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HEALTH CARE LAWYERS & ADVISORS

HFMA Southern California Chapter Virtual Summer Symposium

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Medicare, Medicaid, and 340B Update

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AGENDA

- Medicare Update (FY 2021 IPPS Rule)
 - Bad Debt
 - Price Transparency
- Medi-Cal Update
- Provider Relief Fund
- 340B Update

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MEDICARE BAD DEBT

Medicare Bad Debt

Medicare pays some of the uncollectible deductible and coinsurance amounts to certain providers for bad debt of Medicare beneficiaries.

- Debt must be **related to covered services** and **derived from deductible and coinsurance amounts**.
- **Reasonable collection efforts** must be made
- Debt must **be actually uncollectible** when claimed as worthless.
- Sound business judgment must establish **no likelihood of recovery**

Sources:

- Social Security Act 1861(v)(1)
- 42 CFR Section 413.89
- Provider Reimbursement Manual, Chapter 3

Medicare Bad Debt [cont'd.]

Medicare FY 2021 IPPS Final Rule (85 Fed. Reg. 32,460 (May 29, 2020))

- CMS proposes changes to “**clarify**” certain Medicare bad debt policies that have been the subject of litigation and generated interest/questions over the past several years
- CMS is proposing to make most of these changes effective **retroactively**

Reasonable Collection Efforts

Proposed Revision (codifying PRM): **Issuance of Bill**

- Similar collection efforts for Medicare and non-Medicare patients
- For cost reporting periods beginning before 10/1/2020, issuance of bill *on or shortly after discharge or death* of the beneficiary.
- For cost reporting periods beginning on or after 10/1/2020, issuance of bill *on or before 120 days after the latter of*:
 - The date of the Medicare RA
 - The date of the RA from secondary payer, if any
- Genuine, not token, collection effort
 - E.g., subsequent billings, collection letters, telephone calls, personal contacts

Reasonable Collection Efforts [cont'd.]

Proposed Revision: **120-day Collection Effort and Reporting Period for Writing Off Bad Debts**

- At least 120 days must have passed since first attempt to receive payment (codifying PRM)
 - Partial payment restarts the 120-day period (clarification of CMS policy)
- Any payment after the write-off date but before end of the cost reporting period must be used to reduce the final bad debt (codifying PRM)
 - Any recovered amount must be used to reduce the provider's reimbursable costs in the period in which the amount is recovered BUT the amount of such reduction must not exceed the actual amount reimbursed by the program for the related bad debt in the applicable prior cost reporting period.

Reasonable Collection Efforts [cont'd.]

Other Proposed Changes

Proposed Revision: **Determining Indigency**

- Addition of detailed specifications for how a provider is to determine indigence for beneficiaries that are not Medicaid eligible

Proposed Revision: **Dual Eligible Beneficiaries**

- Addition of provisions addressing partial Medicaid programs and issues where Medicaid may not provide information on whether it has payment obligation
- Provider must determine whether Medicaid is responsible to pay any/all of the beneficiary's deductible and/or coinsurance amount by satisfying:
 - Must Bill Requirement
 - RA requirement
- The Medicare deductible and/or coinsurance amount, or any portion thereof that the state IS NOT obligated to pay, CAN BE INCLUDED as an allowable Medicare bad debt.

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PRICE TRANSPARENCY

June 24, 2019 Executive Order

Exec. Order No. 13877, Improving Price and Quality Transparency in American Healthcare to Put Patients First, 84 Fed. Reg. 30,849 (June 24, 2019), directs HHS Secretary to:

“propose a regulation, consistent with applicable law, requir[ing] hospitals **to publicly post standard charge information, including charges and information based on negotiated rates** and for common or shoppable items and services,” in easy-to-understand formats so as to “inform[] patients about actual prices.”

