Coastal Carolinas Health Alliance Medicare Update: Day 1

FY2022 IPPS Updates, Medical Necessity, Utilization Review, and other Medicare Updates

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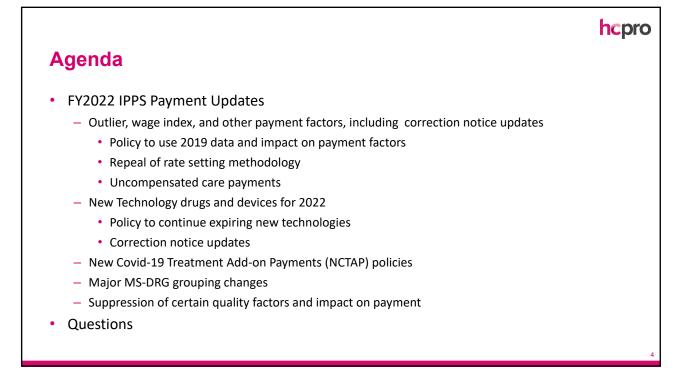
Presented By Simperfy Anderwood Hoy, JD, CPC Wimberly State Simperfy Anderwood Hoy, JD, CPC Simperfy State Simperfy State Simperfy State Simperfy State Simperfy State Simplify Compliance, LLC. She oversees HCPro's Medicare

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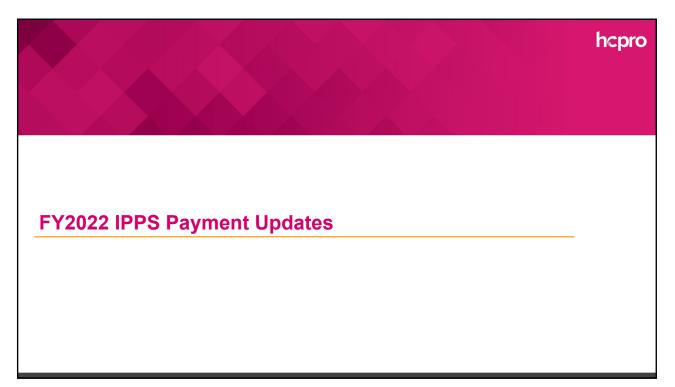
Learning Objectives

- At the completion of this educational activity, the learner will be able to:
- Discuss CMS rate setting changes for 2022 and how they affect New Technology
- Identify proper post-acute care transfer rule coding for home health transfers
- Review two situations where a physician certification applies to an inpatient stay



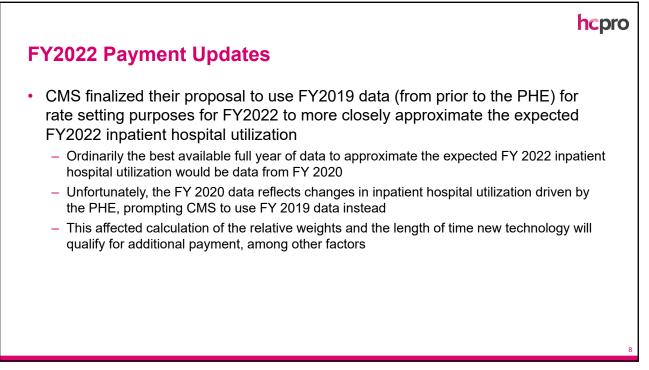
Agenda

- Transfers and Post-Acute Care Transfers
 - Updated guidance in Special Editions and revised Manual
 - OIG focus on home health transfers
- Repeal of MCIT and 'Reasonable and Necessary" rule incorporating private insurance BREAK
- Regroup on Utilization Review
 - Certification requirements for long stays, outliers, and no available SNF bed
 - Short stay review guidance from reversal of IPO list elimination
 - QIO Short Stay Reviews and audit strategies and exemption from denial
 - Observation as basis of admission and the inpatient level of care myth
 - OIG's reviews and observation outliers
 - Leveraging self-denials to save UR resources



Source Authority

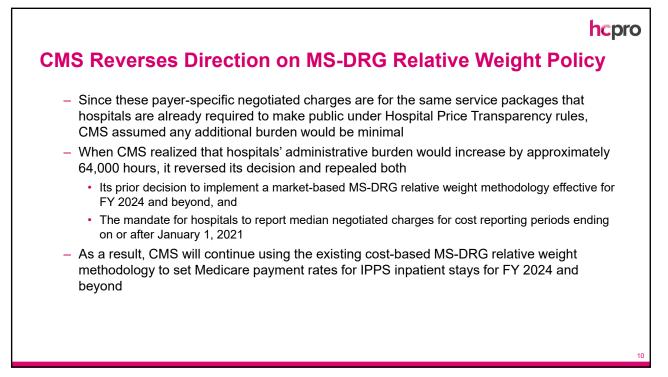
- IPPS final rule is effective October 1 each year
 - FY 2022 IPPS Proposed Rule
 - 86 Fed. Reg. 25070–25790
 - FY 2022 IPPS Final Rule
 - 86 Fed. Reg. 44774–45615
 - FY2022 IPPS Final Rule, correction and correcting amendment
 - 86 Fed. Reg. 58019-58039
 - FY2022 IPPS Final Rule, correction (to the correction and correcting amendment)
 - 86 Fed. Reg. 67874–67876
 - FY 2022 IPPS Tables
 - CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/AcuteInpatientPPS/index.html
 - Click on the link on the left side of the screen titled, "FY 2022 IPPS Final rule Home Page" or "Acute Inpatient—Files for Download."



CMS Reverses Direction on MS-DRG Relative Weight Policy

- CMS currently uses chargemaster (gross) rates to calculate MS-DRG relative weights
 - This requires CMS to first reduce average gross charges for all discharges assigned to the same MS-DRG to costs by multiplying them by national average cost-to-charge ratios
 - Based upon concerns that this methodology may result in inflated payment rates, in the FY 2021 IPPS final rule
 - CMS changed the methodology for calculating future relative weights, shifting from gross charges to market-based information for FY 2024 and beyond
 - To obtain relevant market-based information, CMS also mandated that hospitals report median payer-specific negotiated charges (by MS-DRG) which the hospital negotiated with Medicare Advantage (MA) payers on their Medicare cost reports for cost reporting periods ending on and after January 1, 2021





Payment Factors: Final FY 2022 Operating Standard Amount (OSA)

Overall 2.5% increase to IPPS operating rates

Summary

+2.7% – Market basket increase

-0.7% – ACA multifactor productivity reduction

+2.0% -- Adjusted market basket update before coding/documentation adj

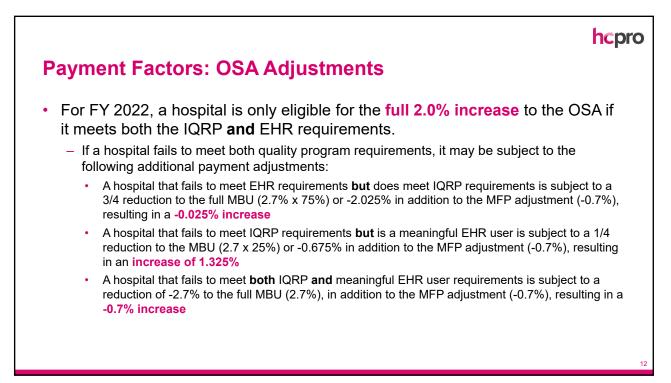
+0.5%* - Coding and documentation adjustment

2.5%** – Adjusted market basket update after coding/documentation adj

*This adjustment, however, does not appear to be factored into the % increases to the IPPS operating payment, as reflected in the respective labor and non-labor related OSAs set out in <u>Tables 1A and 1B</u>

**Assuming hospital met IQRP and EHR (MPIP) requirements





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
Market Basket Increase	2.7	2.7	2.7	2.7
Failed to submit quality data	0	0	-0.675	-0.675
Failed to meet EHR requirements	0	-2.025	0	-2.025
MFP adjustment	-0.7	-0.7	-0.7	-0.7
% increase to OSA	2.0	-0.025	1.325	-0.7

