in column 2, "Y" for yes or "N" for no. (see instructions)

40 Is the hospital subject to the IMAC program reduction adjustment? Enter "Y" for yes or "N" for no in column 1, for discharges prior to October 1. Enter "Y" for yes or "N" for no in column 2, for discharges on or after October 1. (see instructions)

FORM CMS-2552-10 (11-2017) (INSTRUCTIONS FOR THIS WORKSHEET ARE PUBLISHED IN CMS PUB. 13-1, SECTION 4004.1)

40-504 Rev. 14

This address will be the address of the parent entity. Any service with a different physical address will have to be individually registered as a child site on OPAIS.

This is used for initial parent entity eligibility, and shows the type of control of the hospital. See instructions for types of entities: [https://www.costreportdata.com/worksheets\\_formats.html](https://www.costreportdata.com/worksheets_formats.html)

There are a few lines that can help identify the type of hospital:  
Line 35: SCH  
Line 116: RRC

Line #33 shows the DSH Adjustment %; this is needed for the entity to be 340B eligible (exception is CAH).

Some hospital types do not file WS E, Part A, but may still need to calculate this to show eligibility. WS S-3 may be used for the data needed for this.



4090 (Cont.) FORM CMS-2552-10 PROVIDER CCN: FREQID FROM TO WORKSHEET #2 PART A 11-17

CALCULATION OF REIMBURSEMENT SETTLEMENT

PART A - INPATIENT HOSPITAL SERVICES UNDER IPPS

1.01	DRG amounts other than outlier payments for discharges occurring prior to October 1. (see instructions)	1.01
1.02	DRG amounts other than outlier payments for discharges occurring on or after October 1. (see instructions)	1.02
1.03	DRG for indirect specific operating payments for Model 4 IPPS for discharges occurring prior to October 1. (see instructions)	1.03
1.04	DRG for indirect specific operating payments for Model 4 IPPS for discharges occurring on or after October 1. (see instructions)	1.04
2	Outlier payments for discharges. (see instructions)	2
2.01	Outlier nontransition amount	2.01
2.02	Outlier payment for discharges for Model 4 IPPS. (see instructions)	2.02
3	Managed care estimated payments	3
4	Bed days payable divided by number of days in the cost reporting period. (see instructions)	4
5	Indirect Medical Education Adjustment Calculation for Hospital:	5
6	FTE count for all hospital and osteopathic programs for the most recent cost reporting period ending on or before 12/31/1996. (see instructions)	6
7	FTE count for all hospital and osteopathic programs which meet the criteria for an add-on to the cap for new programs in accordance with 42 CFR 413.79(c)	7
8	MMA 842 reduction amount to the IME cap as specified under 42 CFR 412.101(b)(2)(ii)	8
9	ACA 5501 reduction amount to the IME cap as specified under 42 CFR 412.101(b)(2)(ii)	9
10	Adjustment (increase or decrease) to the FTE count for all hospital and osteopathic programs for affiliated programs in accordance with 42 CFR 413.79(b), 413.79(c)(2)(a), 413.79(c)(2)(b), 413.79(c)(2)(c), 1099(a), and 42 CFR 5096(a) (August 1, 2003).	10
11	The amount of increase if the hospital was awarded FTE cap slots under 5501 of the ACA. If the cost report straddles July 1, 2011, see instructions.	11
12	The amount of increase if the hospital was awarded FTE cap slots from a closed waiting hospital under 5506 of the ACA. (see instructions)	12