Price Transparency Final Rule

Price Transparency Requirements for Hospitals to Make Standard Charges Public, 84 Fed. Reg. 65,524 (Nov. 27, 2019)

- Effective January 1, 2021
- Requires that hospitals make standard charges for all items and services publicly available via:
 - Comprehensive machine-readable file
 - Consumer-friendly list for at least 300 shoppable services

Price Transparency Final Rule (cont'd)

- Finalized definition of standard changes to include:
 - **Gross Charges:** “the charge . . . that is reflected on a hospital’s chargemaster, absent any discounts.” (the “standard” charges for uninsured patients or patients who seek out-of-network care)
 - **Payer-Specific Negotiated Charges:** “the charge[s] that a hospital has negotiated with a third-party payer for an item or service.” (the “usual or common rate for the members of” “a specific plan through a specific insurer”)
 - **Discounted Cash Prices:** charge that applies to an individual who pays cash (or cash equivalent) for a hospital item or service.
 - **De-identified Minimum and Maximum Negotiated Charges:** the highest and lowest charges that a hospital has negotiated with all third-party payers for an item or service but are not linked to the particular third-party payer.

FY 2021 Litigation

- December 2019: Hospital associations challenge the Final Rule provisions re hospital price transparency in D.C. District Court, alleging that the requirement:
 - Exceeds statutory authority
 - Violates 1st Amendment (mandates speech in a manner that fails to directly advance a substantial government interest, let alone in a narrowly tailored way)
 - Is arbitrary and capricious and lacks any rational basis

FY 2021 Litigation

- June 2020: D.C. District Court grants government's Motion for Summary Judgment and denies Plaintiffs' Motion for Summary Judgment
 - Secretary Azar: "Today's court decision is a resounding victory for President Trump and HHS's **agenda to lower Americans' healthcare costs**. President Trump has been clear: American patients deserve to be in control of their healthcare. With today's decision, we will continue delivering on the President's promise to give patients **easy access to healthcare prices**. Especially when American patients are seeking care during a nationwide public health emergency, it is more important than ever that they have **ready access to the actual prices of healthcare services**."
 - June 24, 2020: Plaintiffs file Notice of Appeal in D.C. Circuit
 - And now we wait.....

FY 2021 IPPS Proposed Rule

- Currently: CMS uses a cost-based methodology to determine the relative hospital resources used for each discharge and adjusts MS-DRG relative weights based on these relative costs (chargemaster)
- Proposal: Require hospitals to calculate the median payer-specific negotiated charge by MS-DRG using the payer-specific negotiated charge data by MS-DRG from the single machine-readable file for all items and services
- Proposal: CMS uses data to update relative MS-DRG weights

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MEDI-CAL UPDATE

Topics

- HQAF PROGRAM
- MANAGED CARE OUT-OF-NETWORK PAYMENTS

HQAF Program

- Effective 2009
- Applies to private hospitals
- New hospitals are exempt
- Rural hospitals are exempt from the fee
- Public hospitals don't pay the fee, but get grants
- Hospitals pay a fee based on historical patient days
- Receive supplemental Medi-Cal fee-for-service payments based on historical data
- Receive additional managed care payments

HQAF Program

- Net benefit of many billions of dollars to California hospitals since 2009; now about \$4 billion annually
- State takes 24% of fee proceeds for “children’s coverage”
- Fee less state 24% plus matching federal funds are paid to hospitals
- 2016 Proposition 52 approved by the voters making the program permanent
- Currently in HQAF 6 (July 1, 2019 – December 31, 2021)

HQAF—Managed Care

- Additional capitation payments are made to Medi-Cal health plans
- Plans must pay 100% to hospitals within 30 days
- Until July 1, 2017 all HQAF managed care payments distributed by plans to hospitals based on historical Medi-Cal managed care utilization
- Change in federal Medicaid regulations required California to divide managed care payments into 2 pieces
 - “Pass Through Payments”
 - Directed Payments