FY 2022 PERCENTAGE INCREASES FOR THE IPPS OPERATING PAYMENT

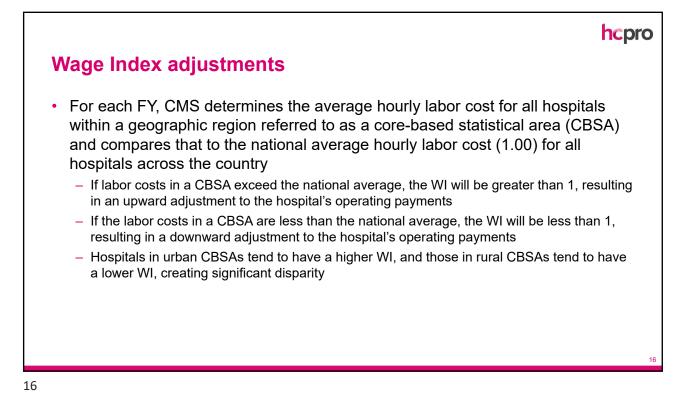
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Depres Payment Factors: Adjustments to Hospital-Specific Rates • For FY 2022, the hospital-specific rates for sole community hospitals (SCH, based on highest rate from 1982, 1987, 1996, or 2006) and Medicare dependent hospitals (MDH, based on highest rate from base years 1982, 1987, or 2002) will be subject to the same OSA adjustments as those that apply to other IPPS hospitals • In particular, SCHs and MDHs are subject to applicable reductions for failure to meet IQRP and/or EHR requirements

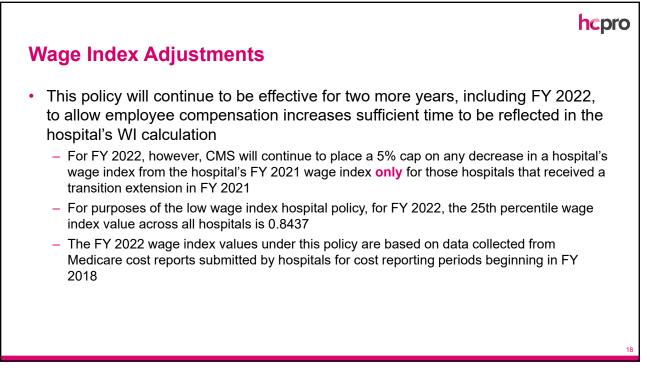
Payment Factors: Wage Index

- Applicable wage indices for all urban and state-wide rural CBSAs are set out in Tables 3 to the FY 2022 IPPS final rule
 - The first step in calculating the MS-DRG operating payment for a specific hospital discharge is to wage-index adjust the labor-related portion of the hospital's OSA
 - Each year CMS determines what the respective labor-related portion of the OSA will be for IPPS hospitals, depending upon whether the hospital's wage index is greater than or equal to (or less than) 1
 - For those hospitals with a wage index greater than 1, the labor-related portion will be 67.6%, which is a downward adjustment from 68.3% in FY 2021
 - For those hospitals with a wage index of 1 or less, the labor-related portion will remain at 62%



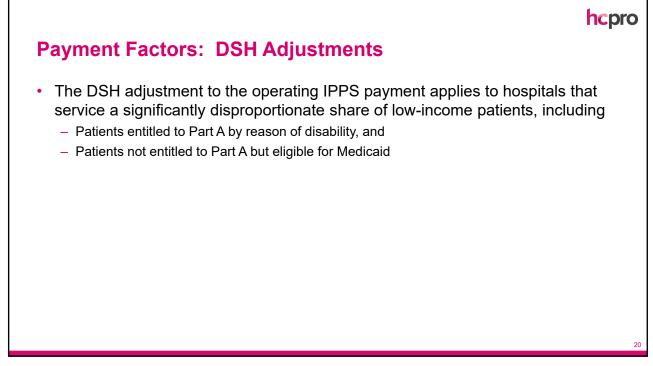
Wage Index Adjustments

- Under the FY 2020 IPPS final rule, CMS implemented the following changes, to be effective for at least 4 years, beginning in FY 2020
 - Adjustments increasing the WI of hospitals with a WI value below the 25th percentile, beginning with FY 2020
 - CMS will increase the WI of hospitals with a WI value below the 25th percentile WI value for a FY by half the difference between the otherwise applicable final WI value for that hospital and the 25th percentile WI value for that FY
 - A budget neutrality adjustment to the operating standardized amount applied across all IPPS hospital
 - To ease the effect of the transition on hospitals with higher wage indices, a 5-percent cap for FY 2020 on any decrease in a hospital's WI from its final WI for FY 2019



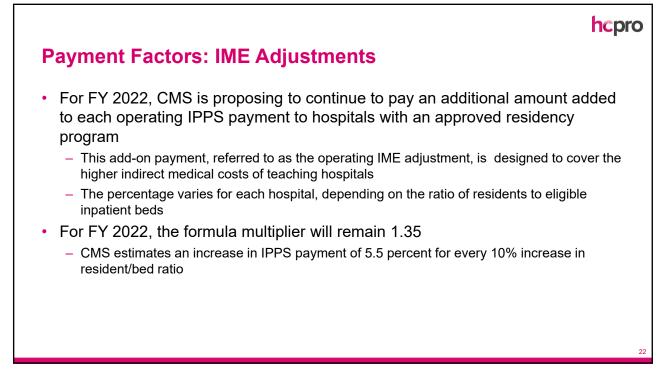
Wage Index Adjustments

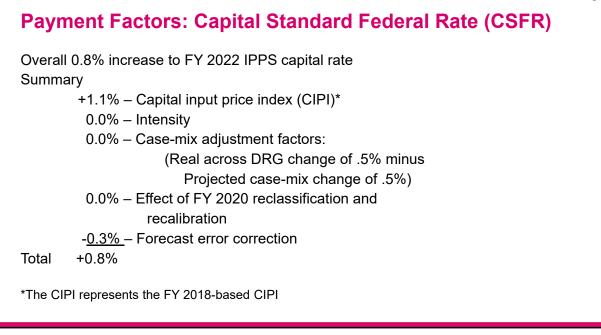
- Other wage-index related policies for FY 2022 include
 - Reinstatement of the imputed floor wage index policy for all-urban states effective for discharges on or after October 1, 2021 (FY 2022) with no expiration date
 - This policy will not, however, be applied in a budget neutral manner, and
 - Continuation of certain ongoing wage-index adjustment policies (rural floor, state frontier floor and outmigration adjustment based on commuting patterns of hospital employees) without change

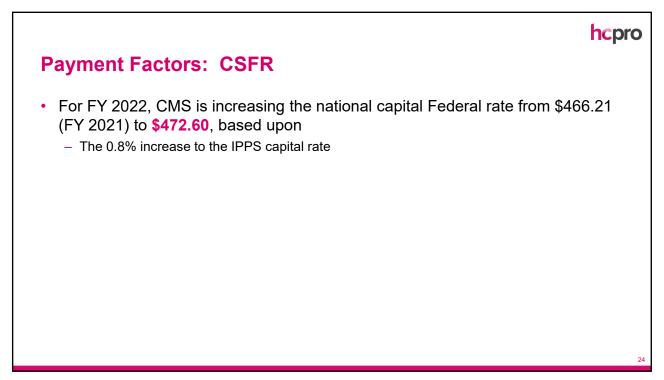


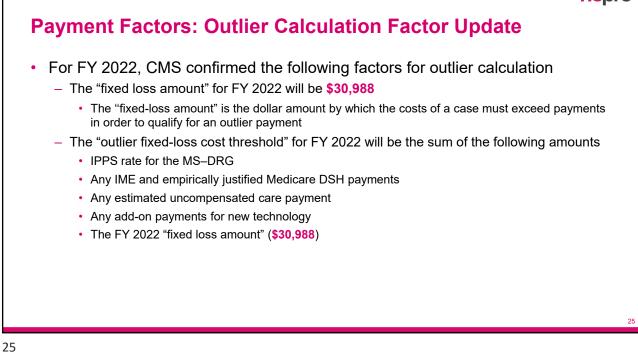
Payment Factors: DSH Adjustments

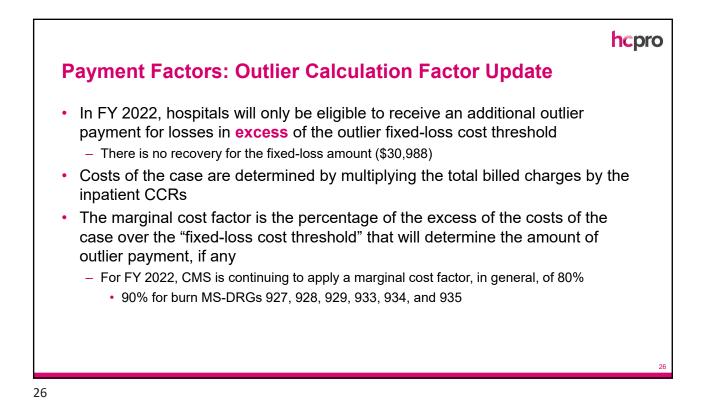
- For FY 2022, the DSH adjustment to the IPPS operating payment has two components
 - A per-discharge adjustment of 25% of what the DSH adjustment would have been under the prior calculation PLUS
 - An additional uncompensated care payment that is the product of three factors
 - CMS' estimate of 75% of estimated DSH payments for 2022, based on the old calculation (\$10,488,564,546.74)
 - An adjustment of **68.57%**, to account for changes in uninsured and under-insured patients,
 - The hospital's % of uncompensated care compared to uncompensated care for all DSH hospitals (\$7,192,008,709.70)
 - CMS will use FY 2018 Worksheet S-10 cost report data in the calculation of hospital's % of uncompensated care for all hospitals except IHS, Tribal and Puerto Rico hospitals