13	Sum of lines 2, 6, 8, 9, 10, 11, and 12. Plus lines 13a and 13b. (see instructions)	13
14	FTE count for all hospital and osteopathic programs in the current year from your records	14
15	Current year allowable FTE. (see instructions)	15
16	Total allowable FTE. (see instructions)	16
17	Adjustment for resident teaching program or hospital closure	17
18	Adjusted allowable FTE count	18
19	Current year resident to bed ratio. (line 18 divided by line 4)	19
20	Post year resident to bed ratio. (see instructions)	20
21	Enter the lower of lines 19 or 20. (see instructions)	21
22	IME payment adjustment. (see instructions)	22
23	IME payment adjustment - Managed Care. (see instructions)	23
24	IME payment adjustment for the Add-on for 602 of the MMA	24
25	Number of additional all-patient and osteopathic IME FTE resident cap slots under 42 CFR 412.101(b)(2)(ii)	25
26	FTE resident count over cap. (see instructions)	26
27	If the amount on line 24 is greater than 0, then enter the lower of line 23 or line 24. (see instructions)	27
28	Resident to bed ratio. (line 27 divided by line 4)	28
29	IME payment adjustment factor. (see instructions)	29
30	IME add-on adjustment amount. (see instructions)	30
31	IME add-on adjustment amount - Managed Care. (see instructions)	31
32	Total IME payment (sum of lines 22 and 23)	32
33	Total IME payment - Managed Care. (sum of lines 23 and 31)	33
34	Disproportionate Share Adjustment	34
35	Percentage of total inpatient days to Medicare Part A patient days. (see instructions)	35
36	Percentage of Medicaid patient days to total patient days. (see instructions)	36
37	Sum of lines 35 and 36	37
38	Disproportionate share percentage. (see instructions)	38
39	Disproportionate share adjustment. (see instructions)	39
40	Uncompensated Care Adjustment	40
41	Total uncompensated care amount. (see instructions)	41
42	Factor 3. (see instructions)	42
43	Hospital uncompensated care payment (if line 34 is zero, enter zero on this line). (see instructions)	43
44	Pre rate share of the hospital uncompensated care payment amount. (see instructions)	44
45	Total uncompensated care payment amount (MMA) (see instructions)	45
46	Pre rate share of the hospital uncompensated care payment amount (DSH). (see instructions)	46
47	Total uncompensated care. (sum of columns 1 and 2 on line 38)	47
48	Additional Payment for 40 Percentages of DSH Beneficiary Discharges (lines 40 through 47)	48
49	Total Medicare discharges, excluding discharges for MS-DRGs 452, 463, 464, 465, and 466. (see instructions)	49
50	Total DSH Medicare discharges excluding MS-DRGs 452, 463, 464, 465, and 466. (see instructions)	50
51	Total DSH Medicare covered and paid discharges excluding MS-DRGs 452, 463, 464, 465, and 466. (see instructions)	51
52	Divide line 41 by line 40 (if less than 10%, you do not qualify for adjustment)	52
53	Total Medicare DSH payment rate excluding MS-DRGs 452, 463, 464, 465, and 466. (see instructions)	53
54	Ratio of average length of stay in one week. (line 43 divided by line 41 divided by 7 days)	54
55	Average weekly cost for dialysis treatments. (see instructions)	55
56	Total additional payment. (sum of lines 44 and 45)	56
57	Subtotal. (see instructions)	57

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11-17 RECLASSIFICATION AND ADJUSTMENT OF TRIAL BALANCE OF EXPENSES FORM CMS-2552-10 PROVIDER CCN: PERIOD: FROM TO: WORKSHEET A