HQAF Payments

HQAF 5

- 51% Fee-for-service
- 27% Pass-through
- 22% Directed

HQAF 6

- 41% Fee-for-service
- 21% Pass-through
- 38% Directed

HQAF—Directed Payments

- Based on **current** period Medi-Cal managed care days and hospital outpatient visits
- Process established for Medi-Cal managed care plans to report contracted days and visits to DHCS and for hospitals to validate data
- Must have a contract with the managed care plan or a plan subcontractor for the data to count
 - Do not need a contract for pass-through payments
- Contract must contain certain provisions—APL 19-001
- DHCS to validate days are contracted
- Non-hospital visits do not count

HQAF—Directed Payments

Issues regarding counting days and visits:

- Capitation
- Payments from plan subcontractors
- Mother-baby days
- ED and outpatient visits paid by IPAs
- DHCS rejected days or visits due to technical deficiencies

Something to Worry About

- Proposed “MFAR” regulations
- Proposed in January 2020, would place significant and unprecedented restrictions on funds that could be used as the non-federal share of Medicaid funding
- If adopted as proposed, could require a restructuring of the HQAF program fee model
- Also issues for IGTs and CPEs
- CHA and many other provider organizations strongly opposed

HQAF and CHOWs

- After a CHOW, to receive supplemental payments must submit a Financial Responsibility Agreement within 30 days of letter from Medi-Cal informing provider of new Medi-Cal certification
- To be a new hospital and exempt from the HQAF program, must submit a new hospital attestation saying successor entity is not financially responsible to DHCS for the predecessor's Medi-Cal obligations
- These are “traps for the unwary”
- DHCS bulletin:
<https://www.dhcs.ca.gov/provgovpart/Documents/HQAF/CHOW-NewHosp.pdf>

Out-Of-Network Payments

- Health plans typically limit payments to Medi-Cal fee-for-service rates without supplemental payments
- Some hospitals have argued that payment for out-of-networks post stabilization services is not limited to AP-DRG rates
- California Court of Appeal sided with the health plans in *Dignity Health v. Local Initiative, etc.*, 44 Cal. App. 5th 144 (2020)
- Rules that the statute establishing the Medi-Cal DRG system means that all Medi-Cal days except contracted days are paid at the DRG rates, decide exception for “managed care days” does not include non-contract days
- Door still open to argument that federal law does not permit the State to mandate the payment rate for post stabilization services
- Given this decision and directed payments, large incentive to contract

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PROVIDER RELIEF FUND

Provider Relief Fund Topics

- Provider Relief Funds Overview
 - General Distribution
 - Targeted Distributions
- Provider Relief Funds Compliance Risks
 - Fraud and false claims exposure
 - How to mitigate exposure