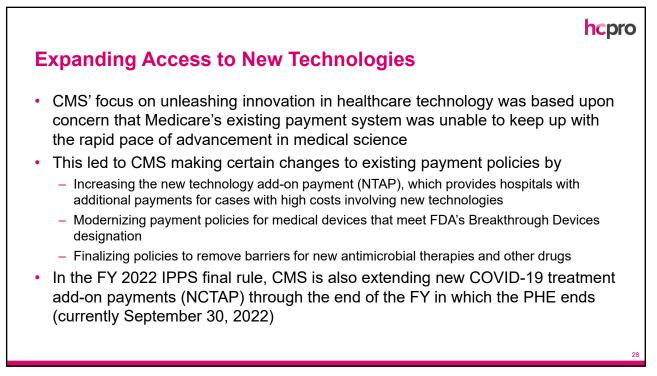






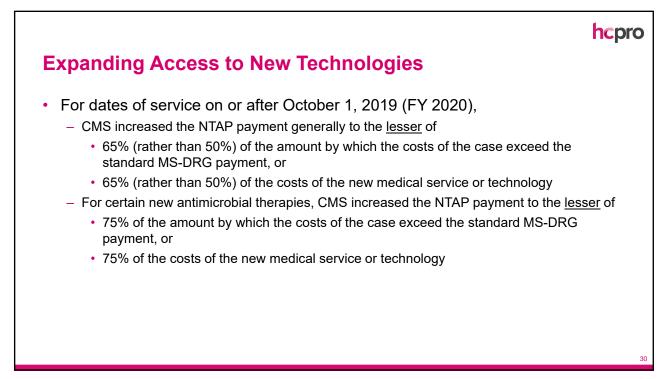


New Technology under the IPPS



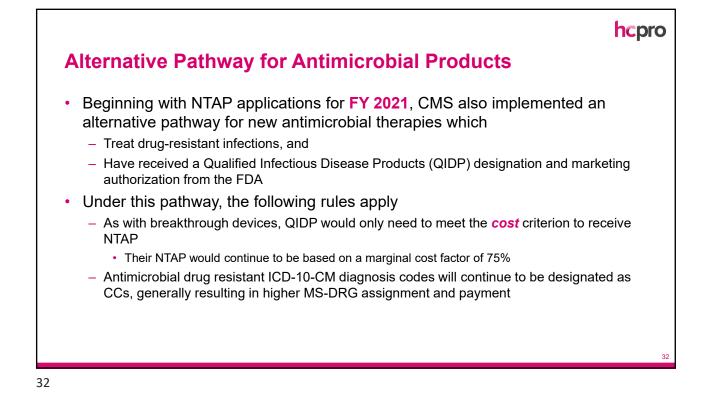
Expanding Access to New Technologies

- Under the IPPS, as part of each FY final rule, certain new technologies are approved for NTAP
 - An NTAP is in addition to the standard MS-DRG payment and is designed to cover the cost of new technologies that generally must meet the following 3 requirements:
 - The new technology must be new and not substantially similar to an existing technology,
 - The cost of the new technology must be great enough that the otherwise applicable MS-DRG payment would be inadequate, <u>and</u>
 - The new technology must demonstrate substantial clinical improvement over existing technologies
 - In general, NTAP is granted for a maximum of 3 years
 - For FY2022, some NTAP were extended an additional year based on CMS payment policy due to available data for FY2020 due to the COVID-19 PHE



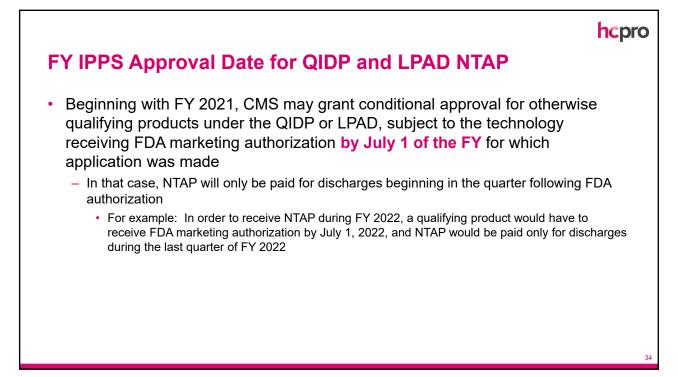
Alternative Pathway for Breakthrough Devices

- Beginning with NTAP applications for FY 2021, CMS implemented an alternative pathway for new medical devices that
 - Are part of the FDA's Breakthrough Devices Program (BDP), and
 - Have received FDA marketing authorization by July 1 preceding the beginning of the FY (October 1) for which they seek NTAP
- Under this pathway, two of the current NTAP requirements would be effectively waived
 - Devices would be assumed to be new and not substantially similar to an existing technology and would not have to demonstrate substantial clinical improvement over existing technologies
 - The breakthrough devices would only need to meet the cost criterion to receive NTAP



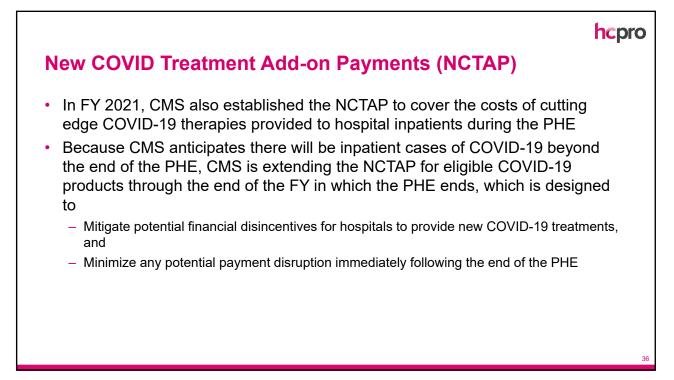
Alternative Pathway for Limited Population Pathway for Antibacterial and Antifungal Drugs

- Beginning with NTAP applications for FY 2022, CMS is expanding the alternative new technology add-on payment pathway for QIDPs to include products approved through FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD pathway).
 - For applications received for NTAP for FY 2022 and subsequently, if an antimicrobial product is approved through FDA's LPAD pathway, it will only need to meet the *cost* criterion to receive NTAP



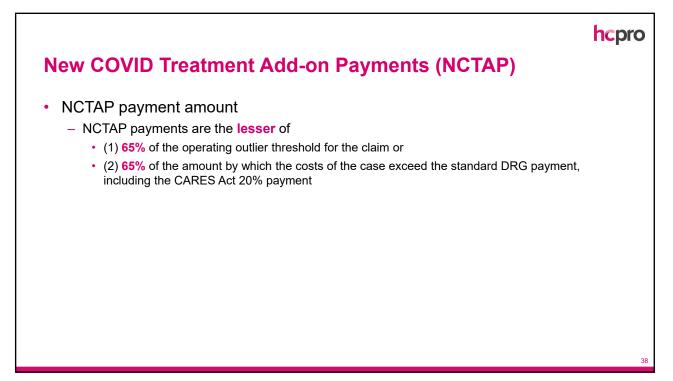
New Technologies for FY2022

- For FY 2022, 40 technologies will be eligible to receive NTAP
 - CMS is continuing NTAP for all 23 of the technologies receiving NTAP in FY 2021
 - 10 remain within their newness period for FY 2022
 - CMS is using its exceptions and adjustments authority during the PHE to provide a one-year extension for the remaining 13 technologies that are no longer new
 - CMS also approved or (conditionally approved) 17 new technologies for FY 2022
- CMS estimates that FY 2022 Medicare spending on NTAP will be approximately \$1.5 billion, nearly a 77% increase over FY 2021 spending
- Two correction notices were published that made significant corrections to the payment limit amounts or qualifying codes for new technologies for FY2022
 - A complete list of new technologies, with qualifying codes and payment add-ons, including corrections is included as an attachment at the end of the presentation.