COST CENTER DESCRIPTIONS (omit costs)	SALARIES 1	OTHER 2	TOTAL (col. 1 + col. 2) 3	RECLASSI- FICATIONS 4	RECLASSIFIED TRIAL BALANCE (col. 3 + col. 4) 5	ADJUSTMENTS 6	NET EXPENSES FOR ALLOCATION (col. 5 + col. 6) 7
<b>ANCILLARY SERVICE COST CENTERS</b>							
50 05900 Operating Room							50
51 05100 Recovery Room							51
52 05500 Labor Room and Delivery Room							52
53 05300 Anesthesiology							53
54 05400 Radiology-Diagnostic							54
55 05500 Radiology-Therapeutic							55
56 05600 Radioisotope							56
57 05700 Computed Tomography (CT) Scan							57
58 05800 Magnetic Resonance Imaging (MRI)							58
59 05900 Cardiac Catheterization							59
60 06000 Laboratory							60
61 06100 HIP Clinical Laboratory Services-Program Only							61
62 06200 Whole Blood & Packed Red Blood Cells							62
63 06300 Blood Storing, Processing, & Trans.							63
64 06400 Intravenous Therapy							64
65 06500 Respiratory Therapy							65
66 06600 Physical Therapy							66
67 06700 Occupational Therapy							67
68 06800 Speech Pathology							68
69 06900 Electrocardiology							69
70 07000 Electroencephalography							70
71 07100 Medical Supplies Charged to Patients							71
72 07200 Implantable Devices Charged to Patients							72
73 07300 Drugs Charged to Patients							73
74 07400 Renal Dialysis							74
75 07500 ASC (Non-Direct Part)							75
76 07600 Other Ancillary (specify)							76
77 07700 Allogeneic Stem Cell Acquisition							77
<b>OUTPATIENT SERVICE COST CENTERS</b>							
88 08800 Rural Health Clinic (RHC)							88
89 08900 Federally Qualified Health Center (FQHC)							89
90 09000 Clinic							90
91 09100 Emergency							91
92 09200 Observation Beds							92
93 09300 Other Outpatient Services (specify)							93
93.001 09301 Dental Hospitalization Program							93.001

Typically, lines 50 - 118 are potentially reimbursable.

Clinics/services 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 OPAIS.

HRSA will also verify that the line has a net expense in order to be eligible.

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11-17 COMPUTATION OF RATIO OF COSTS TO CHARGES FORM CMS-2552-10 PROVIDER CCN: PERIOD: FROM TO: WORKSHEET C PART 1

COST CENTER DESCRIPTIONS	Total Cost (from W-9, B, Part I, col. 26) 1	Therapy Limit Adj. 2	Costs			Charges			Total (column 6 + column 7) 8	Cost or Other Ratio 9	TEJRA Inpatient Ratio 10	PPS Inpatient Ratio 11
			Total Costs 3	RCE Dis- allowance 4	Total Costs 5	Inpatient 6	Outpatient 7					
<b>INPATIENT ROUTINE SERVICE COST CENTERS</b>												
30 Adults and Pediatrics (General Routine Care)												30
31 Intensive Care Unit												31
32 Convalescent Care Unit												32
33 Burn Intensive Care Unit												33
34 Surgical Intensive Care Unit												34
35 Other Special Care (specify)												35
40 Subpoisoned (IP)												40
41 Subpoisoned (BE)												41
42 Subpoisoned (Specify)												42
43 Nursery												43
44 Skilled Nursing Facility												44
45 Nursing Facility												45
46 Other Long Term Care												46
<b>ANCILLARY SERVICE COST CENTERS</b>												
50 Operating Room												50
51 Recovery Room												51
52 Labor Room and Delivery Room												52
53 Anesthesiology												53
54 Radiology-Diagnostic												54
55 Radiology-Therapeutic												55
56 Radioisotope												56
57 Computed Tomography (CT) Scan												57
58 Magnetic Resonance Imaging (MRI)												58
59 Cardiac Catheterization												59
60 Laboratory												60
61 HIP Clinical Laboratory Services-Program Only												61
62 Whole Blood & Packed Red Blood Cells												62
63 Blood Storing, Processing, & Trans.												63
64 Intravenous Therapy												64
65 Respiratory Therapy												65
66 Physical Therapy												66
67 Occupational Therapy												67
68 Speech Pathology												68

Reimbursable clinics must show outpatient charges in column 7

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**OPA University Hospital**  
**FY2011 Trial Balance 7/1/2010-6/30/12**

