State of the Healthcare Industry:
Updates for Rural Strategy – Q2 2021

NOSORH Quarterly Updates

July 27, 2021

Eric Shell, CPA, MBA, Chairman

Stroudwater Associates

Panelist

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Agenda

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- **COVID-19 Updates**
- **Legislative/Regulatory Updates**
- **Other Market Events**

COVID-19 UPDATES

Public Health and Social Services Emergency Grant Fund (PHSSEF)

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- *Consolidated Appropriations Act of 2021 (CAA), signed into law on 12/27/2020, provided an additional $3B for provider relief funds (PRFs)*
  - *As of 3/25, reported that of the $178B available, HHS had spent $151B on general and targeted distributions and $3B testing/treatment claims*
  - *85% of funds to cover providers' financial losses and changes in operating expenses for the second half of 2020 and Q1 2021*
  - *15% of funds to be distributed at discretion of HHS*
- *American Rescue Plan Act of 2021 provided no new PRFs*
  - *However, $8.5B to rural providers, separate from but similar to PRFs*
  - *As of 7/27/2021, amount has not been spent*

Public Health and Social Services Emergency Grant Fund (PHSSEF) (continued)

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PHSSEF Grants (continued)

- Qualifying expenses include all non-reimbursable expenses attributable to COVID-19 including:
  - Building or retrofitting new Intensive Care Units (ICUs)
  - Increased staffing or training
  - Personal Protective Equipment (PPE)
  - Building of temporary structures
  - Foregone revenue from cancelled procedures
    - Revenue losses associated with fewer outpatient visits, canceled elective procedures or services, or increased uncompensated care
    - "HHS encourages the use of funds to cover lost revenue so that providers can respond to Covid-19 by maintaining healthcare delivery capacity"

Public Health and Social Services Emergency Grant Fund (PHSSEF) (continued)

- May 10th letter from AHA, AEH, etc. to HHS
  - *"we are writing to urge you to continue support for our hospitals, health care workers, and most importantly, our patients during the ongoing pandemic by extending the June 30 deadline by which providers must use their COVID-19 PRF payments, and instead use as a guideline the length of the PHE."*

- June 8th Update - *Xavier Becerra, HHS Secretary to House Ways and Means*
  - *"We are trying to provide some flexibility. We want to be sure everyone keeps the deadlines as best as possible"*
  - Regarding distribution of remaining $24B:
    - *"We're trying to make sure we don't make the mistakes of the past"*

AMERICA'S HOSPITALS AND HEALTH SYSTEMS

May 10, 2021

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W. Washington, D.C. 20201

Dear Secretary Becerra:

As representatives of our nation's hospitals and health systems, we are writing to urge you to continue support for our hospitals, health care workers, and most importantly, our patients during the ongoing pandemic by extending the June 30 deadline by which providers must use their COVID-19 Provider Relief Fund (PRF) payments, and instead use as a guideline the length of the Public Health Emergency (PHE). We also ask you to expedite distribution of the remaining PRF resources.

The work of addressing the COVID-19 pandemic continues, despite the relief that is currently being provided by an increase in vaccination levels. Our facilities continue to treat tens of thousands of patients and intensive care unit capacity is still high in some parts of the country. We anticipate financial challenges will persist for America's hospitals and health systems, with more financial impact expected due to the pandemic. According to reports released by the American Hospital Association, hospitals were projected to lose to at least $323.1 billion through the end of 2020, with additional projected losses this year of as much as $122 billion.

Congress has allocated $178 billion to date to aid all types of health care providers through the PRF, and designated in the most recent COVID-19 relief package an additional $8.5 billion through the Rural Relief Fund. However, not all of the funds have been distributed, and those that have may not yet have been fully utilized by the recipients. We previously noted the ongoing financial burden our members are facing; add to this the uncertainty regarding when the pandemic will ease more considerably to allow for a full return to "business as usual," such as regular wellness visits and the resumption of scheduled surgeries. Our hospitals will continue to face challenges beyond June 30 in providing adequate staffing, supplies, personal protective equipment, testing and vaccinations. We therefore request that you intercede on behalf of our hospitals and health systems and provide critical assistance by expending the remaining PRF resources and tying the utilization date to the PHE.

Thank you for assisting us with this request and for your ongoing support for our nation's hospitals, providers and patients. We look forward to continuing to work with you as we recover from the COVID-19 public health pandemic.

Sincerely,

America's Essential Hospitals
American Hospital Association
Association of American Medical Colleges
Catholic Health Association of the United States
Children's Hospital Association
Federation of American Hospitals
National Association for Behavioral Healthcare
Premier healthcare alliance

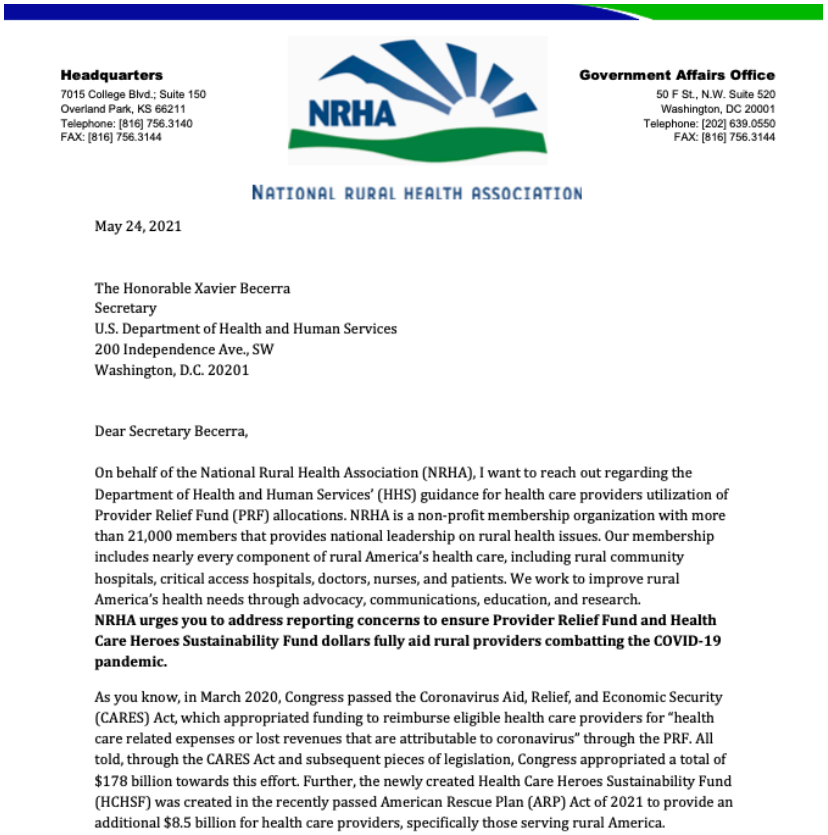
Source: https://www.aha.org/lettercomment/2021-05-10-letter-americas-hospitals-and-health-systems-urging-hhs-extend-deadline

Public Health and Social Services Emergency Grant Fund (PHSSEF) (continued)

- May 24th letter from NRHA to HHS
  1) **HHS should allow flexibility in the reporting of lost revenues**.
  - NRHA believes that calendar year 2020 is an arbitrary period to use as a measurement period for lost revenues

  2) HHS should allow for the use of PRF dollars past June 30, 2021
  - NRHA requests that all project costs be included in reporting when the project is put under contract in order to accommodate those essential activities that may not be complete by the current deadline.

  3) Reporting of lost revenue should be reflective of each providers situation
  - Including COVID-19 revenues (i.e. reimbursement) in the lost revenue calculation inappropriately doubles the impact on providers if that reimbursement has already been included in the COVID-19 expense calculation, especially for cost-based providers like CAHs and RHCs.



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NRHA
NATIONAL RURAL HEALTH ASSOCIATION

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May 24, 2021

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Ave., SW
Washington, D.C. 20201

Dear Secretary Becerra,

On behalf of the National Rural Health Association (NRHA), I want to reach out regarding the Department of Health and Human Services' (HHS) guidance for health care providers utilization of Provider Relief Fund (PRF) allocations. NRHA is a non-profit membership organization with more than 21,000 members that provides national leadership on rural health issues. Our membership includes nearly every component of rural America's health care, including rural community hospitals, critical access hospitals, doctors, nurses, and patients. We work to improve rural America's health needs through advocacy, communications, education, and research.
NRHA urges you to address reporting concerns to ensure Provider Relief Fund and Health Care Heroes Sustainability Fund dollars fully aid rural providers combatting the COVID-19 pandemic.

As you know, in March 2020, Congress passed the Coronavirus Aid, Relief, and Economic Security (CARES) Act, which appropriated funding to reimburse eligible health care providers for "health care related expenses or lost revenues that are attributable to coronavirus" through the PRF. All told, through the CARES Act and subsequent pieces of legislation, Congress appropriated a total of $178 billion towards this effort. Further, the newly created Health Care Heroes Sustainability Fund (HCHSF) was created in the recently passed American Rescue Plan (ARP) Act of 2021 to provide an additional $8.5 billion for health care providers, specifically those serving rural America.