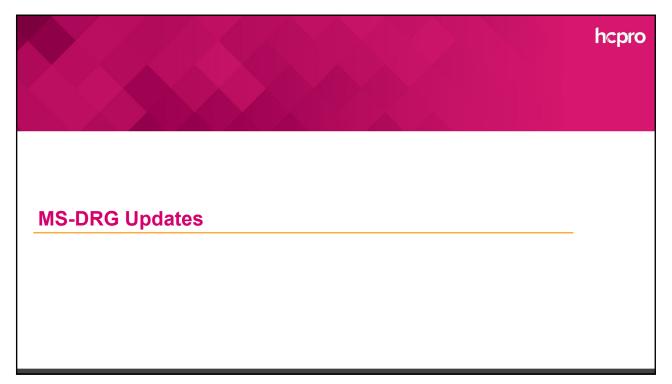
New COVID Treatment Add-on Payments (NCTAP)

- · Qualifying cases:
 - Case must include a drug or biological authorized to treat COVID-19 by the FDA, including through an emergency use authorization (EUA)
 - Products currently approved according to the CMS NCTAP website:
 - Beginning 8/23/20, COVID-19 convalescent plasma
 - Beginnig 10/22/20, remdesivir (Veklury®)
 - Beginning 11/19/20, baricitinib (Olumiant®) in combination with remdesivir (Veklury®)
 - See the CMS NCTAP website (<u>https://www.cms.gov/medicare/covid-19/new-covid-19-</u> <u>treatments-add-payment-nctap</u>) for coding details for eligible cases
 - Case must be eligible for the 20% increase to the DRG weight for individuals diagnosed with COVID-19
 - The operating costs of the case must exceed the IPPS operating payment, including the 20% add on payment



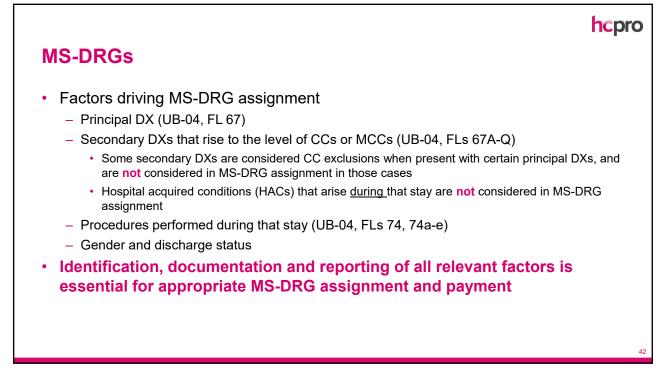
New COVID Treatment Add-on Payments (NCTAP)

- CMS did not finalize its proposal to discontinue the NCTAP for discharges on or after October 1, 2021, for a product that is approved for NTAP beginning in FY 2022
 - Instead, hospitals will be eligible to receive both a NCTAP and the traditional NTAP for qualifying inpatient stays through the end of the FY in which the PHE ends
 - The amount of the NCTAP, however, will be reduced by the amount of the NTAP
 - Currently one product qualifies for both NTAP and NCTAP
 - VEKLURY[®] (remdesivir, a nucleotide analog that inhibits viral RNA-dependent RNA polymerases, demonstrating activity countering viral pathogens such as SARS-CoV-2 (COVID-19))



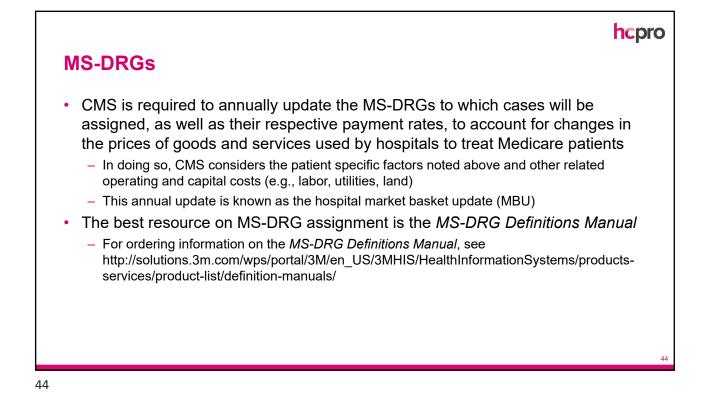
MS-DRGs

- Payment under the IPPS is based upon the MS-DRG to which the case is assigned
 - List of MS-DRGs is published as Table 5 to annual IPPS final rule
 - MS-DRGs are grouped into one of 25 "MDCs" based on organ/body system or nature of disease or injury
 - Every discharge is assigned to only one MS-DRG
 - Each MS-DRG is assigned a relative weight reflecting "estimated relative cost of hospital resources" for cases assigned to that MS-DRG



MS-DRGs

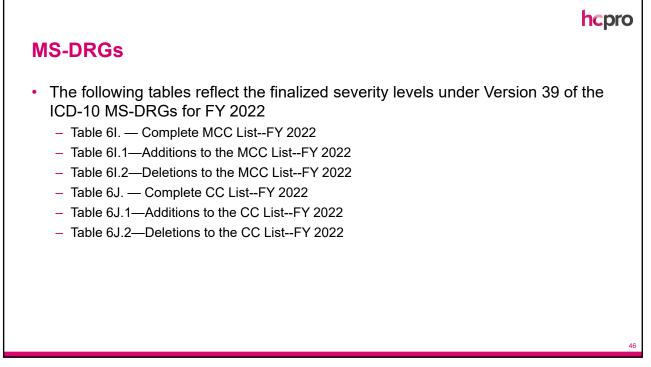
- For cases with the same principal diagnosis and principal procedure, there may be as many as three separate payment groups:
 - 1. A base DRG with no additional secondary diagnosis that increases resource use
 - 2. A slightly higher paying DRG with at least one secondary diagnosis designated as a complication or comorbidity (CC) that increases resource use
 - 3. An even higher paying DRG with at least one secondary diagnosis designated as a major CC (MCC) that significantly increases resource use



MS-DRGs

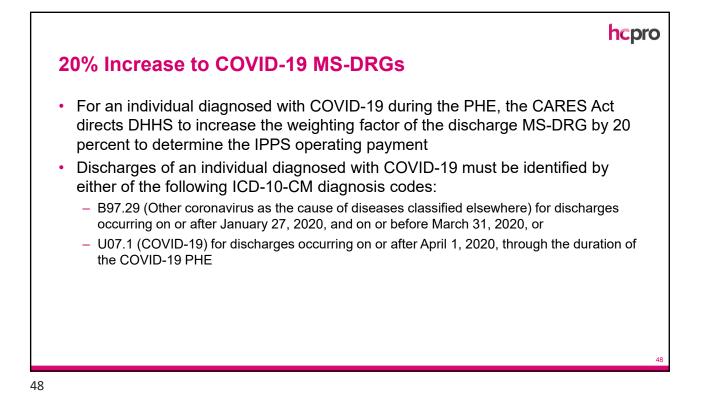
- As part of this ongoing refinement process, CMS applies the following criteria to determine if the creation of a new NonCC, CC or MCC subgroup within a base MS–DRG is warranted:
 - A reduction in variance of costs of at least 3 percent;
 - At least 5 percent of the patients in the MS–DRG fall within the NonCC, CC, or MCC subgroup;
 - At least 500 cases are in the NonCC, CC, or MCC subgroup;
 - There is at least a 20-percent difference in average costs between subgroups; and
 - There is a \$2,000 difference in average costs between subgroups
- All 5 criteria must be met to create a new subgroup





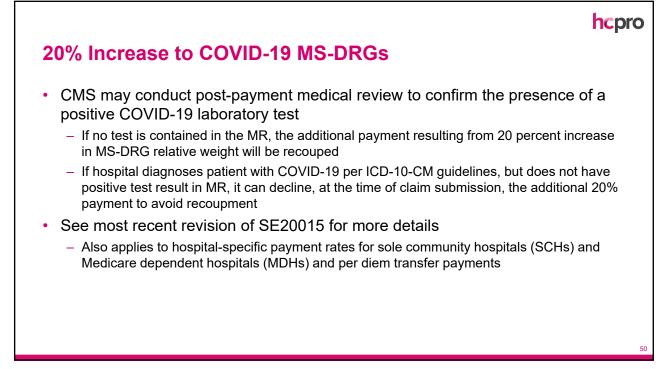
MS-DRG Changes: CAR-T

- In FY 2021, CMS created new MS-DRG 018 (Chimeric Antigen Receptor [CAR] T-cell Immunotherapy) for cases that include procedures describing CAR T-cell therapies
- For FY 2022, CMS finalized the following related proposals:
 - To continue to assign listed procedure codes describing CAR T-cell, non-CAR T-cell and other immunotherapies to Pre-MDC MS–DRG 018,
 - To modify the title of Pre-MDC MS–DRG 018 to "Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies" to better reflect the cases reporting the administration of non-CAR T-cell therapies and other immunotherapies, and
 - To continue to apply an adjustment of 0.17 as part of the calculation of the payment for claims determined to be applicable clinical trial or expanded use access immunotherapy claims that group to MS–DRG 018