Dept ID	Clinic name	CR Line	Salary Expenses	Non-Salary Expenses	Total Expenses	Inpatient Rev	Outpatient Rev	Total Pat Revenue
H0122	Hand Clinic	50	\$ 50.00	\$ 865.00	\$ 915.00	\$ 452.00	\$ 879.00	\$ 1,331.00
H0123	Physical Therapy Clinic	50	\$ 76.00	\$ 367.00	\$ 443.00	\$ 586.00	\$ 846.00	\$ 1,432.00
H0124	Occupational Therapy Clinic	50	\$ 23.00	\$ 298.00	\$ 1,358.00	\$ 553.00	\$ 254.00	\$ 2,763.00
H0125	Outpatient Pediatric Therapy	50	\$ 138.00	\$ 442.00	\$ 580.00	\$ 125.00	\$ 564.00	\$ 689.00
	<b>total</b>		\$ 287.00	\$ 1,972.00	\$ 2,259.00	\$ 1,716.00	\$ 2,543.00	\$ 5,727.00
H1123	Neurology Clinic	90	\$ 586.00	\$ 984.00	\$ 1,570.00	\$ 852.00	\$ 789.00	\$ 1,641.00
H3021	Eye Institute	90	\$ 423.00	\$ 256.00	\$ 679.00	\$ 456.00	\$ 654.00	\$ 1,110.00
H2561	Dermatology Clinic	90	\$ 46.00	\$ 872.00	\$ 2,249.00	\$ 213.00	\$ 321.00	\$ 2,751.00
H5543	Radiology Clinic	90	\$ 986.00	\$ 423.00	\$ 1,409.00	\$ 852.00	\$ 258.00	\$ 1,110.00
H2614	Cardiology Clinic	90	\$ 365.00	\$ 5,896.00	\$ 6,261.00	\$ 963.00	\$ 369.00	\$ 1,332.00
	<b>total</b>		\$ 2,406.00	\$ 8,431.00	\$ 10,837.00	\$ 3,336.00	\$ 2,391.00	\$ 5,727.00
H1234	Pain Clinic	90	\$ 231.00	\$ 714.00	945			
H2345	OBGYN Associates	90	\$ 462.00	\$ 753.00	1215			
H34567	OPA ENT Clinic	90	\$ 11.00	\$ 357.00	2160			
H5678	Surgery Clinic	90.1	\$ 1,852.00	\$ 1,824.00	3676			

Trail Balance Sheet allows CEs to show individual clinics/services operating under a single line. It is very common to have many different clinics under line 90. In order to be eligible, each should also show expenses and outpatient revenues. Please consult the cost report instructions when adding a line to the cost center to ensure it is subscripted correctly.

## 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

### *Maintenance of Auditable Records*

Section 340B(a)(5)(C) of the PHSA 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 PHSA. A covered entity's failure to maintain auditable records is grounds for losing eligibility to participate in the 340B Program.

340B Program stakeholders have requested a standard for records retention, and HHS agrees that it is important, especially in assisting covered entities and manufacturers in preparing for audits and understanding the time and scope limitations of 340B Program audits. Therefore, HHS is proposing a record retention standard for all 340B Program records for a period of not less than 5 years, which HHS believes appropriately balances the need for a covered entity to document its compliance with 340B Program requirements and the covered entity's effort and expense required to maintain records for an extended period of time. This standard would also apply to records pertaining to all child sites and contract pharmacies. In the case of termination, a terminated covered entity or associated site is expected to maintain records pertaining to compliance with 340B statutory requirements for five years after the date of termination. If during an audit, HHS