Provider Relief Funds Revised Notice of Reporting Requirements (6/11/2021)

- Important Updates
  - Period of availability of funds based on the date payment is received
  - Recipients are required to report for each Payment Received Period in which they received greater than $10K
  - Recipients will have 90 days to complete reporting (rather than 30 days)
  - PRF reporting portal opened 7/1
- Reporting requirements do not pertain to
  - RHC Covid-19 Testing program,
  - Covid-19 Uninsured program, and
  - Covid-19 Coverage Assistance Fund

HHS.gov U.S. Department of Health & Human Services

Home > About > News > HHS Issues Revised Notice of Reporting Requirements and Reporting Timeline for Recipients of Provider Relief Fund Payments

FOR IMMEDIATE RELEASE
June 11, 2021

Contact: HHS Press Office
202-690-6343
media@hhs.gov

HHS Issues Revised Notice of Reporting Requirements and Reporting Timeline for Recipients of Provider Relief Fund Payments

	Payment Received Period (Payments Exceeding $10,000 in Aggregate Received)	Deadline to Use Funds	Reporting Time Period
Period 1	From April 10, 2020 to June 30, 2020	June 30, 2021	July 1 to September 30, 2021
Period 2	From July 1, 2020 to December 31, 2020	December 31, 2021	January 1 to March 31, 2022
Period 3	From January 1, 2021 to June 30, 2021	June 30, 2022	July 1 to September 30, 2022
Period 4	From July 1, 2021 to December 31, 2021	December 31, 2022	January 1 to March 31, 2023

Source: HHS.Gov Press Office Immediate Release, June 11, 2021
https/www.hhs.gov/sites/default/files/provider-post-payment-notice-of-reporting-requirements-june-2021

Provider Relief Fund Post-Payment Reporting Requirements – Stakeholder Tool Kit (7/1/21)

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- HHS released Tool Kit on 7/1 to provide guidance on PRF reporting
  - Information includes:
    - Sample email content
    - Sample newsletter content
    - Reporting requirements fact sheet
    - Social media posts
    - Top 5 FAQs

Top 5 Frequently Asked Questions

1. **May providers request an extension on the use of funds beyond the period of availability indicated in the Post-Payment Notice of Reporting Requirements?**

   No. The updated deadlines to use PRF funds are based on Payment Received Dates. HRSA will not be granting extensions. As a reminder, PRF payments may be used to reimburse allowable expenses and lost revenues within the Period of Availability.

2. **Are PRF recipients required to report on each payment received separately?**

   PRF recipients must submit consolidated reports for payments received in each applicable Reporting Time Period. PRF recipients will only be able to register their recipient TIN once in the PRF Reporting Portal and a recipient TIN is able to report once per Reporting Time Period.

3. **May PRF recipients report on the use of all PRF payments received in calendar year 2020 and 2021 during the initial reporting period (July 1, 2021 – September 30, 2021) if all funds have been used?**

   During the initial reporting period July 1, 2021 – September 30, 2021, PRF recipients must only report on the use of funds received from April 10, 2020 through June 30, 2020. They will be unable to report on funds received after June 30, 2020 at this time.

4. **Are providers able to request extensions on submissions of their required reports for any of the required reporting periods?**

   No. Providers that received one or more payments exceeding $10,000, in the aggregate, during a Payment Received Period are required to report in each applicable Reporting Time Period. Providers that are required to report and do not submit a completed report by the applicable deadlines will be deemed out of compliance with the program Terms and Conditions and may be subject to recoupment.

5. **After PRF recipients complete their reporting on the use of funds, will HRSA send a notification that indicates acceptance or agreement with the report?**

   HRSA will not provide notification that states agreement with reporting. PRF recipients are responsible to maintain supporting documentation for a minimum of 3 years from the date of the final report in accordance with the payment terms and conditions.

   Per the §75.361 Retention requirements for records. Financial records, supporting documents, statistical records, and all other non-Federal entity records pertinent to a Federal award must be retained for a period of 3 years from the date of submission of the final expenditure report. One exception to the record retention policy is (a) If any litigation, claim, or audit is started before the expiration of the 3-year period, the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken.

Source: https://www.hhs.gov/sites/default/files/toolkit-reporting.pdf

Small Business Association (SBA) Payroll Protection Program (PPP)

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CAA of 2021 (12/27/20) – Division N, Title III, Continuing the PPP and Small Business Support (Sections 301-348)

- **$284B included for second round of PPP**
- **Loans**
  - 2.5 times borrower's average monthly payroll costs
    - Payroll costs determined based on: one year prior to loan application; or CY2019
  - Excluded costs include compensation of an individual in excess of an annual salary of $100K, as prorated for the period 2/15/20-6/30/20
- **Differences from First Round**
  - Maximum loan amounts reduced from $10M to $2M (only applicable to second-time borrowers)
  - Businesses employ 300 FTEs (or alternative size definition), down from 500 FTEs
  - Must have used (or will have used) the entire first round proceeds
  - Gross receipts during Q2, Q3, or Q4 25% less than gross receipts in prior year quarters
- ***American Rescue Plan Act of 2021***
  - *Provides an additional $7.25B for the program*
  - *501(c)(3) organizations that employ not more than 500 employees per physical location of the organization are eligible for the program (affiliation rules do not apply)*
    - ***Question as to organizations that took employer tax credit***
- ***PPP Extension Act of 2021***
  - *Signed into law on 3/30 extends deadline to apply from 3/31/21 to 5/31/21*
- ***As of 5/4/21, PPP funding has been extinguished***

American Rescue Plan Act (ARPA) of 2021

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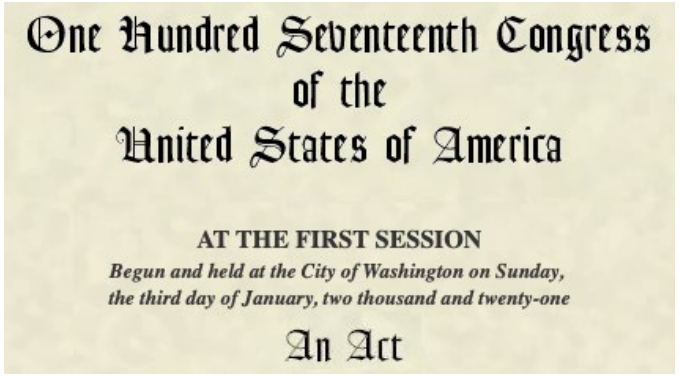
- **Financial Relief for Rural Providers**
  - $8.5B fund to reimburse rural healthcare providers for Covid-19 related expenses or lost revenue
    - Separate from, but similar to PRF
    - HHS must create process by which eligible providers will apply for funds which includes a statement from providers justifying need for payment
  - Definition of rural provider is broad and includes:
    - Located outside an MSA; or
    - Located in a rural census tract of an MSA; or
    - Located in area designated by the state as rural; or
    - Sole community hospital or rural referral center; or
    - Located in area that serves rural patients, such as a small MSA; or
    - A rural health clinic; or
    - Provide home health, hospice, or long-term services and supports in patients' homes that are located in rural areas; or
    - Otherwise qualify as a rural provider, as defined by the Health and Human Services (HHS) Secretary.



One Hundred Seventeenth Congress
of the
United States of America

AT THE FIRST SESSION

Begun and held at the City of Washington on Sunday, the third day of January, two thousand and twenty-one

An Act

To provide for reconciliation pursuant to title II of S. Con. Res. 5.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.
This Act may be cited as the "American Rescue Plan Act of 2021".

Source: American Hospital Association Summary of American Rescue Plan Act of 2021, March 17, 2021
https://www.aha.org/advisory/2021-03-17-summary-american-rescue-plan-act-2021-and-provisions-affecting-hospitals

ARPA of 2021 – Other Changes

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- **Vaccines/Testing**
  - $70B to fund Covid-19 vaccine, testing and workforce efforts
    - Includes $1B for rural Covid-19 Response
      - $460M to 4,600 RHCs "*to maintain and increase COVID-19 testing, expand access to testing for rural residents, and broaden efforts to mitigate the spread of the virus in ways tailored to their local communities*"
      - $398M to 1,730 SHIP eligible hospitals
        - *SHIP state grantees will use the funding to support all eligible rural hospitals, up to $230,000 per hospital*
          - *7/12 Update: some states have received more funds allowing $250K per hospital*
        - *The hospital must demonstrate that the related expense is directly and reasonably related to the provision of COVID-19 testing or COVID-19 mitigation activities.*
      - $100M in grants to fund RHC Vaccine Confidence (RHCVC) Program "to address health equity gaps by offering support and resources to medically underserved rural communities where COVID-19 vaccine uptake lags in comparison to populated areas
          - *"HRSA will fund all eligible RHCs that apply"*
        - NOFO issued 5/26 with application deadlines due 6/23
          - Period of performance 7/1/2021-6/30/2022
          - Approximate funding of $50K per RHC
          - HRSA will award grants to all eligible RHCs that submit an acceptable and fundable grant

Source: American Hospital Association Summary of American Rescue Plan Act of 2021, March 17, 2021
White House Fact Sheet, March 25, 2021 https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/25/fact-sheet-biden-administration-announces-historic-10-billion-investment-to-expand-access-to-covid-19-vaccines-and-build-vaccine-confidence-in-hardest-hit-and-highest-risk-communities/HHS Fact Sheet 5/5/2021 HHS Announces Nearly $1B

ARPA of 2021 – Other Changes

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- **Vaccines/Testing**
  - $70B to fund Covid-19 vaccine, testing and workforce efforts (continued)
    - Rural Health Clinic Covid-19 Vaccine Distribution (RHCVD) Program
      - Direct distribution of Covid-19 vaccines to RHCs to increase availability of vaccines in rural communities
      - *The RHCVD Program aims to improve COVID-19 vaccine access and vaccination rates to medically underserved rural communities.*
      - *Working in partnership with the Centers for Disease Control and Prevention (CDC), HRSA invites all Medicare-certified RHCs to join the RHCVD Program to directly receive federal vaccine allocations separate from jurisdictions' weekly allocations.*
      - *Through RHCVD program, HRSA is now able to ship 450 doses of the Pfizer vaccine, rather than the previous minimum of 1,170. Also, the storage requirements of the Pfizer vaccine have been updated to a longer shelf life without ultra- cold storage.*
  - $10B for activities under the Defense Production Act to manufacture and procure vaccines, supplies and equipment
    - Includes $6B investment in Community Health Centers to expand access to vaccines in underserved areas
      - "..deliver preventive and primary health care services to people at higher risk for COVID-19; and expand health centers' operational capacity during the pandemic and beyond, including modifying and improving physical infrastructure and adding mobile units."
      - HRSA will provide funding starting in April to nearly 1,400 centers across the country