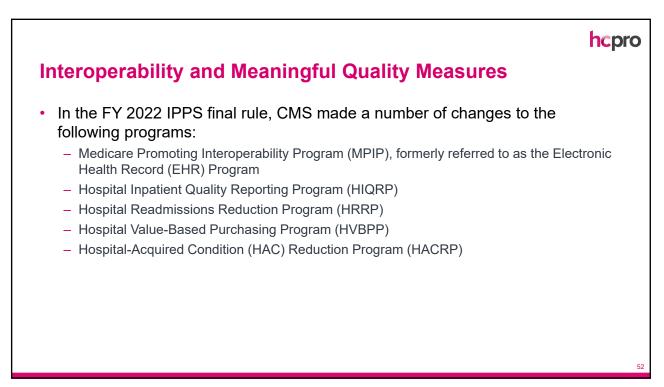


20% Increase to COVID-19 MS-DRGs

- Effective for admission on/after 9/1/20, claims eligible for 20 percent increase require a positive COVID-19 laboratory test documented in the MR
 - Positive tests must be based only on results of viral testing (i.e., molecular or antigen), consistent with CDC guidelines
 - Test may be performed either during, or prior to, the hospital admission
 - If prior to admission, must generally be performed within 14 days of admission
 - OIG has indicated it will be auditing COVID-19 cases, beginning with admissions on/after 9/1/20

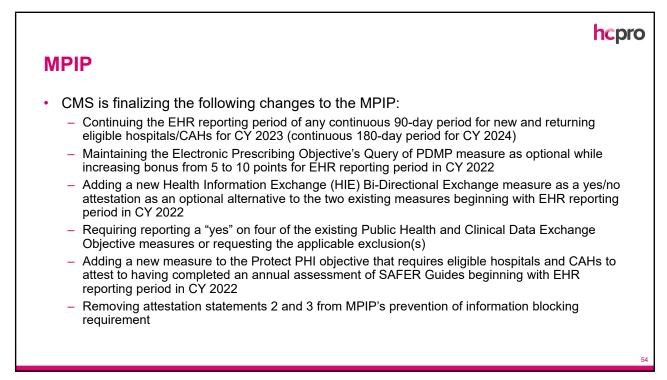


IPPS Quality Update



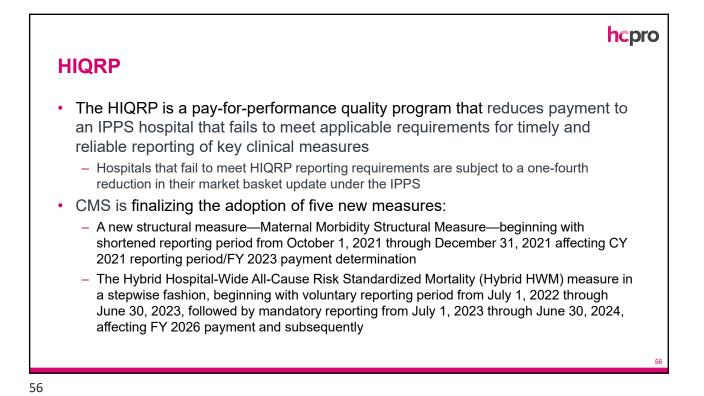
MPIP

- CMS established the MPIP to encourage eligible professionals, hospitals, and critical access hospitals (CAH) to adopt, implement, upgrade, and demonstrate meaningful use of CEHRT.
 - IPPS hospitals that fail to meet their MPIP/EHR requirements are subject to a three-fourths reduction in their IPPS market basket update



MPIP

- Increasing minimum required score for objectives and measures from 50 points to 60 points (out of 100 points) to be considered a meaningful EHR user
- Adopting two new eCQMs to the MPIP's eCQM measure set, beginning with reporting period in CY 2023 and removing three eCQMs from the measure set, beginning with reporting period in CY 2024, in alignment with eCQM updates being finalized for HIQRP
- CMS is not, however, finalizing two of its proposals:
 - To remove the Anticoagulation Therapy for Atrial Fibrillation/Flutter eCQM (STK-03) (NQF #0436) in alignment with HIQRP
 - To modify the Provide Patients Electronic Access to Their Health Information measure by requiring eligible hospitals and CAHs to ensure that PHI remains available to the patient (or their representative)



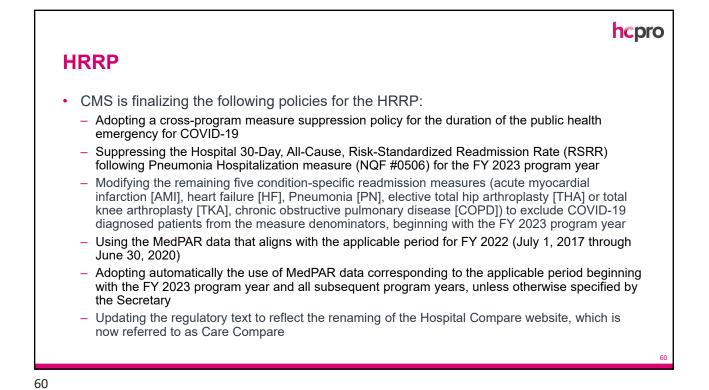
HIQRP

- The COVID-19 Vaccination Coverage among Health Care Personnel (HCP) measure, beginning with a shortened reporting period from October 1, 2021 through December 31, 2021, affecting CY 2021 reporting period/FY 2023 payment determination and quarterly reporting beginning with FY 2024 payment and subsequently
- Two medication-related adverse event eCQMs, beginning with CY 2023 reporting period/FY 2025 payment determination
 - Hospital Harm-Severe Hyperglycemia eCQM (NQF #3533e)
 - Hospital Harm-Severe Hypoglycemia eCQM (NQF #3503e)
- CMS is also finalizing the removal of three measures:
 - The Exclusive Breast Milk Feeding (PC-05) (NQF #0480), beginning with FY 2026 payment determination
 - The Admit Decision Time to ED Departure Time for Admitted Patients (ED-2) (NQF #0497), beginning with FY 2026 payment determination
 - The Discharged on Statin Medication eCQM (STK-06) (NQF #0439), beginning with the FY 2026 payment determination

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HIQRP	
 Finally, CMS is finalizing its proposal that, beginning with CY 2023 reporting period/FY 2025 payment determination, hospitals will be required to use certified EHR technology (CEHRT) that has been updated consistent with the 2015 Edition Cures Update and supports the reporting requirements for all available eCQMs Hybrid measures will also be required to comply with the same certification requirements a eCQMs 	S
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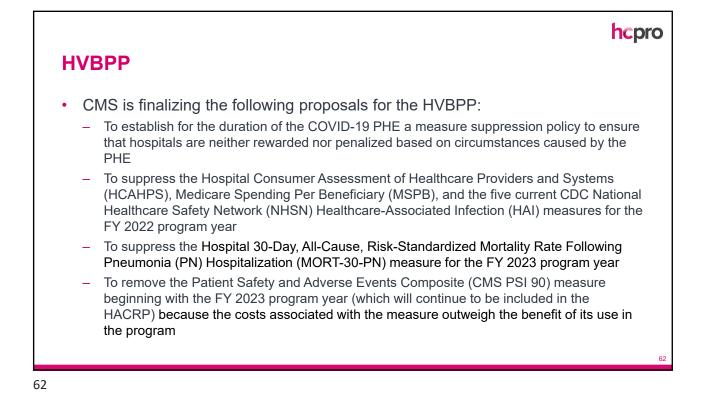
HRRP

- The HRRP is a pay-for-performance quality program that reduces payment to an IPPS hospital for a discharge to account for excess readmissions for selected conditions
 - When hospital has excess readmissions during the applicable period (July 1, 2017 June 30, 2020 for FY 2022 payment), CMS will reduce the hospital's base operating DRG payments up to 3% for *all* discharges during that payment year to account for excess readmissions for selected conditions during the applicable period
 - A readmission occurs when a patient is discharged from an initial index hospital and admitted to the same or a different hospital within 30 days of discharge.
 - CMS does not count certain patients (e.g., discharge AMA, under 65) or readmissions (e.g., transfers, planned readmissions) for purposes of determining the number of excess readmissions.