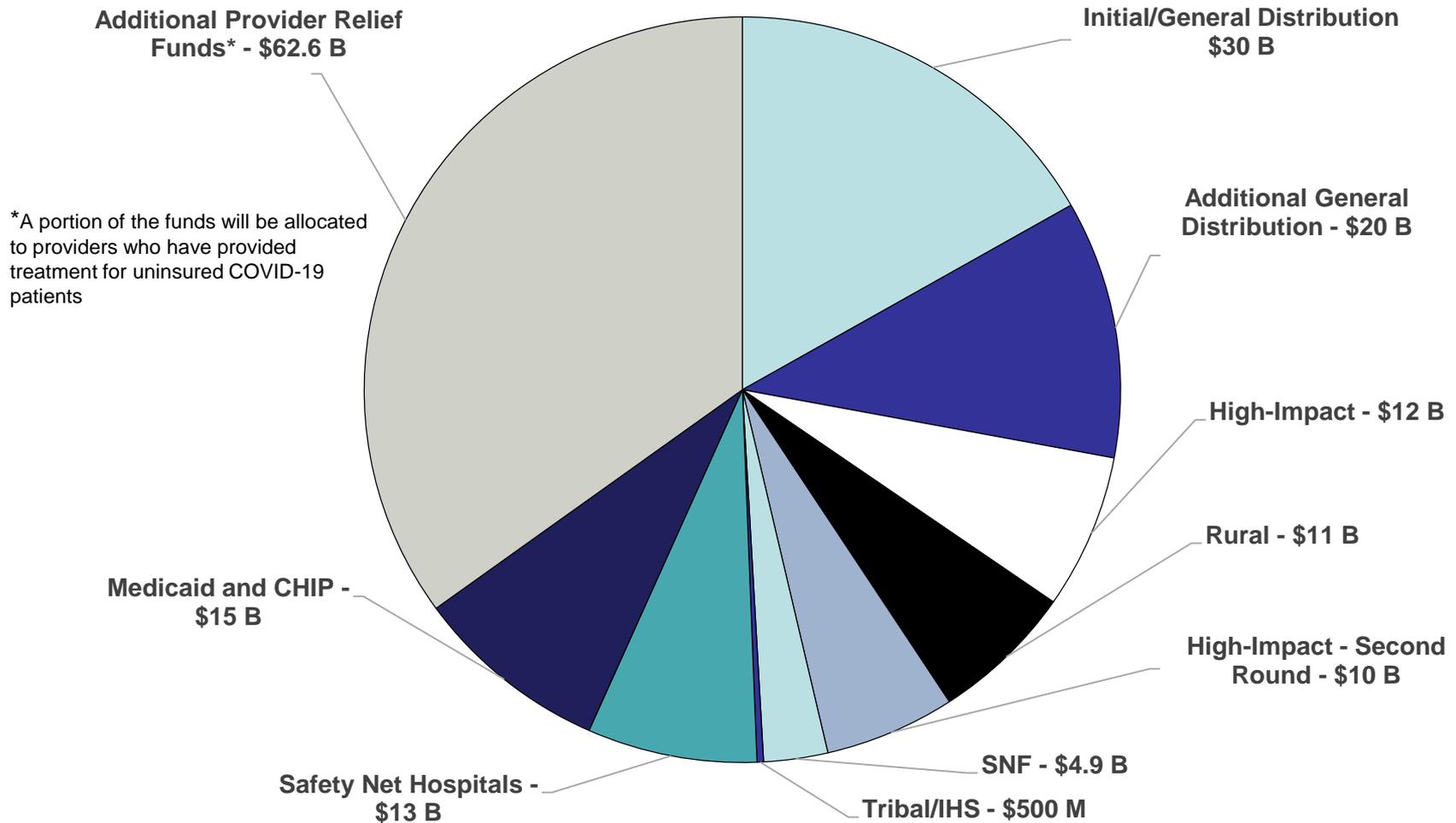
Provider Relief Fund Appropriations

Authority	Appropriation
CARES Act	\$100 billion
PPP and Health Care Enhancement Act	\$75 billion
Total	\$175 Billion