Source: American Hospital Association Summary of American Rescue Plan Act of 2021, March 17, 2021
White House Fact Sheet, March 25, 2021 https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/25/fact-sheet-biden-administration-announces-historic-10-billion-investment-to-expand-access-to-covid-19-vaccines-and-build-vaccine-confidence-in-hardest-hit-and-highest-risk-communities/HHS Fact Sheet 5/5/2021 HHS Announces Nearly $1B

ARPA of 2021 – Other Changes (continued)

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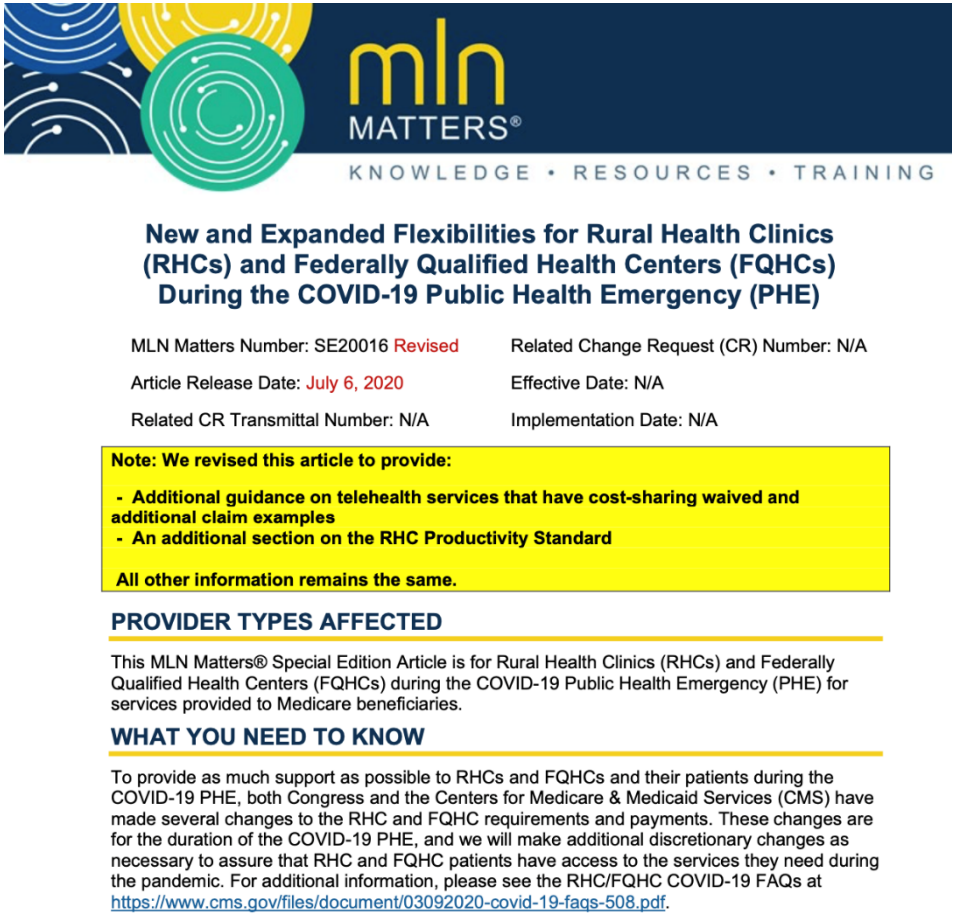
- **Vaccines/Testing**
  - Covid-19 Coverage Assistance Fund (CAF) – Announced 5/4/2021
    - Goal is to provide free access to Covid-19 vaccines for every adult living in US
    - CAF will cover the administering vaccines to patients whose health insurance doesn't cover vaccine administration fees or does but has patient cost sharing
    - Eligible providers will be reimbursed at national Medicare rates for vaccine administration fees, and for any patient cost sharing related to vaccination, including:
      - co-pays
      - deductibles, and
      - co-insurance
    - Necessary Actions:
      - Providers may enroll in the program through the HRSA COVID-19 Coverage Assistance Fund (CAF) Portal https://bit.ly/3aSyijU
      - After submitting a claim(s) for COVID-19 vaccine administration fees to patients' health plan carrier for payment, if the claim is either denied by that insurer or only partially paid, providers may then submit a claim(s) to the CAF Portal for payment consideration.
      - Claims are accepted via clearinghouses or through electronic or manual submissions via the CAF Portal.

Source: https://covid19coverageassistance.ssigroup.com/ 5/4/2021

RHC Productivity Waivers (7/6/2020)

- **Exception to the Productivity Standards for RHCs**
  - *Many RHCs have had to change the way they staff their clinics and bill for RHC services during the COVID- 19 public health emergency (PHE). As a result, these RHCs may have difficulty in meeting the productivity standards. To minimize the burden on RHCs, exceptions to the productivity standard may be granted by your MAC during the COVID-19 PHE. Further direction* will be forthcoming from your MAC.



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KNOWLEDGE • RESOURCES • TRAINING

New and Expanded Flexibilities for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) During the COVID-19 Public Health Emergency (PHE)

MLN Matters Number: SE20016 Revised | Related Change Request (CR) Number: N/A
Article Release Date: July 6, 2020 | Effective Date: N/A
Related CR Transmittal Number: N/A | Implementation Date: N/A

Note: We revised this article to provide:

- Additional guidance on telehealth services that have cost-sharing waived and additional claim examples
- An additional section on the RHC Productivity Standard

All other information remains the same.

PROVIDER TYPES AFFECTED

This MLN Matters® Special Edition Article is for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) during the COVID-19 Public Health Emergency (PHE) for services provided to Medicare beneficiaries.

WHAT YOU NEED TO KNOW

To provide as much support as possible to RHCs and FQHCs and their patients during the COVID-19 PHE, both Congress and the Centers for Medicare & Medicaid Services (CMS) have made several changes to the RHC and FQHC requirements and payments. These changes are for the duration of the COVID-19 PHE, and we will make additional discretionary changes as necessary to assure that RHC and FQHC patients have access to the services they need during the pandemic. For additional information, please see the RHC/FQHC COVID-19 FAQs at https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf.

Source: https://covid19coverageassistance.ssigroup.com/ 5/4/2021

Revenue Recognition: Possible Revenue Recognition Example

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CARES ACT COST REPORT/REVENUE RECOGNITION
CRITICAL ACCESS HOSPITAL EXAMPLE

ASSUMPTIONS:	
Pre Covid Revenue	$ 30,000,000
Pre Covid Expense	$ 30,000,000
Cost-Based Payer Mix	45%
Payroll Protection Funds Received	$ 3,000,000
PHSSEF Funds Received	$ 5,000,000
Covid Volume Change	-11%
Covid Related Capital Expense	$ 1,000,000
Change in Expense due to Covid	2%

Revenue:	Pre-Covid	PPP Funds (1)	Covid Exp Impact	Covid Rev Impact	Reduced Volume	
Cost Based	$ 13,500,000	$ -	$ -	$ 270,000	$ 13,770,000	(2)
Non Cost-Based	$ 16,500,000	$ -	$ -	$ (1,815,000)	$ 14,685,000	
Total Revenue	$ 30,000,000	$ -	$ -	$ (1,545,000)	$ 28,455,000	
Expenses:						
Cost-Based	$ 13,500,000	$ -	$ 270,000	$ -	$ 13,770,000	
Non Cost-Based	$ 16,500,000	$ -	$ 330,000	$ -	$ 16,830,000	
Total Expense	$ 30,000,000	$ -	$ 600,000	$ -	$ 30,600,000	
Net Margin:	$ -	$ -	$ (600,000)	$ (1,545,000)	$ (2,145,000)	
PHSSEF Funds Received					$ 5,000,000	
Covid Related Capital Expense (How will Cost-Based Portion be recognized?)					$ (1,000,000)	
Payroll Protection Funds Received					$ -	
Unused (Deficit of) PHSSEF Funds					$ 1,855,000	

(1) Updated guidance suggest PPP funds assumed NOT as a reduction in allowable cost base
(2) Cost-based revenue is equal to cost-based expense under any volume or expense scenario

Information related to the COVID-19 pandemic changes frequently. The content of this presentation is accurate to the best of our knowledge as of the day and time it was presented and will not be updated continuously once it is posted. Please reach out to the presenters with any questions or concerns.

LEGISLATIVE/REGULATORY UPDATES

Supreme Court Upholds Affordable Care Act (6/17/2021)

STROUDWATER

- The Supreme Court upheld the Affordable Care Act after Texas and other Republican-led states challenged its constitutionality
- While the plaintiffs argued that the issue of "severability" made the entire law unconstitutional after Congress repealed the individual mandate in 2017, the court voted 7-2 that the states had not been, and would not be, harmed by allowing more individuals gaining insurance coverage under the law
- Because the verdict was based on the plaintiff's standing, the court did not have to determine whether the law was severable
- A RAND Corp. analysis showed that eliminating the ACA would
  - **Cut the number of insured by 19.7 million**
  - **Increasing enrollees' average out-of-pocket costs by $4,000 - $7,400 annually**
  - **Drive up the federal deficit by $33.1 billion annually**

"With the penalty zeroed out, the IRS can no longer seek a penalty from those who fail to comply…Because of this, there is no possible government action that is causally connected to the plaintiffs' injury—the costs of purchasing health insurance."

Justice Stephen Breyer

Source: Modern Healthcare, *Affordable Care Act survives Texas' Supreme Court challenge*, Jessie Hellman, Michael Brady, Nona Tepper, 6/17/21 https://www.modernhealthcare.com/legal/affordable-care-act-survives-texas-supreme-court-challenge?utm_source=modern-healthcare-alert

Supreme Court Won't Hear Challenge to Site-Neutral Pay Policy (6/26/2021)

STROUDWATER

The Supreme Court declined to hear the latest challenge to HHS's site-neutral payment policy, meaning that the regulation stands. The Court did not issue a reason for its decision.

After being struck down in 2019, the regulation was upheld on appeal in 2020 when the panel said the cuts to off-site outpatient departments were legal because the changes were volume-control measures that don't have to be budget-neutral.