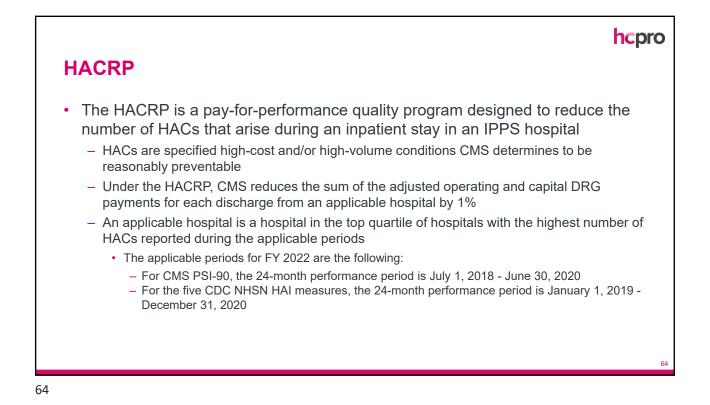
HVBPP

- The HVBPP is a pay-for-performance quality program that provides valuebased incentive payments to an eligible IPPS hospital that meets or exceeds certain performance standards, resulting in an increase to the hospital's base operating DRG payments
 - A hospital's eligibility for and amount of incentive payments is based on its FY Total Performance Score (TPS), which is the **higher** of two scores for each measure:
 - Improvement: comparing a hospital's performance during a base year to its performance during the performance period
 - Comparison to peers: comparing a hospital's performance against that of its peers during the performance period
 - Because the HVBPP is budget neutral, these incentive payments are funded by a prescribed percentage reduction (currently 2%) to total base operating DRG payments of all eligible participating hospitals



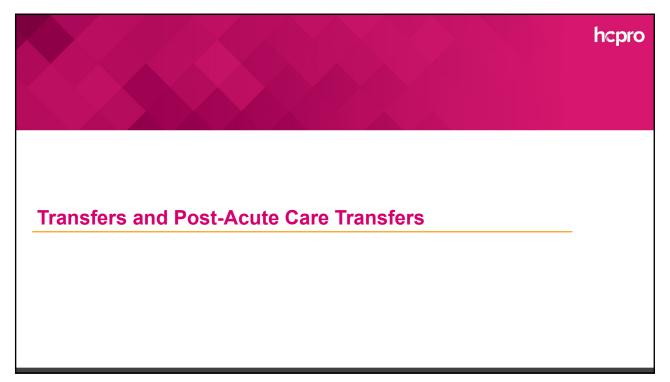
HVBPP

- Because of suppression of measures in all but the Clinical Care Domain, CMS believes calculating a TPS for hospitals using only data from the remaining measures would not result in a fair national comparison
- Instead, CMS is finalizing the following proposals:
 - To award each hospital a payment incentive multiplier that results in a value-based incentive payment that is equal to the amount withheld for the fiscal year (two percent)
 - To update the baseline periods for certain measures affected by the Extraordinary Circumstances Exception (ECE) granted in response to the COVID-19 PHE and make related technical updates to terminology used in the HVBPP regulations

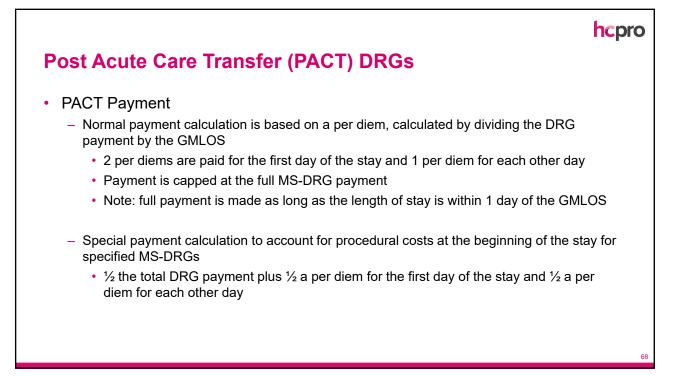


HACRP

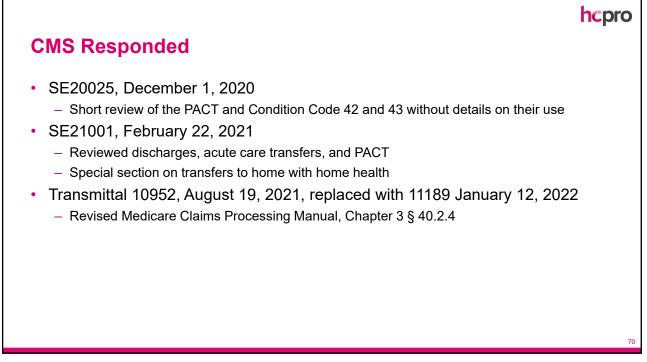
- Beginning in FY 2023, the applicable period for both the CMS PSI 90 and CDC NHSN HAI measures will be the 24-month period beginning one year after the start of the applicable period for the previous program year
- In the FY 2022 IPPS final rule, CMS is also clarifying its ECE policy and finalizing the following three proposals:
 - To adopt a cross-program measure suppression policy for the duration of the PHE for COVID-19
 - To apply that measure suppression policy to suppress certain program data from the HACRP for FYs 2022, 2023, and 2024
 - To update the regulatory text to reflect that the Hospital Compare website has been renamed and is now referred to as Care Compare



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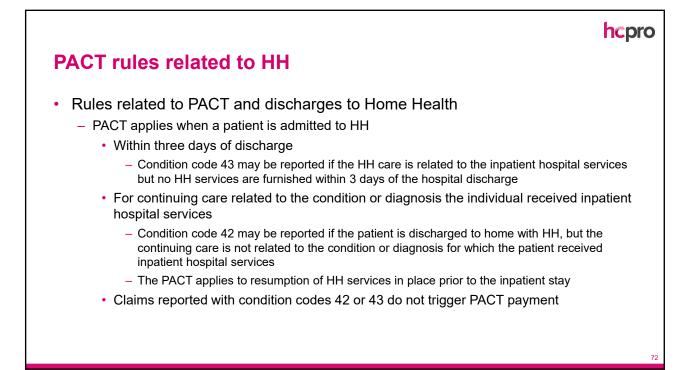


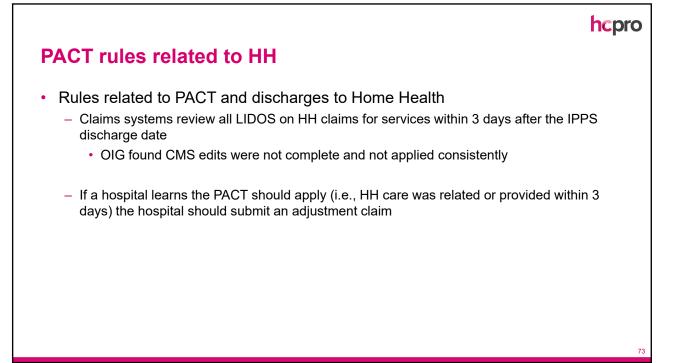
CDG reports on PACT Prior Audits related to PACT 10/1999 – 9/2000 - \$61 million overpayments 10/2002 – 9/2005 - \$24.8 million overpayments 1/2009 – 9/2012 - \$19.5 million overpayments – edits not working properly Provember 2019 Audit 1/2016 – 12/2018 - \$54.4 million overpayment 83% were followed by a claim for Home Health OIG identified hospitals can override automatic edits with condition codes for HH claims Proventified hospitals can overpayment Audit focused on inpatient claims with a HH claim within 3 days of discharge 147 errors of 150 claims reviewed Recommended legislative action to make all HH discharged defined as "related"



CMS Responded

- Medicare Claims Processing Manual, Chapter 3 § 40.2.4
 - Clarified acute care transfer occurs when:
 - · Transfer to another IPPS hospital for related care
 - · Admitted to another IPPS hospital on same day after leaving against medical advice
 - · Admitted to another IPPS hospital on the same day as discharge, unless unrelated
 - Transfer to a non-participating hospital that would otherwise be eligible to be paid under IPPS
 - Transfer to a Critical Access Hospital (CAH)
 - Added all discharge status codes for planned readmissions
 - Added hospice discharges to the PACT section
 - A new section on discharges where the patient receives home health