## 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

**Medicare Cost Report Crosswalk to Hospital EMR (SAMPLE)**

Location Code (Epic Dept ID)	Patient Class	MCR Description	MCR Line	HRSA Registration Description	Dept Code (Gal. Code)	NPI Number	Medicare Provider Number	Address	City	340B Eligible	Net Expenses (worksheet A)	Outpatient charges (worksheet C)	Specific Service/Clinic cost (Trial Balance)
10010107	Inpatient	MMC BURN CENTER	33.00	Burn Intensive Care Unit	104203	1073576740	1111111	9876 Welcome Street	Hometown	Y	\$ 6,168,817.00	\$ 25,947,635.00	\$ 5,831,865.98
10010107	Inpatient	MMC 4E SHORT STAY	30.00	Adults and Pediatrics (General Routine Care)	104400	1073576740	1111111	9877 Welcome Street	Hometown	Y	\$ 28,290,965.60	\$ 37,473,300.00	\$ 1,338,339.66
10010107	Mixed	MMC BURN THERAPY	90.12	Burn Clinic	105524	1073576740	1111111	9878 Welcome Street	Hometown	Y	\$ 1,651,682.43	\$ 6,994,633.00	\$ 1,320,489.43
10010107	Mixed	MMC BURN OT	90.12	Burn Clinic	105524	1073576740	1111111	9879 Welcome Street	Hometown	Y	\$ 1,651,682.43	\$ 6,994,633.00	\$ 1,320,489.43
10010107	Mixed	MMC BURN PT	90.12	Burn Clinic	105524	1073576740	1111111	9880 Welcome Street	Hometown	Y	\$ 1,651,682.43	\$ 6,994,633.00	\$ 1,320,489.43
10010108	Emergency	MMC ED ADULT	91.00	Emergency	105482	1073576740	1111111	9881 Welcome Street	Hometown	Y	\$ 13,980,569.99	\$ 137,900,608.00	\$ 12,846,999.96
10010108	Emergency	MMC ED PEDI	91.01	Peds ER	105484	1073576740	1111111	9882 Welcome Street	Hometown	Y	\$ 4,798,812.52	\$ 34,794,472.00	\$ 4,798,812.52
10010108	Emergency	MMC ED PEDI	91.02	Burn ER	104209	1073576740	1111111	9883 Welcome Street	Hometown	Y	\$ 241,866.68	\$ 9,704,888.00	\$ 241,866.68
10010110	Mixed	MMC LAB	60.00	Laboratory	105420	1073576740	1111111	9884 Welcome Street	Hometown	Y	\$ 14,285,843.21	\$ 381,996,560.00	\$ 14,285,843.21
10010110	Mixed	MMC ECHO LAB	69.00	Electrocardiology	105451	1073576740	1111111	9885 Welcome Street	Hometown	Y	\$ 226,579.81	\$ 9,339,822.00	\$ 226,579.81
10010110	Mixed	MMC CATH LAB	54.01	Cardiac Cath	105460	1073576740	1111111	9886 Welcome Street	Hometown	Y	\$ 3,037,939.40	\$ 5,563,635.00	\$ 3,037,939.40
10010110	Mixed	MMC MICROBIOLOGY	60.00	Laboratory	105420	1073576740	1111111	9887 Welcome Street	Hometown	Y	\$ 14,285,843.21	\$ 381,996,560.00	\$ 14,285,843.21
10010110	Mixed	MMC RAD CT	57.00	Computed Tomography (CT) Scan	105541	1073576740	1111111	9888 Welcome Street	Hometown	Y	\$ 1,373,479.41	\$ 104,396,629.00	\$ 1,373,479.41
10010112	Mixed	MMC RAD MRI	58.00	Magnetic Resonance Imaging (MRI)	105543	1073576740	1111111	9889 Welcome Street	Hometown	Y	\$ 665,380.86	\$ 20,838,190.00	\$ 665,380.86
10010114	Mixed	MMC RAD NUCMED	54.05	Nuclear Medicine	105545	1073576740	1111111	9890 Welcome Street	Hometown	Y	\$ 338,267.74	\$ 1,876,284.00	\$ 338,267.74
10010115	Mixed	MMC RAD SPECIAL	54.06	Angiography	105546	1073576740	1111111	9891 Welcome Street	Hometown	Y	\$ 1,234,387.12	\$ 6,349,397.00	\$ 1,234,387.12
10010116	Inpatient	MMC RAD PICC	13.00	Nursing Administration	107603	1073576740	1111111	9892 Welcome Street	Hometown	N	\$ 6,849,603.14	\$ -	\$ (3,851.81)
10010117	Mixed	MMC RAD ULTRASOUND	54.03	Ultrasound	105544	1073576740	1111111	9893 Welcome Street	Hometown	Y	\$ 2,710,769.84	\$ 45,782,071.00	\$ 2,710,769.84
10010118	Mixed	MMC RAD DIAGNOSTIC	54.00	Radiology-Diagnostic	105542	1073576740	1111111	9894 Welcome Street	Hometown	Y	\$ 2,465,237.98	\$ 44,564,568.00	\$ 1,590,200.74



## Thank you