The AHA and AAMA pushed against the new policy, saying it could cost providers as much as $380M in 2019

Source: Modern Healthcare: *Supreme Court Won't Review HHS' site-neutral pay rule,* 6/28/21 https://www.modernhealthcare.com/legal/supreme-court-wont-review-hhs-site-neutral-pay-rule?utm_source=modern-healthcare-am-tuesday

Supreme Court to Hear Case on 340B Payment Cuts (7/05/2021)

STROUDWATER

The Supreme Court will hear case brought by AHA challenging HHS' cuts to 340B drugs administered in hospital outpatient setting

Two lower courts including the US District Court of Appeals ruled in favor of CMS

AHA argued that the lower courts allowed HHS to make changes to reimbursement rates for 340B hospitals that were beyond the scope of their authority

Source: Modern Healthcare: *Supreme Court Won't Review HHS' site-neutral pay rule,* 6/28/21 https://www.modernhealthcare.com/legal/supreme-court-wont-review-hhs-site-neutral-pay-rule?utm_source=modern-healthcare-am-tuesday

Interim Final Rule to Ban Surprise Billing (7/1/2021)

STROUDWATER

"No patient should forgo care for fear of surprise billing…Health insurance should offer patients peace of mind that they won't be saddled with unexpected costs. The Biden-Harris Administration remains committed to ensuring transparency and affordable care, and with this rule, Americans will get the assurance of no surprises."

HHS Secretary Xavier Becerra

On July 1, CMS unveiled an interim final rule banning surprise billing for emergency services and high out-of-network cost-sharing for emergency and non-emergency services

The rule also bans out-of-network charges for ancillary services as well as other out-of-network charges without advance notice. Health plans must reimburse for these services regardless of whether the provider is in-network or an emergency provider, and insurers cannot charge higher out-of-pocket costs for out-of-network providers.

This rule applies to providers, air ambulance providers, group health plans, health insurance issuers and Federal Employees Health Benefits Program carriers, and takes effect in 60 days

Per CMS, two-thirds of all bankruptcies in the U.S. are tied to medical expenses, and an estimated 1 in 6 emergency department visits result in an unexpected bill

Source: Modern Healthcare: *CMS bans surprise billing,* 7/1/21 https://www.modernhealthcare.com/finance/cms-bans-surprise-billing

Executive Order on Promoting Competition in the American Economy (7/9/2021)


THE WHITE HOUSE

MENU

BRIEFING ROOM

FACT SHEET: Executive Order on Promoting Competition in the American Economy

JULY 09, 2021 • STATEMENTS AND RELEASES

- Executive Order tackles four areas in healthcare (as well as other industries) where lack of competition increases prices and reduces access to quality care
  - Prescription Drugs
    - Safely import drugs from Canada
    - Increase support for generic and biosimilar drugs
    - HHS to develop plan to address price gouging
    - FTC to ban “pay for delay”
  - Hearing Aids
    - HHS to issue proposed rules for hearing aids to be sold over the counter
  - Hospitals
    - Encourages Justice Department and FTC to revise merger guidelines
    - Support existing price transparency rules and implement surprise hospital billing
  - Health Insurance
    - HHS to standardize plan options in the National Health Insurance Marketplace

Source: Executive Order on promoting competition in the American Economy https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/09/fact-sheet-executive-order-on-promoting-competition-in-the-american-economy/

CMS 2022 Inpatient Perspective Payment Proposed Rule (4/27/21)

STROUDWATER

- Payment Rate Update

PROPOSED FY 2022 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS				
FY 2022	**Hospital Submitted Quality Data and is a Meaningful EHR User**	**Hospital Submitted Quality Data and is NOT a Meaningful EHR User**	**Hospital Did NOT Submit Quality Data and is a Meaningful EHR User**	**Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User**
Proposed Market Basket Rate-of-Increase	2.5	2.5	2.5	2.5
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.625	-0.625
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-1.875	0	-1.875
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.2	-0.2	-0.2	-0.2
Proposed Applicable Percentage Increase Applied to Standardized Amount	**2.3**	**0.425**	**1.675**	**-0.2**

  - Payment increase of 2.3% for 2022 plus statutory increase of .5%
- Price Transparency
  - Repeal requirement that hospitals report median payer specific negotiated rates by MS-DRG with Medicare Advantage plans
- Disproportionate Share Payments
  - Distribute $7.6B, a reduction of $660M from 2021

Source: Beckers Healthcare: CMS' proposed inpatient payment rule for 2022: 8 things to know; CMS Fact Sheet, 4/27/2021

CMS 2022 IPPS Proposed Rule (4/27/21) (continued)

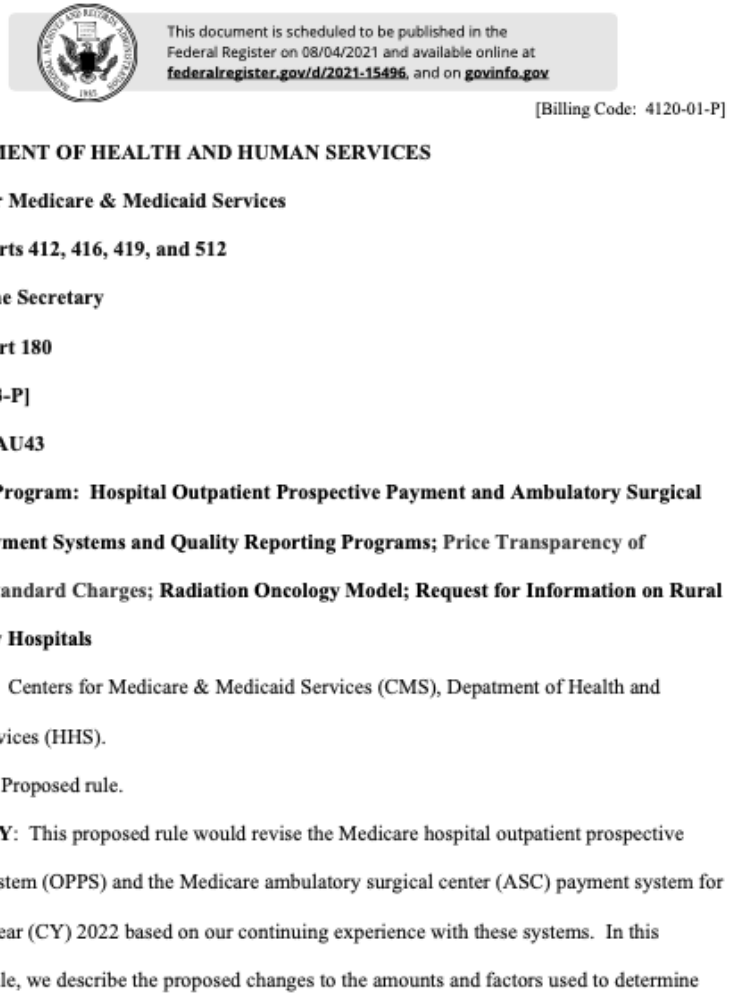
STROUDWATER

- Covid-19 Add-On Payment
  - Extend 20% add-on through end of fiscal year in which PHE ends
- Value Based Payment programs
  - Suppress VBP program measures during PHE
- Inpatient Quality Reporting
  - Add 5 new measures including Covid-19 vaccination rates among healthcare professionals
- Graduate Medical Education
  - Add 1,000 new Medicare funded medical residency slots, adding 200 slots a year beginning in FY 2023

Source: Beckers Healthcare: CMS' proposed inpatient payment rule for 2022: 8 things to know; CMS Fact Sheet, 4/27/2021

Calendar Year (CY) 2022 Medicare Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule (7/19/2021)

- On July 19th, CMS issued the CY2022 Medicare OPPS proposed rule that announces and solicits public comments on proposed policy changes for Medicare OPPS, on or after January 1, 2022
  - Comment period through 9/17/2021 with issuance of final rule in early November
- Key elements include:
  - Payment rate updates
  - Price transparency
  - Temporary polices for the public health emergency (PHE)
  - Rural Emergency Hospital (REH)
  - Inpatient Only list (IPO)
  - OPPS payment for 340B drugs



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[Billing Code: 4120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 416, 419, and 512

Office of the Secretary

45 CFR Part 180

[CMS-1753-P]

RIN 0938-AU43

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals

AGENCY: Centers for Medicare & Medicaid Services (CMS), Depatment of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for Calendar Year (CY) 2022 based on our continuing experience with these systems. In this proposed rule, we describe the proposed changes to the amounts and factors used to determine

Source: CMS CY 2022 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS-1753-P); https://www.cms.gov/newsroom/fact-sheets/cy-2022-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center

CY 2022 Medicare Hospital OPPS Proposed Rule (7/19/2021) (continued)

STROUDWATER

- Key elements include:
  - Payment Rate Updates
    - Update OPPS payment rates for hospitals meeting quality reporting requirements by 2.3%
      - Market basket of 2.5% less .2% productivity adjustment
  - Price Transparency
    - For non-compliance, proposed minimum civil monetary penalties beginning at $300/day for hospitals less than 30 beds, increasing by $10/bed/day not to exceed maximum of $5,500/day
      - Maximum annual penalty between $110K and $2.0M
    - Require that machine-readable file is accessible to automated searches and direct downloads
    - Online price tool estimator, in lieu of posting standard charges for 300 shoppable services, to provide a cost estimate to an individual that accounts for that individual's insurance information
    - Seeking comment on best practices for online price estimator tools, expectations related to "plain language", methods to identify and highlight best practices, etc.
  - Temporary Policies for the PHE for Covid-19
    - CMS seeking comment on whether stakeholders believe certain policies should be permanent
      - Mental health services billed by hospitals for services furnished in homes through communication technology
      - Presence of physicians for direct supervision of pulmonary and cardiac rehab to include virtual options (currently set to expire later of end of PHE or 12/31/21)

Source: CMS CY 2022 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS-1753-P); https://www.cms.gov/newsroom/fact-sheets/cy-2022-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center