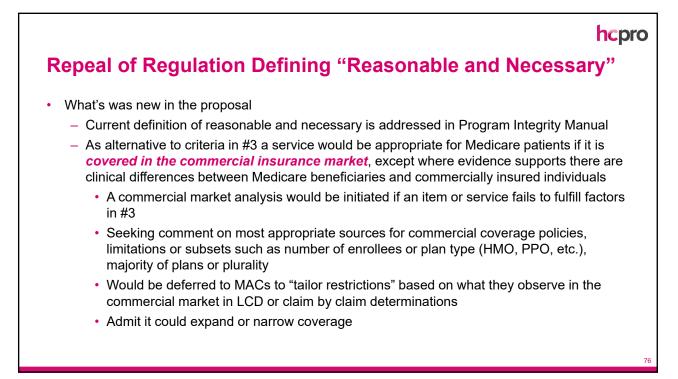




Repeal of Regulation Defining "Reasonable and Necessary"

- January 14, 2021, CMS published a final rule:
 - To adopt a regulatory definition of reasonable and necessary and
 - Medicare Coverage of Innovative Technology (MCIT)
- Reasonable and Necessary
 - 1. Safe and effective
 - 2. Not experimental or investigational
 - 3. Appropriate for Medicare patients, including the duration and frequency considered appropriate for the item or service, in terms of whether it is:
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
 - Furnished in a setting appropriate to the patient's medical needs and condition;
 - · Ordered and furnished by qualified personnel;
 - · One that meets, but does not exceed, the patient's medical need; and
 - · At least as beneficial as an existing and available medically appropriate alternative

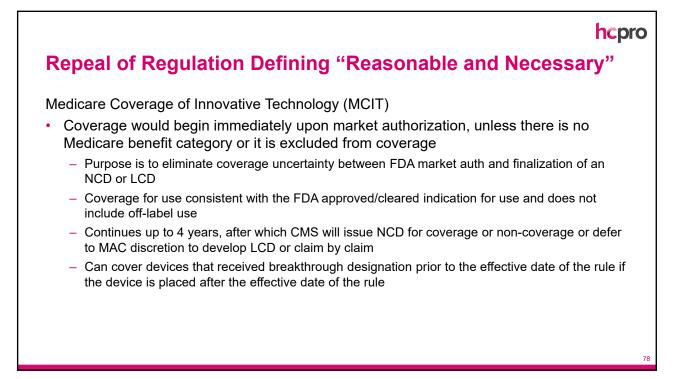




Repeal of Regulation Defining "Reasonable and Necessary"

Medicare Coverage of Innovative Technology (MCIT)

- Provides coverage for devices designated an FDA Breakthrough Device and are market authorized
- FDA Breakthrough Device:
 - Device provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or condition
 - Meets one of these criteria
 - · Represents a breakthrough technology, or
 - · No approved/cleared alternative exists, or
 - · it offers advantages over existing alternatives, or
 - availability is in the best interest of patients



Repeal of Regulation Defining "Reasonable and Necessary"

Regulatory delays and repeal timeline:

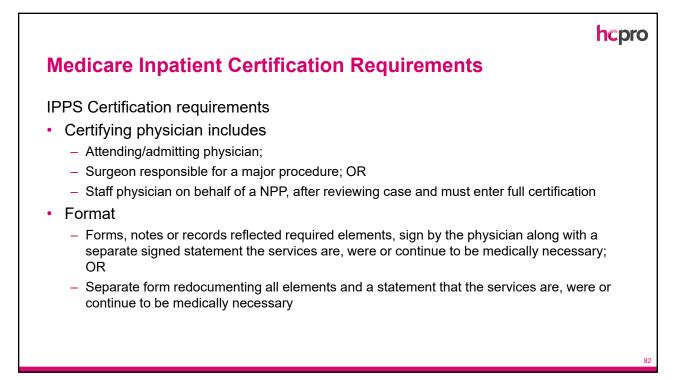
- January 14, 2021: Final Rule published by CMS prior to the change of administration adopting new reasonable and necessary definition (R&N) and MCIT
- January 20, 2021: 60 day "Regulatory Freeze Pending Review" delayed implementation of R&N/MCIT rule
- March 17, 2021: Interim Final Rule with Comment Period effective March 12 delayed R&N/MCIT rule until May 15 and opened a 30-day comment period
- May 18, 2021: Final Rule effective May 14 delayed R&N/MCIT rule until December 15
- September 15, 2021: Proposed Rule to repeal R&N/MCIT rule with 30-day comment period
- November 15, 2021: Final Rule repealing R&N/MCIT effective December 15, 2021

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Regroup on Utilization Review	

Medicare Inpatient Certification Requirements

Certification is required as a condition of payment for certain cases under Part A

- For PPS hospitals, Medicare requires certification for two distinct situations:
 - $-\,$ Cases 20 days in length, by the 20th day
 - Outlier, if no 20-day certification, by the date the hospital requests outlier payment
- For Critical Access Hospitals (CAH), a "good faith" certification that the patient will be transferred or discharged within 96 hours, by one day before the claim
- Inpatient psychiatric facilities (IPFs) have separate certification and recertification requirements for each admission
 - See 42 CFR 424.14, Medicare General Information, Eligibility, and Entitlement Manual, Chapter 4 § 10.9, Medicare Benefit Policy Manual, Chapter 2 § 30.2.1
- Inpatient rehabilitation facilities (IRFs) have additional pre-screening and initial evaluation requirements

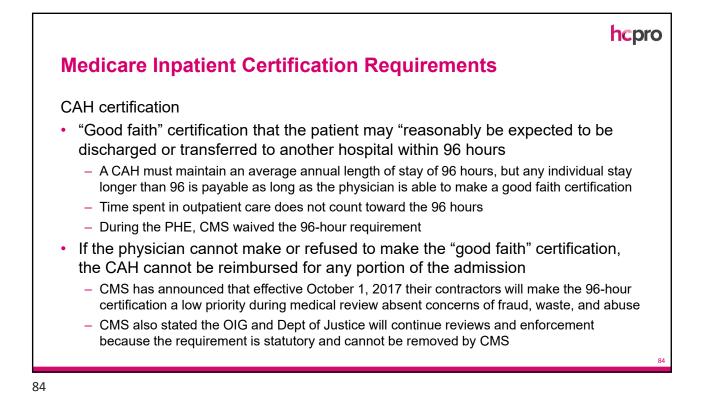


Medicare Inpatient Certification Requirements

IPPS Certification requirements

- Elements of the certification
 - The reason for continued hospitalization for inpatient medical treatment or diagnostic testing (extended stay) or the special or unusual services resulting in cost outlier
 - The estimated time the patient requires hospitalization, if before discharge, or the actual time the patient was hospitalized if after discharge (outlier)
 - Plans for post discharge care, if appropriate

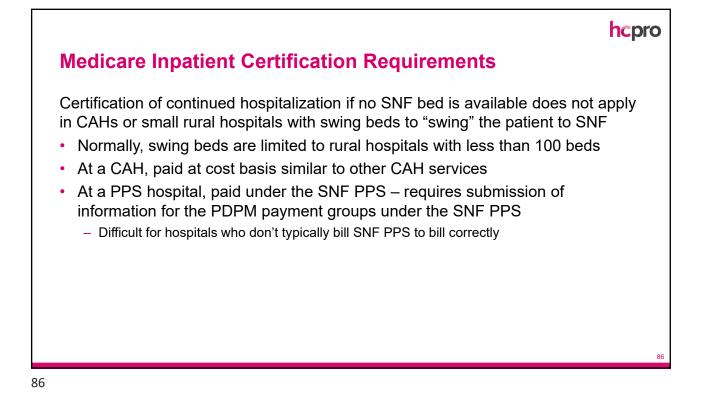




Medicare Inpatient Certification Requirements

Certification of continued hospitalization if no SNF bed is available

- Continued inpatient hospitalization is covered if
 - The patient requires skilled care at a SNF
 - No SNF bed is available at a participating SNF
 - The physician certifies the need for continued hospitalization on that basis
 - The physician (?) continues to make placement efforts
- Coverage ends when
 - A bed becomes available at a participating SNF
 - The patient no longer needs SNF care
 - The patient exhausts their Part A inpatient hospital benefit days
- "Alternate placement days can count toward three-night requirement for SNF coverage



Medicare Inpatient Certification Requirements

During the PHE, CMS also expanded the ability of large and urban hospitals to offer "swing bed" services for patients they are unable to find placement in a SNF