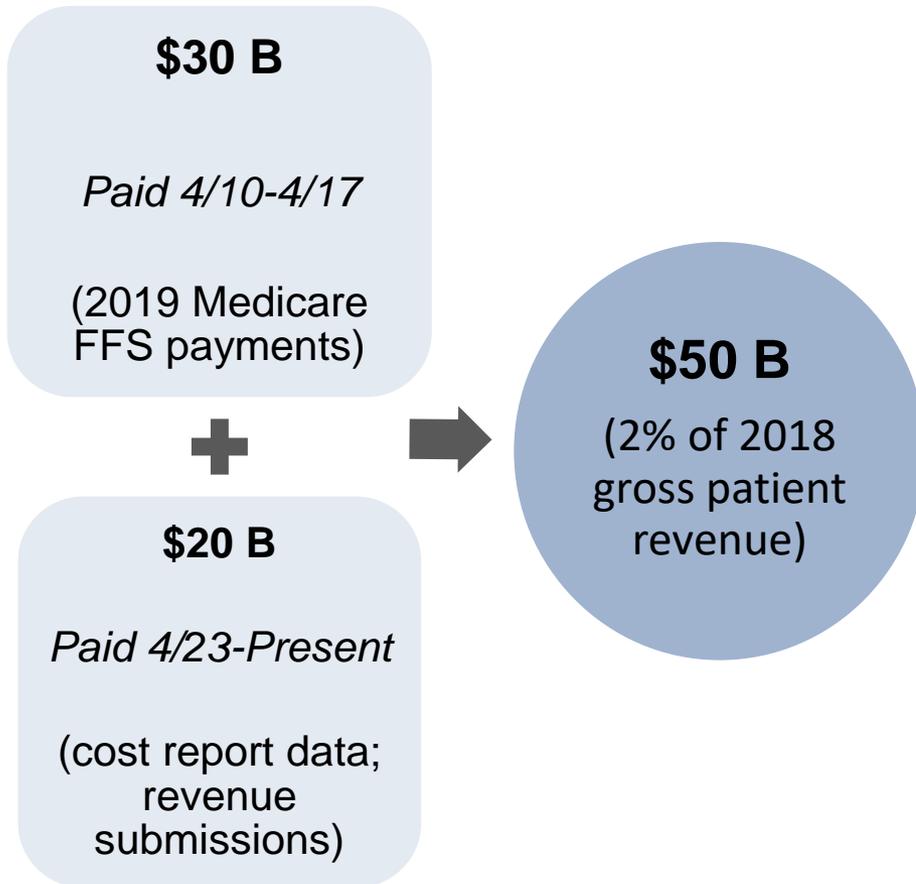
Purpose

- Prevent, prepare for, and respond to coronavirus... for **necessary expenses** to reimburse... eligible health care providers for **health care related expenses** or **lost revenues** that are attributable to coronavirus.”

Provider Relief Fund Allocations



\$50 Billion General Distribution



Highlights

- Must sign attestation:
 - confirming receipt of funds
 - agreeing to terms & conditions for **each** distribution
 - confirming payment amount
- Retaining funds for 90 days is deemed acceptance
- HHS funds go to organization's TIN
- No appeal process

Targeted Allocations

Highlights

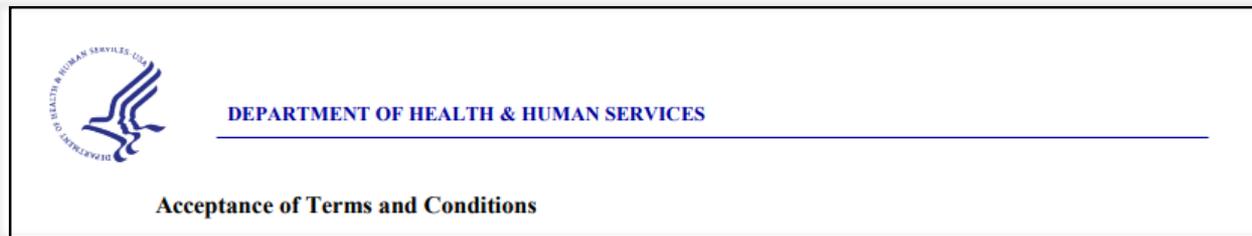
- Targeted Distributions include:
 - High-Impact Distribution (\$12B; \$10B)
 - Rural Distribution (\$11B)
 - Medicaid & CHIP Distribution* (~\$15B)
 - Safety Net Allocation (\$13B)
 - Others: SNFs, Tribal Hospitals, Clinics and Urban Health Centers
- Specific formulas determine targeted allocations
- Each targeted distribution has its own terms and conditions
- Additional targeted distributions?