CY 2022 Medicare Hospital OPPS Proposed Rule (7/19/2021) (continued)

STROUDWATER

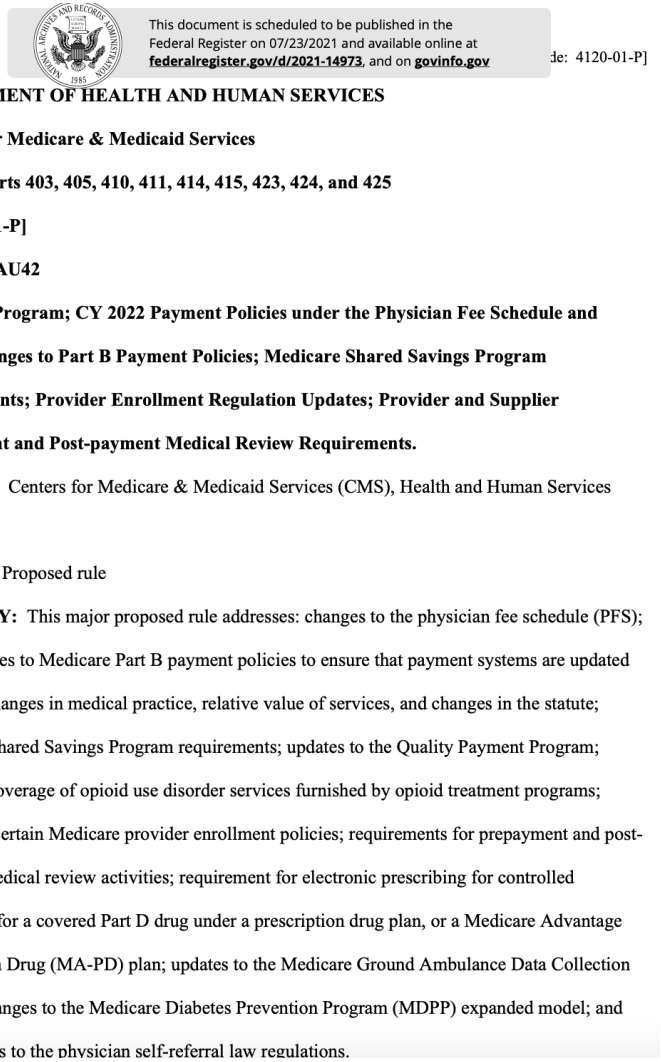
- Key elements include (continued):
  - Rural Emergency Hospital (REH)
    - Per the Consolidated Appropriations Act:
      - Facilities that convert from either a CAH or rural hospital with less than 50 beds, that do not provide acute care inpatient services, and are required to provide emergency department services and observation care
      - Payment based on 105% of APCs, plus fixed monthly payment
        - Fixed monthly payment will be calculated by (a) subtracting from the total amount paid to all CAHs in 2019 by the amount that would have been paid under PPS rates, (b) dividing that number by the total number of CAHS in 2019 (about 1,350), and (c) dividing that number by 12
    - CMS has included a Request for Information (RFI) to seek public input on a broad range of issues including health and safety standards, payment policies and quality measures
  - Inpatient Only (IPO) List
    - Proposing to halt the elimination of the IPO list, and add back the 298 services removed from the IPO during CY 2021
    - Codify the criteria for removal of procedures from the IP list
  - OPPS Payment for Drugs Acquired through the 340B Program
    - Maintain payment rate of ASP minus 22.5% for certain separately payable drugs acquired through the 340B program
    - Exempted from the program are rural sole community hospitals and CAHs

Source: CMS CY 2022 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS-1753-P), Fact Sheet; https://www.cms.gov/newsroom/fact-sheets/cy-2022-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center

Calendar Year (CY) 2022 Payment Policies under the Physician Fee Schedule (PFS) and other Part B Payment Policies (7/13/2021)

STROUDWATER

- CMS issued a proposed rule that announces and solicits public comments on proposed policy changes for Medicare payments under the PFS, and other Part B issues, on or after January 1, 2022.
  - Comment period through 9/13/2021
- Key elements include:
  - Conversion factor reduction from $34.89 in CY21 to $33.58 in CY22
  - Expansion of telehealth by allowing certain services added during the pandemic to remain until 12/31/23
    - Allows Medicare patients to access telehealth services from their homes
  - Physician Assistants would be able to bill Medicare directly for services and then reassign payment for services
  - MIPS performance threshold for allowing providers bonuses to be increased



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de: 4120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 405, 410, 411, 414, 415, 423, 424, and 425

[CMS-1751-P]

RIN 0938-AU42

Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements.

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

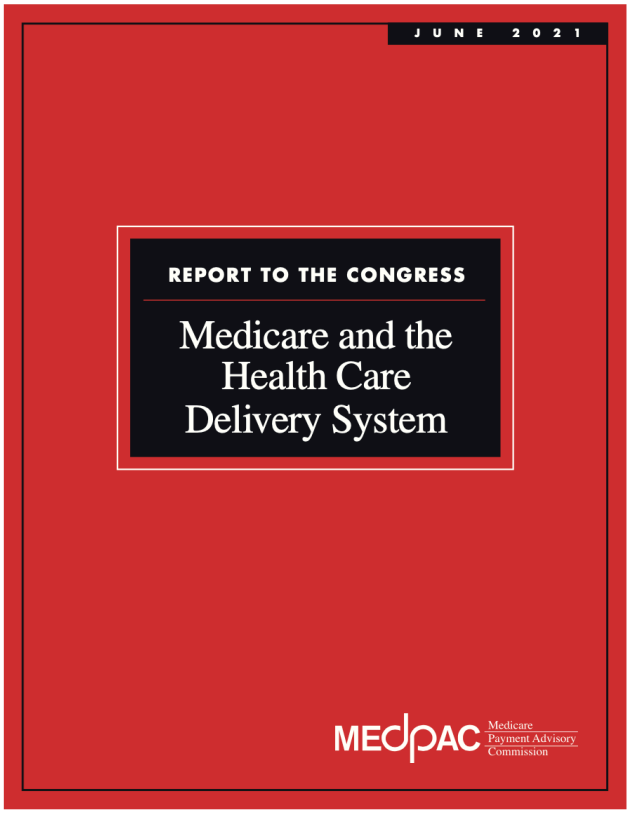
ACTION: Proposed rule

SUMMARY: This major proposed rule addresses: changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; Medicare Shared Savings Program requirements; updates to the Quality Payment Program; Medicare coverage of opioid use disorder services furnished by opioid treatment programs; updates to certain Medicare provider enrollment policies; requirements for prepayment and post-payment medical review activities; requirement for electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan, or a Medicare Advantage Prescription Drug (MA-PD) plan; updates to the Medicare Ground Ambulance Data Collection System; changes to the Medicare Diabetes Prevention Program (MDPP) expanded model; and amendments to the physician self-referral law regulations.

Source: Becker's Hospital CFO Report: CMS Pitches Physician payment rule for 2022: 9 things to know; July 14, 2021

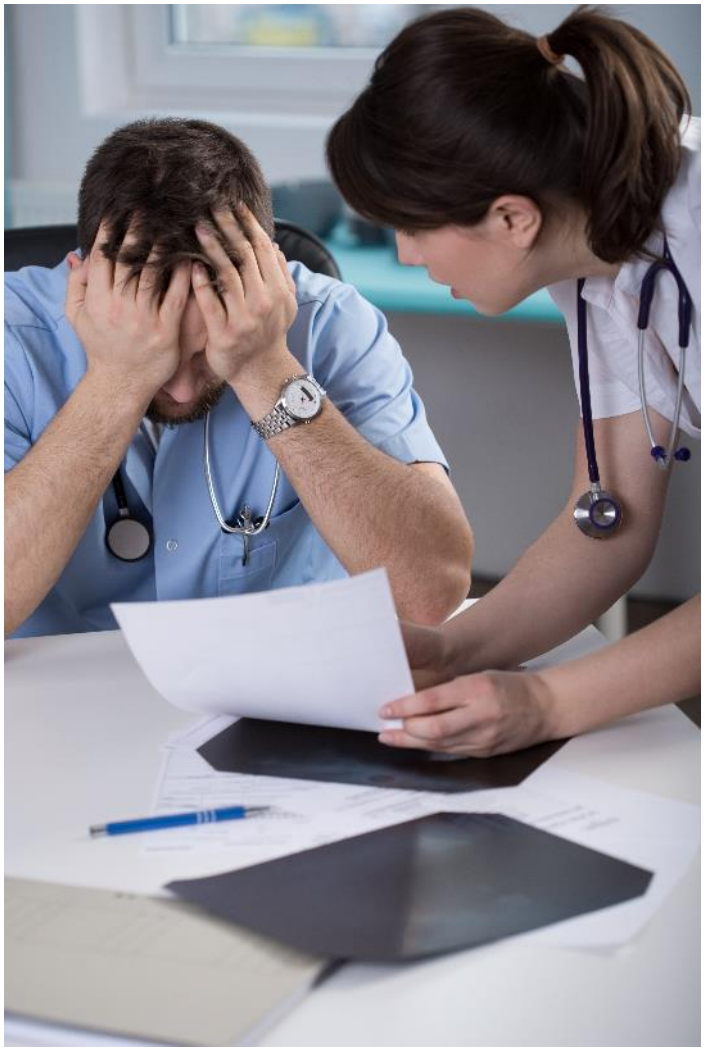
June 2021 MedPAC Annual Report: Major Considerations

- **Rebalance Medicare Advantage benchmark**
  - Require 2% discount
  - Uses a relatively equal blend of per capita local area FFS spending and standardized national FFS spending
- **Streamline portfolio of Alternative Payment Methods (APMs) and harmonize them Medicare Vaccine Coverage and Payment**
  - Medicare Part B to cover vaccine payment
  - Vaccine fee schedule changed from average wholesale price to 103% of average wholesale cost
- **Replace the SNF VBP with a Value Incentive Program**
- **Study of rural beneficiary access to care**
  - Rural and urban beneficiaries have comparable utilization
  - Rural hospital close primarily because patients opting to by-pass their local hospital for IP care
  - 4 drawbacks of cost-based payment including:
    - Does not prevent closures,
    - Distorts competition,
    - Benefits wealthier communities, and
    - Distorts incentives for cost control



Source: *Report to the Congress: Medicare and the Health Care Delivery System,* MedPAC, June 2021 http://www.medpac.gov/docs/default-source/reports/jun21_reporttocongress_sec.pdf?sfvrsn=0

CMS Issues First Round of Price Transparency Letters (5/6/21)



In April 2021, CMS issued its first round of warning letters to hospitals that did not comply with its price transparency rule, which took effect January 1.

Per the final rule, hospitals are required to post a "machine-readable" file online with the prices of its services and provide the prices of 300 shoppable services in a consumer-friendly format to allow consumers to make more informed choices.

Hospitals receiving warning letters will have 90 days to comply with the CMS requirement before they are reviewed again.

Hospitals that do not comply after the 90 days could face a fine of up to $300 per day and/or have their name publicized by CMS.

Source: Becker's Hospital Review, *Hospitals get 1st CMS warning on price transparency failure*, Alia Paavola, 5/7/21
https://www.beckershospitalreview.com/finance/hospitals-get-1st-cms-warning-for-noncompliance-with-price-transparency-rule.html?origin=CIOE

OTHER MARKET UPDATES

340B Program Drug Manufacturers' Actions

- July letter from Drug manufacturer Eli Lilly limiting 340B pricing to drug shipments directly to covered entities and not to contracted pharmacies beginning 9/1/2020
  - Drug manufacturers Merck and Sanofi directly communicated to hospital members requesting detailed information about 340B drugs distributed through contract pharmacies
- Actions in direct conflict with statute directing manufacturer to sell the drug at a price not to exceed the statutory 340B discount price
- HRSA evaluating options to address
- Significant efforts by AHA and NRHA to preserve access to 340B providers

Limited Distribution Plan Notice for Eli Lilly and Company Products

This notice provides information to 340B eligible covered entities seeking to purchase any product manufactured or distributed by Eli Lilly and Company or its subsidiaries and affiliates (labeler codes 00002, 00077, and 66713). Effective September 1, 2020, Lilly is limiting distribution of all 340B ceiling priced product directly to covered entities and their child sites only. Covered entities will not be eligible to purchase Eli Lilly and Company products at the 340B ceiling price for shipment to a contract pharmacy.

Covered entities that do not have an in-house pharmacy may contact 340B@lilly.com regarding the exception process to designate a contract pharmacy location.

Special Exception for Insulins: Contract Pharmacies that Pass on 340B Discounts

Consistent with the spirit of Executive Order 13,937, "Access to Affordable Life-saving Medications" (July 24, 2020), Lilly will grant an exception to the limited distribution program described above for Lilly insulin products (NDCs attached) subject to a 340B covered entity and their contract pharmacies' ability to ensure that the following conditions are met:

- Any and all 340B eligible patients will be able to acquire their Lilly insulins through the contract pharmacy at the 340B price (typically $.03 per 3 mL pen or $.10 per 10 mL vial) at the point-of-sale;
- Neither the covered entity nor the contract pharmacy marks-up or otherwise charges a dispensing fee for the Lilly insulin;
- No insurer or payer is billed for the Lilly insulin dispensed; and,
- The covered entity provides claim-level detail (CLD) demonstrating satisfaction of these terms and conditions.

Lilly shares the goal of ensuring that 340B patients directly benefit from the significant 340B discounts on Lilly insulins.

To take advantage of this exception for insulins contact 340B@lilly.com. Please be prepared to submit documentation demonstrating that the conditions set forth above will be satisfied.

Lilly is committed to compliance with the 340B statute and to responsible distribution of its products. If you have any questions regarding this notice please contact Lilly at 340B@lilly.com.

****

Source Eli Lilly Letter/AHA and NRHA letters to Secretary Azar

HSS Letter to Drug Manufacturers (6/16/21 update)

STROUDWATER

- 5/17 Letter from HHS to drug manufacturers instructing them to:
  - *"Begin offering covered OP drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through in-house pharmacy"*
  - *"Continued failure to comply could result in not to exceed penalty of $5,000 for each instance of overcharging"*
- On 5/20, Eli Lily requested to a federal court a preliminary injunction and temporary restraining order
- HHS requested the case be dismissed
- On 6/16, federal judge denied HHS request for dismissal
  - *"policy making is for Congress and not the courts"*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

May 17, 2021

Ms. Odalys Caprisecca
Executive Director, US Strategic Price & Operations
AstraZeneca Pharmaceuticals, LP
1800 Concord Pike
Wilmington, DE 19803

Dear Ms. Caprisecca:

The Health Resources and Services Administration (HRSA) has completed its review of AstraZeneca Pharmaceuticals, LP's (AstraZeneca) policy that places restrictions on 340B pricing to covered entities that dispense medications through pharmacies under contract, unless the covered entity lacks an in-house pharmacy. After review of this policy and an analysis of the complaints HRSA has received from covered entities, HRSA has determined that AstraZeneca's actions have resulted in overcharges and are in direct violation of the 340B statute.

For the reasons set forth above, AstraZeneca must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy. AstraZeneca must comply with its 340B statutory obligations and the 340B Program's CMP final rule and credit or refund all covered entities for overcharges that have resulted from AstraZeneca's policy. AstraZeneca must work with all of its distribution/wholesale partners to ensure all impacted covered entities are contacted and efforts are made to pursue mutually agreed upon refund arrangements.

Continued failure to provide the 340B price to covered entities utilizing contract pharmacies, and the resultant charges to covered entities of more than the 340B ceiling price, may result in CMPs as described in the CMP final rule. The CMP final rule states that any manufacturer with a PPA that knowingly and intentionally charges a covered entity more than the ceiling price for a covered outpatient drug may be subject to a CMP not to exceed $5,000 for each instance of overcharging.[3] Assessed CMPs would be in addition to repayment for an instance of overcharging as required by section 340B(d)(1)(B)(ii) of the PHS Act. The Department of Health and Human Services will determine whether CMPs are warranted based on AstraZeneca's willingness to comply with its obligations under section 340B(a)(1) of the PHS Act.

Source HHS Letter to Drug Manufactures 5/17; Fierce Healthcare update on 5/24

New CMMI Director Dr. Liz Fowler on "Strategic Refresh" (4/25/21)

STROUDWATER

"WE NEED TO FIND A WAY TO BRING EVERYONE ALONG. WE CAN'T HAVE FEE-FOR-SERVICE REMAIN A COMFORTABLE PLACE TO STAY."

"We need to have a clear path for the innovators who are ready and willing and able to take on…risk, but I think we also need to push the laggards and then we need to reach those who have challenges participating….It may not be one-size-fits-all."

On CMMI innovation models: "A lot of what we've done has been aimed toward certification of models to become a permanent part of Medicare….In trying to get a model certified, it really does suggest a very specific model and a very specific way of thinking about evaluations and the assessment by actuaries. I wonder if we can instead think about the overall goal being transformation of the system instead of certification, or both."

CMS Center for Medicare & Medicaid INNOVATION

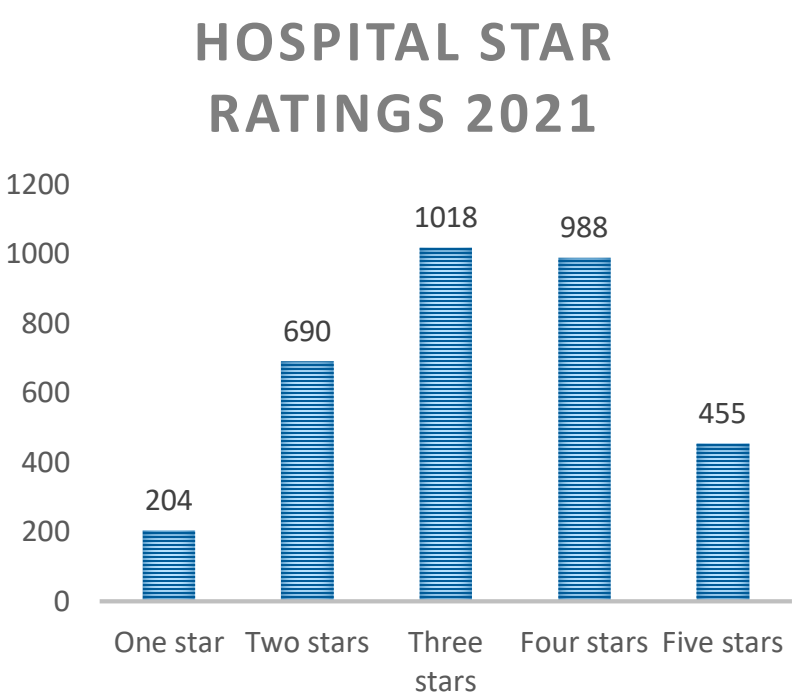
Fowler asked for patience **"as we take time to review the portfolio of models, make adjustments where necessary and make sure that our path forward is sustainable and meaningful."**

Source: HFMA.org, *Why the federal agency that oversees healthcare payment innovation is rethinking its approach,* Nick Hut, 4/26/21 https://www.hfma.org/topics/news/2021/04/why-the-federal-agency-…utm_source=rasa_io&PostID=29248522&MessageRunDetailID=5032322143

Acute-care Hospitals Score Higher Under New Star Rating Methodology (4/27/21)

STROUDWATER

- CMS has assigned new star ratings based on its updated scoring methodology, which is based on 48 measures across the categories of mortality, safety of care, readmission, patient experience, and timely and effective care.
  - Previous methodology scored based on 65 measures across 7 categories.
- Under the new system, **nearly one third of hospitals scored higher, 45% received the same score, and 22% scored lower than before.**
- The new system is intended to show hospital quality and safety more clearly after strong objection to the previous system.
- **Under the current formula, each measure is weighted equally, and hospitals are grouped by how many measures they report.**