Not available to providers who received payments from the \$50B General Distribution

Attestation Requirements

- If a provider chooses to retain the funds, it must attest that it meets the terms and conditions of the payment
- Not returning the payment within 90 days of receipt is deemed acceptance of the terms and conditions
- The CARES Act Provider Relief Fund Payment Attestation Portal guides providers through the attestation process to accept or reject funds:
<https://covid19.linkhealth.com/#/step/1>

Terms and Conditions



- Providers must certify that:
 - Provider Relief Fund monies “will only be used to prevent, prepare for, and respond to coronavirus” and only to reimburse for “health care related expenses or lost revenues that are attributable to coronavirus.”
 - Funds will not be used to reimburse expenses or losses that have “been reimbursed from other sources or that other sources are obligated to reimburse.”

Terms and Conditions [cont'd]

- Providers must maintain “appropriate records and cost documentation.” This includes:
 - Substantiating documentation for use of funds
 - Maintenance of records for at least three years
 - Prompt submission to HHS upon HHS request
 - Cooperation in all audits by Secretary, Inspector General, or Pandemic Response Accountability Committee

Risk Types

- Overpayment Risk
- False Claims Act
 - “Scienter”
 - Is there a “claim”
 - Retention of an overpayment as a reverse false claim
 - Treble damages
 - Whistleblowers
- Criminal Liability

Risk Reduction

- Carefully Review the Terms and Conditions
- Carefully Review the FAQs
- Make a reasoned decision to support expenditures consistent with T & C's and FAQs
- Document decision making and reasons
- Document advice received and act consistent with the advice or document why acting inconsistent with the advice
- Auditable documentation concerning use of the funds

Risk Area—Use of Funds

- “The Recipient certifies that the Payment will only be used to prevent, prepare for, and respond to coronavirus, and that the Payment shall reimburse the Recipient only for health care related expenses or lost revenues that are attributable to coronavirus.”
- 2 ways to satisfy:
 - Health care related expenses attributable to coronavirus
 - Lost revenue attributable to coronavirus

Risk Area—Use of Funds

Health care related expenses (FAQs)

- “Healthcare related expenses attributable to coronavirus” is a broad term that may cover a range of items and services purchased to prevent, prepare for, and respond to coronavirus, including:
 - supplies and equipment used to provide healthcare services for possible or actual COVID-19 patients;
 - workforce training;
 - developing and staffing emergency operation centers;
 - reporting COVID-19 test results to federal, state, or local governments;

Risk Area—Use of Funds

More health care related expenses:

- building or constructing temporary structures to expand capacity for COVID-19 patient care or to provide healthcare services to non-COVID-19 patients in a separate area from where COVID-19 patients are being treated; and
- acquiring additional resources, including facilities, equipment, supplies, healthcare practices, staffing, and technology to expand or preserve care delivery.

Eligible expense may be incurred on any day, but “highly unusual” if incurred before 1/1/2020.

Risk Area—Use of Funds

Lost Revenue

- Any revenue that the provider lost due to coronavirus.
- Fewer outpatient visits or elective services
- More uncompensated care

Can cover any cost that the lost revenue would have covered, so long as that cost prevents, prepares for, or responds to coronavirus

Costs do not need to be specific to providing care for possible or actual coronavirus patients

Risk Area—Use of Funds

Examples of permissible costs tied to lost revenue:

- Employee or contractor payroll
- Employee health insurance
- Rent or mortgage payments
- Equipment lease payments
- Electronic health record licensing fees

Risk Area—Use of Funds Tips

Do you have lost revenue attributable to coronavirus?

- Can be measured in any reasonable way
- Comparison of pre-pandemic revenue to post-pandemic revenue
- Compare budgeted to actual performance
- Document calculation

If you have documented lost revenue

- Can expend the funds broadly
- Document expenditures in view of guidance

Risk Area—Use of Funds Tips

- If do not have sufficient lost revenue to cover funds, do you have health care expenses attributable to coronavirus?
- If so, document what the expenses are and how they are attributable to coronavirus?