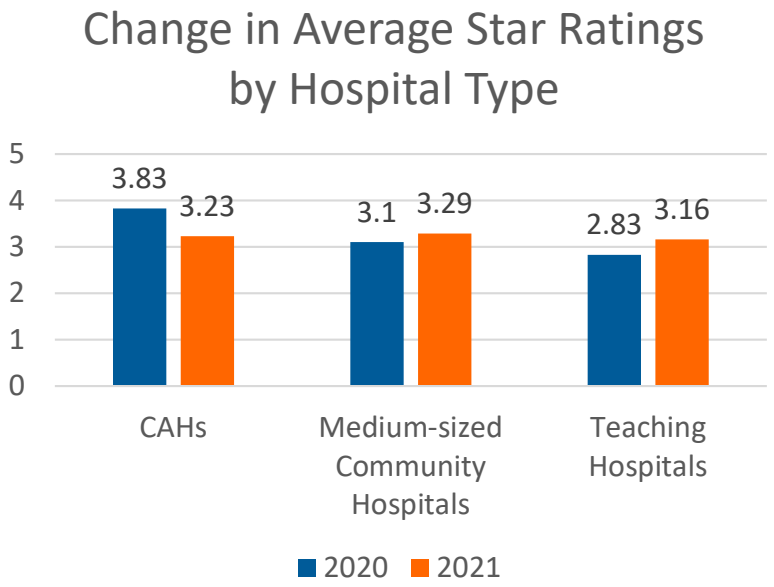


Sources: Modern Healthcare, *Acute-care hospitals see higher star ratings on new CMS methodology,* Lisa Gillespie, 4/28/21 https://www.modernhealthcare.com/safety-quality/acute-care-hospitals-see-higher-star-ratings-new-cms-methodology; Becker's Hospital Review, *CMS star ratings are out: 4 things to know,* Erica Carbajal, 4/28/21 https://www.beckershospitalreview.com/rankings-and-ratings/cms-star-ratings-are-out-4-things-to-know.html?origin=RCME

Affects of New Star Rating Methodology on Critical Access Hospitals (CAHs) (4/27/21)

STROUDWATER

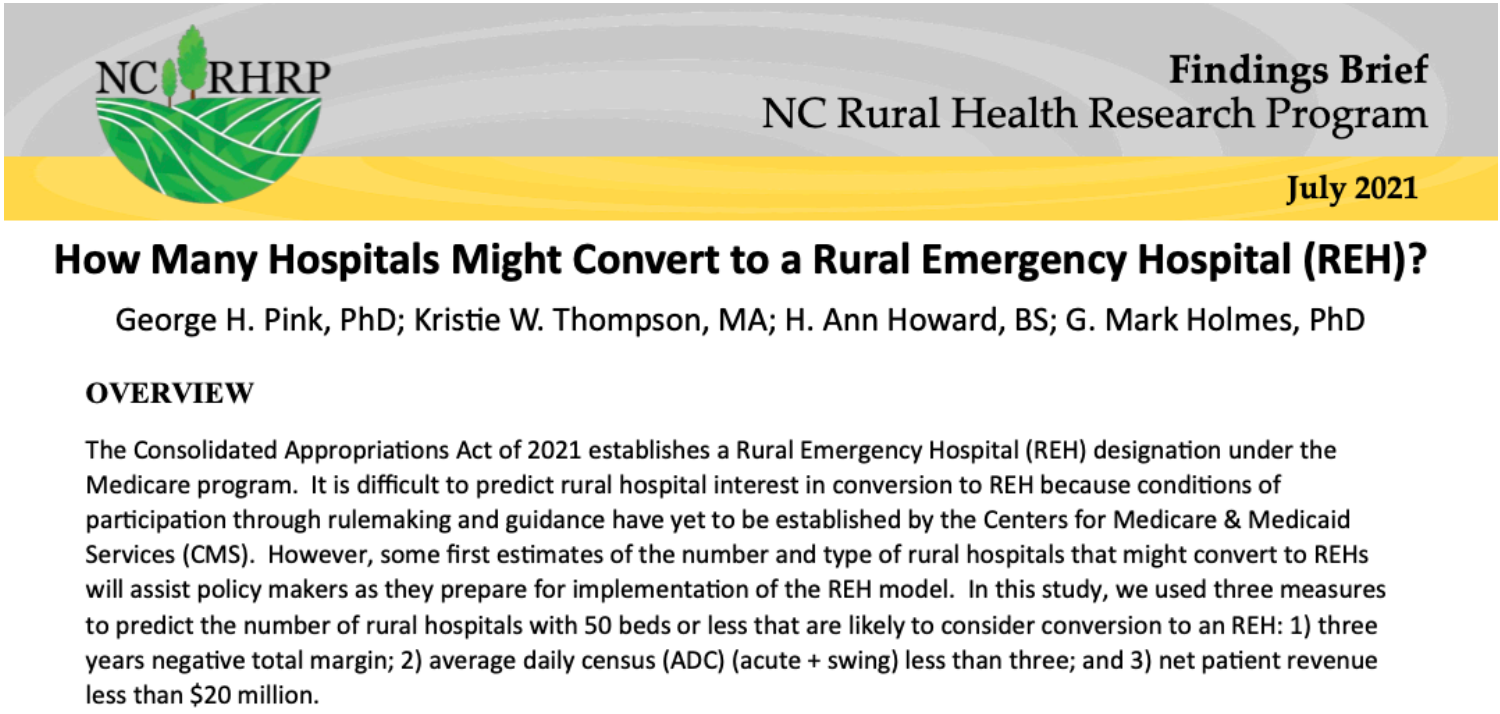
- **CAHs saw a significant decrease in star ratings, raising the question of whether the new system represents CAH quality accurately**
  - Only 76.3% scored 3 or more stars under the new methodology, down from 94.3%
- CAHs also saw a decline in the percentage of 4-star ratings, while acute-care hospitals saw a slight increase in the percentage of 4- and 5-star ratings.
- **Some hospitals may have scored lower due to measures in which they excel no longer being counted.**



- Since hospitals are now scored on how many measures they can report based on patient volume, **low volume (always an issue for CAHs) may be to blame for the low scores.**
- CAH participation in the rating system is voluntary, and some CAHs have opted out this year.
- Industry leaders had mixed reactions to the updated methodology, calling it an improvement but citing the need for further update.

Sources: Modern Healthcare, *Acute-care hospitals see higher star ratings on new CMS methodology,* Lisa Gillespie, 4/28/21 https://www.modernhealthcare.com/safety-quality/acute-care-hospitals-see-higher-star-ratings-new-cms-methodology; Becker's Hospital Review, *CMS star ratings are out: 4 things to know,* Erica Carbajal, 4/28/21 https://www.beckershospitalreview.com/rankings-and-ratings/cms-star-ratings-are-out-4-things-to-know.html?origin=RCME; Modern Healthcare, *From 4s to 1s: critical access hospitals grapple with new star methodology,* Lisa Gillespie, 5/5/21 https://www.modernhealthcare.com/safety-quality/4s-1s-critical-access-hospitals-grapple-new-star-methodology?utm_source=modern-healthcare-am-Thursday

Limited Number of Hospitals Anticipated to Convert to Rural Emergency Hospital (REH) (July 2021)



NC RHRP

Findings Brief
NC Rural Health Research Program

July 2021

How Many Hospitals Might Convert to a Rural Emergency Hospital (REH)?

George H. Pink, PhD; Kristie W. Thompson, MA; H. Ann Howard, BS; G. Mark Holmes, PhD

OVERVIEW

The Consolidated Appropriations Act of 2021 establishes a Rural Emergency Hospital (REH) designation under the Medicare program. It is difficult to predict rural hospital interest in conversion to REH because conditions of participation through rulemaking and guidance have yet to be established by the Centers for Medicare & Medicaid Services (CMS). However, some first estimates of the number and type of rural hospitals that might convert to REHs will assist policy makers as they prepare for implementation of the REH model. In this study, we used three measures to predict the number of rural hospitals with 50 beds or less that are likely to consider conversion to an REH: 1) three years negative total margin; 2) average daily census (ADC) (acute + swing) less than three; and 3) net patient revenue less than $20 million.

- NC Rural Health Research Program studied hospitals likely to convert to REH based on a number of predictive criteria including long-term profitability, acute and swing bed ADC less than 3, and revenue of less than $20M
  - 68 hospitals were identified as potential converters, of which 56 were CAHs
  - States with most potential converters include KS, TX, NE, OK, and IA

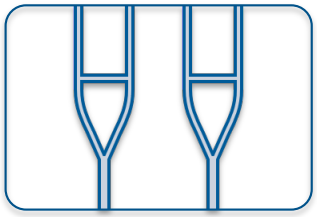
Source NC Rural Health Research Program

UnitedHealth Ends Non-Emergency Coverage at Out-of-Network Facilities (7/1/2021)

STROUDWATER

Following a trend of insurers tightening their belts and lowering reimbursement, major insurer UnitedHealth Group announced that it will no longer cover non-emergency services at out-of-network facilities

In a statement, UnitedHealthcare urged its 49.4M enrollees to seek care within its large provider network for lower costs