Risk Area—Other Responsible Party

- Provider must certify “it will not use the Payment to reimburse expenses or losses that have been reimbursed from other sources or that other sources are obligated to reimburse.”
- Ambiguous
- No clarification from HHS

Risk Area—Other Responsible Party

Consider

- Cost reimbursement
- DRG-based reimbursement
- Other fee-for-service payments
- Capitation
- DSH and other supplemental payments
- FEMA
- Insurance proceeds

Document why you have concluded no other source of payment

In the absence of guidance, explain cost report treatment in cover letter

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340B

The 340B Program: Basics

- Federal drug discount program: allows eligible entities to purchase certain covered outpatient drugs at discounted prices from drug manufacturers
 - Eligible entities: registered hospitals and federal grantees/programs (known as covered entities)
 - Limited to certain covered outpatient drugs that are dispensed to covered entity's eligible patients
- Administered by the Office of Pharmacy Affairs, within the Health Resources and Services Administration of the Department of Health and Human Services

2018 OPPS Final Rule re Payment for 340B Drugs

- Rate change for separately payable drugs acquired under 340B program, except pass-through drugs and vaccines
 - Prior to 1/1/2018: Average Sales Price (“ASP”) + 6%
 - Effective 1/1/2018: ASP - 22.5%.
 - Drugs not purchased with the 340B discount: ASP + 6%
- No phase-in period for rate reduction
- Budget-neutral implementation (~\$1.6 billion)
 - Adjustment to OPPS conversion factor

Legal Challenge to 2018 Payment Change

- **Plaintiffs:** Hospital associations (American Hospital Association, America's Essential Hospitals, and the Association of American Medical Colleges)
- **Nature of Suit:** Challenge to CMS authority to implement the payment cuts (violation of APA, in excess of statutory authority); sought injunction to keep payment cuts from going into effect
- **District Court:** Granted government's motion to dismiss. Dismissed plaintiffs' motion for preliminary injunction
 - Court lacked subject matter jurisdiction because hospitals failed to first present any claim to the HHS for final decision
- **Court of Appeals:** Affirmed
- **September 5, 2018:** Hospital associations re-filed lawsuit after claims submitted and appealed

2019 OPPS Final Rule re Payment for 340B Drugs

- Maintained payment rate of ASP - 22.5% for separately payable drugs acquired under the 340B program
- Expanded payment rate to Part B drugs furnished in non-excepted off-campus HOPDs
 - Previous payment rate for these HOPDs: ASP + 6%
 - Estimated savings: \$48.5 million

340B Payment Reduction Litigation

- December 2018: Court issues opinion re 2018 reduction
 - Secretary's action was ultra vires
 - Statute authorizes adjustments; here, Secretary made basic and fundamental changes to statutory scheme (in part due to magnitude and wide applicability)
 - Does not address rate cut for 2019 because plaintiffs have not yet presented a claim
 - Invites briefing from parties re appropriate remedy

340B Payment Reduction Litigation [cont'd]

- May 2019: Court issues opinion re 2019 reduction
 - Rate is unlawful for same reasons 2018 reduction was unlawful
 - Remands to agency
 - Vacating 2018 and 2019 rules could wreak “havoc” on Medicare’s administration
 - Remand gives agency “first crack” at crafting appropriate remedial measures
 - Court expresses “expectation” that HHS resolve the issue “promptly”

340B Payment Reduction Litigation [cont'd]

- June 2019: Government moves for court to enter final judgment
 - Allows for appeal to D.C. Circuit
- Late 2019: Parties exchanged briefs in D.C. Circuit
- And now we wait...

340B and COVID-19

- 340B Child Sites: must be listed as reimbursable on the hospital's **most recently filed Medicare cost report** and have associated outpatient costs and charges
- COVID-19 Flexibility (New HRSA COVID-19 FAQ): For hospitals who are unable to register their outpatient facilities because they are not yet on the most recently filed Medicare Cost Report, the patients of the new site may still be 340B eligible to the extent that they are patients of the covered entity.
- BUT not all HRSA and Apexus FAQs have been updated to reflect this flexibility

To treat a site as a child site, ensure that it qualifies to be reported on the cost report AND that patient definition is met

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