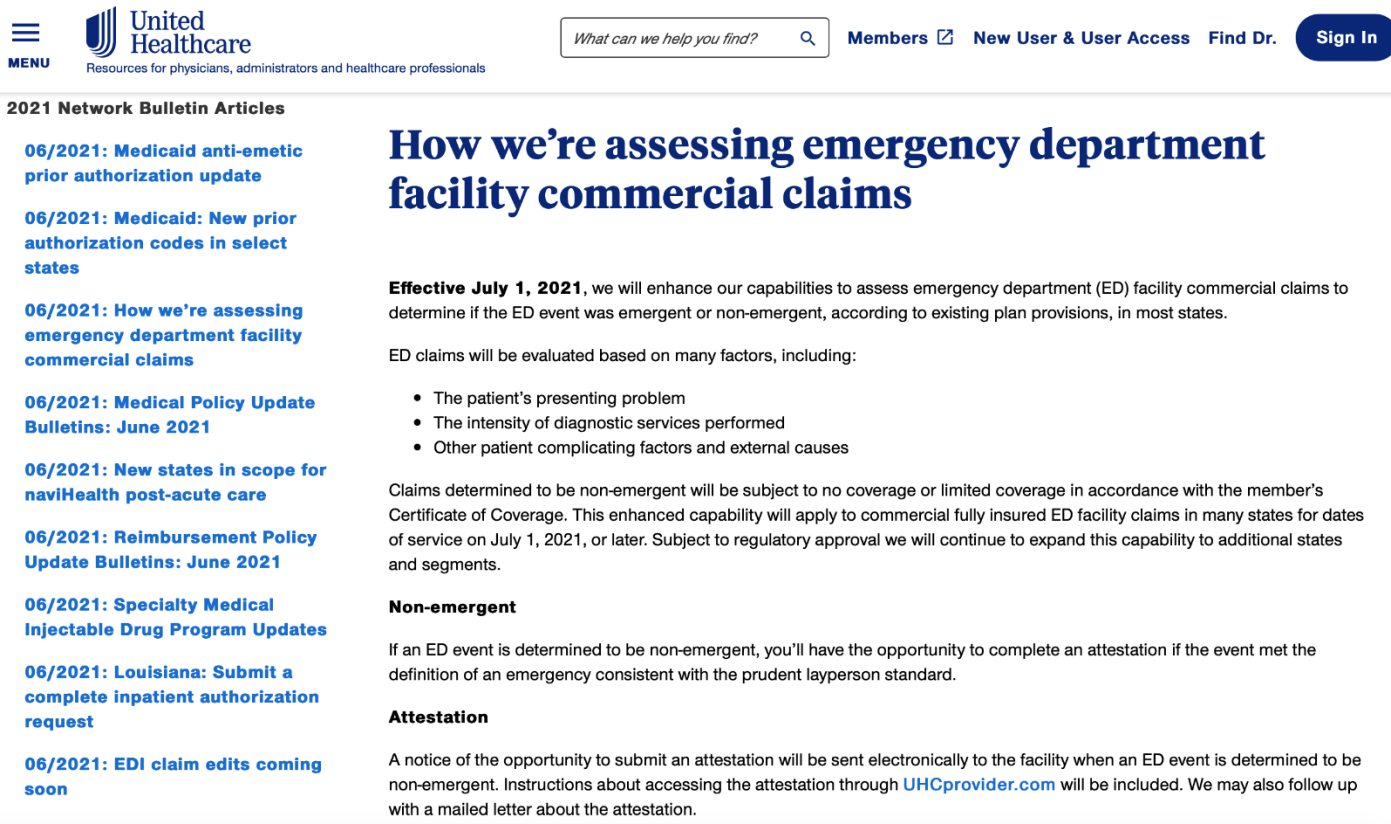
The new policy could affect members seeking services such as addiction treatment or rehabilitation following surgery

UnitedHealth Group has faced several challenges in court recently, including from a plastic surgery group accusing it of denying legally required coverage to cancer survivors and a laboratory alleging denied claims for COVID-19 tests

Source: Modern Healthcare: *New UnitedHealth policy ends some non-emergency coverage*, 7/2/21 https://www.modernhealthcare.com/insurance/new-unitedhealth-policy-ends-some-non-emergency-coverage?utm_source=modern-healthcare-am-tuesday

United Healthcare Emergency Department Denials (6/4/2021)

- UnitedHealthcare Bulletin
  - New policy beginning July 1 whereby ED claims will be evaluated for appropriateness
  - On June 10th, after outcry from providers, UH delays implementation until the pandemic has passed – but still plans to implement



MENU

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2021 Network Bulletin Articles

- 06/2021: Medicaid anti-emetic prior authorization update
- 06/2021: Medicaid: New prior authorization codes in select states
- 06/2021: How we're assessing emergency department facility commercial claims
- 06/2021: Medical Policy Update Bulletins: June 2021
- 06/2021: New states in scope for naviHealth post-acute care
- 06/2021: Reimbursement Policy Update Bulletins: June 2021
- 06/2021: Specialty Medical Injectable Drug Program Updates
- 06/2021: Louisiana: Submit a complete inpatient authorization request
- 06/2021: EDI claim edits coming soon

How we're assessing emergency department facility commercial claims

Effective July 1, 2021, we will enhance our capabilities to assess emergency department (ED) facility commercial claims to determine if the ED event was emergent or non-emergent, according to existing plan provisions, in most states.

ED claims will be evaluated based on many factors, including:

- The patient's presenting problem
- The intensity of diagnostic services performed
- Other patient complicating factors and external causes

Claims determined to be non-emergent will be subject to no coverage or limited coverage in accordance with the member's Certificate of Coverage. This enhanced capability will apply to commercial fully insured ED facility claims in many states for dates of service on July 1, 2021, or later. Subject to regulatory approval we will continue to expand this capability to additional states and segments.

Non-emergent

If an ED event is determined to be non-emergent, you'll have the opportunity to complete an attestation if the event met the definition of an emergency consistent with the prudent layperson standard.

Attestation

A notice of the opportunity to submit an attestation will be sent electronically to the facility when an ED event is determined to be non-emergent. Instructions about accessing the attestation through UHCprovider.com will be included. We may also follow up with a mailed letter about the attestation.

Source Eli Lilly Letter/AHA and NRHA letters to Secretary Azar

UnitedHealth Buys OptumCare (4/23/21)

STROUDWATER

"When you begin to pencil out the math, as we move people into value-based arrangements, that will be a major driver of how we'll move to a $100 billion book of business."

OptumHealth CEO
Wyatt Decker, MD

Managed care company UnitedHealth Group has purchased OptumCare, which comprises 56,000 physicians and 1600 clinics, and plans to grow it to a $100B business through value-based arrangements.

Per OptumHealth (OptumCare parent) CEO Dr. Wyatt Decker, under the new arrangement, physicians will be paid to keep patients healthy instead of for treating them when they are sick.

OptumCare is also launching a virtual care platform called Optum Virtual Care that supports its plan to integrate virtual care, home care, and care clinics across all 50 states.

Source: Becker's Hospital Review, *How UnitedHealth plans to make Optum a $100B business,* Ayla Ellison, April 23, 2021, https://www.beckershospitalreview.com/finance/how-unitedhealth-plans-to-make-optum-a-100b-business.html?origin=CIOE

Amazon Expands Amazon Care, Moving Into Primary Care Outside Its Workforce (6/11/21 update)

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- Amazon announced the expansion of Amazon Care, its first primary care offering accessible by non-Amazon employees.
- Until now, Amazon Care has been available only to Amazon employees in Washington State. It is now available to employees in every state and will be available to non-Amazon nationwide later this year.
- Amazon care has two components
  - Telemedicine
  - In-person care, where a professional is dispatched to a patient's home
- Per its news release, **"Amazon Care gives instant access to a range of urgent and primary care services, including COVID-19 and flu testing, vaccinations, treatment of illnesses and injuries, preventive care, sexual health, prescription requests, refills, and delivery, and much more."**
- June 11th Update (Fierce Healthcare): Amazon reports having signed multiple corporate accounts as part of national expansion of Amazon Care

Source: https://www.aboutamazon.com/news/workplace/amazon-care-to-launch-across-u-s-this-summer-offering-millions-of-individuals-and-families-immediate-access-to-high-quality-medical-care-and-advice-24-hours-a-day-365-days-a-year; https://www.modernhealthcare.com/information-technology/amazon-jumps-healthcare-telemedicine-initiative?utm_source=modern-healthcare-am-Thursday; https://www.beckershospitalreview.com/strategy/amazon-care-has-its-first-enterprise-client.html

Walmart Telehealth Offering with MeMD Acquisition (5/6/21)

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- Joining other major retailers such as CVS and Amazon, Walmart has acquired telehealth provider MeMD to expand its telehealth services.
- The acquisition is still pending regulatory approval.
- Founded in 2010, MeMD currently provides medical and mental health visits to 5 million members across the U.S.
- Among other healthcare ventures, Walmart currently operates and/or provides:
  - Walmart Health Centers within its stores
  - Freestanding health centers in Georgia, Texas, Arkansas and Chicago
  - Direct-to-consumer telehealth through purchased app Ro
  - Telehealth partnership with Doctor on Demand to offer services to its 1.3 million workers at a reduced price
- July 19th Update: Walmart has filed paperwork to operate its healthcare business in 37 states, an increase of 17 states

"Today people expect omnichannel access to care and adding telehealth to our Walmart Health care strategies allows us to provide in-person and digital care across our multiple assets and solutions."

Cheryl Pegus, MD, executive vice president of health and wellness at Walmart

Source: Becker's Hospital Review, *Walmart to bring telehealth nationwide with acquisition of MeMD: 8 details,* Jackie Drees and Hannah Mitchell, 5/6/21 https://www.beckershospitalreview.com/telehealth/walmart-health-to-acquire-telehealth-provider-6-details.html?origin=CIOE

Privia Enters Public Market with Outsized $778 IPO (5/4/21)

- Physician enablement platform Privia Health launched its IPO, aiming to raise $516M but soaring to $778M instead.
  - Privia joins several other health tech startups, including Agilon Health and VillageMD, that have joined the public market recently.
- Privia owns and manages medical groups that include over 2770 providers, operates 650 care centers across the country, and reports $430M in annual shared savings.
  - The company says it aims to transition to value-based relationships.
- About 90% of Privia's revenue came from fee-for-service contracts, with $93 million from recurring per member per month cash and shared savings with providers.
- The company has expressed interested in direct contracting and was included in a letter by several similar firms asking CMMI to allow new applicants to its Direct Contracting program.

QUESTIONS?

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