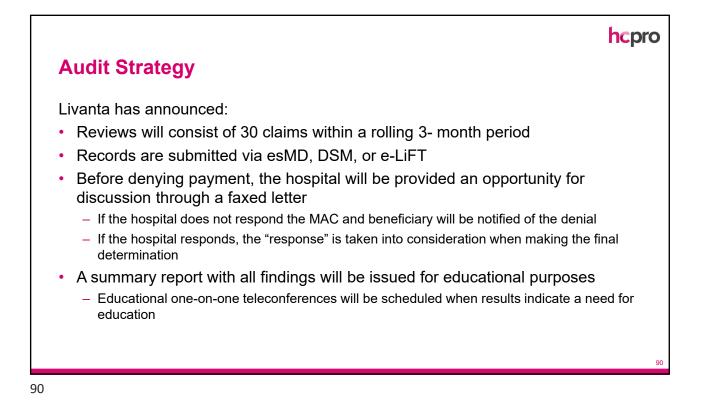
- Requirements
 - The SNF swing beds can't be used for acute level care
 - The hospital must comply with all non-waived CoPs
 - Be consistent with the state emergency preparedness plan
- Hospital must attest to CMS
 - They have made a good faith effort to exhaust all other options
 - There are no SNFs within the hospital's catchment area currently willing to accept or able to take patients because of the COVID-19 PHE
 - The hospital meets the waiver eligibility requirements
 - They have a plan to discharge patients as soon as practicable when a SNF bed becomes available or the PHE ends, whichever is earlier

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Short Stay Audits	

Audit Strategy

History of CMS audits for short stays (i.e., less than two midnights)

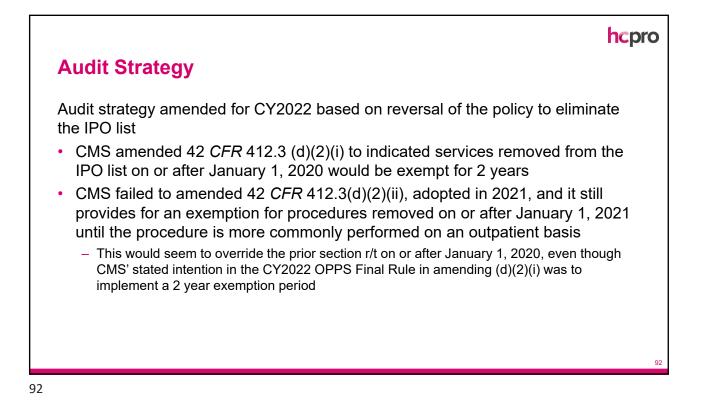
- Prior to 10/1/13 RACs did inpatient medical necessity reviews
- 10/1/13 10/1/15 MACs audit compliance with new policies for admission (the two midnight rule), orders and certification adopted 10/1/13
- 10/1/15 5/8/19 QIOs conduct short stay audits
 - From May to September of 2016, CMS paused QIO audits and instructed the QIOs to reaudit certain claims and pay other denied claims due to poor quality of the audits
 - 5/8/19 CMS paused audits due to changes in QIO jurisdictions causing delays with other regulatory functions of the QIOs – intended to restart third quarter 2019
- 4/2021 Livanta received sole contract to audit short stays
 - Livanta posted a schedule for monthly audits beginning 10/4/21, but few details on how they would conduct audits



Audit Strategy

Audit strategy adopted for CY2021 for procedures removed from the IPO list

- Services removed from IPO list in 2020 (i.e., THA) 42 CFR 412.3(d)(2)(i)
 - Exempt from denial (but not audit) for 2 years (CY2020 and CY2021)
- Services removed from IPO list in 2021 and later 42 CFR 412.3(d)(2)(ii)
 - Exempt from denial (but not audit) for *an indefinite period* until data shows procedure is more commonly performed on an outpatient basis (i.e., more than 50% of the time)
 - Determination is based on Medicare claims data
 - *Evaluated on a yearly basis* and CMS will "revisit in rulemaking whether and when an exemption for a procedure should be ended" (CY2021 OPPS Final Rule, 85 Fed. Reg. 86119)



Audit Strategy

During exemption period, contractors

- Will continue medical review of short stays for procedures removed from the IPO List
 - Medical necessity of the procedure; and
 - Medical necessity for the site of service
- Will not deny cases for the incorrect site of service (i.e., noncompliance with the two-midnight rule)
 - Will provide education to the provider for the noncompliant claims
 - Will not be used for referral to RAC for non-compliance reviews
 - RAC will not conduct site of service reviews
- · CMS reserved the right to conduct audits if there is evidence of fraud or abuse

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Audit Strategy	
CMS regarding the exemption: Whether a procedure has an <i>exemption or not</i> , does not change what site-of-service is necessary or appropriate for an individual beneficiary. Providers are still expected to use a <i>complex medical judgment to determine the appropriate site of service</i> for each patient compliance with the 2-Midnight rule. The exemption is not from the 2-Midnight rule but certain medical review procedures and site-of-service claim denials. (CY2022 OPPS Final F Reg. 63739)	their and to bill in from
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Audit Strategy

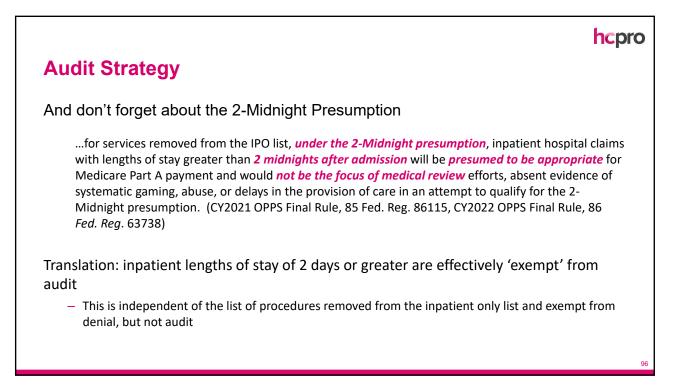
CMS regarding the exemption:

Old language:

...The *indefinite exemption* will help hospitals and clinicians become used to the *availability of payment* under both the hospital *inpatient and outpatient* setting for procedures removed from the IPO list. (CY2021 OPPS Final Rule, 85 Fed. Reg. 86120)

New language:

...we explained that it was our belief that the *2-year exemption* from referrals to RACs, RAC patient status review, and claim denials would be sufficient to allow providers time to update their billing systems and gain experience with respect to newly removed procedures *eligible to be paid under either the IPPS or the OPPS*, while avoiding potential adverse site-of-service determinations. (CY2022 OPPS Final Rule, 86 Fed. Reg. 63739)



Audit Strategy

And we might get some help from CMS:

...in the future, we *plan* to provide *information on appropriate site of service selection* to support physicians' decision-making. We note that these considerations will be for *informational or educational purposes* only and will not supersede physicians' medical judgment about whether a procedure should be performed in the inpatient or outpatient hospital setting. (CY2021 OPPS Final Rule, 85 Fed. Reg. 86088)

Although 2022 seems less certain:

...In the future, we *may* provide additional *educational material* regarding considerations for the *selection of site-of-service* for a procedure to support physicians' decision making. We note that this additional information will be for *informational or educational purposes only* and will not be intended to prohibit payment of procedures that were previously included on the IPO list in the outpatient setting. (CY2022 OPPS Final Rule, 86 *Fed. Reg.* 63740)

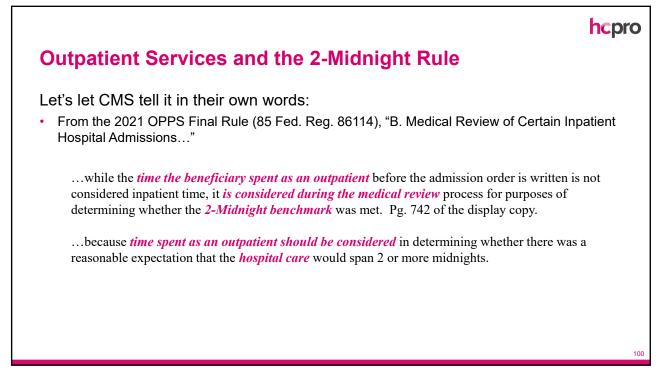


Outpatient Services and the 2-Midnight Rule

Let's let CMS tell it in their own words:

• From the 2021 OPPS Final Rule (85 Fed. Reg. 86114), "B. Medical Review of Certain Inpatient Hospital Admissions..."

...for purposes of determining whether the 2-Midnight benchmark is met and, therefore, whether an inpatient admission is appropriate for Medicare Part A payment, we consider the physician's expectation including the total time spent receiving hospital care—not only the expected duration of care after inpatient admission, but also any time the beneficiary has spent (before inpatient admission) receiving outpatient services, such as observation services, treatments in the emergency department, and procedures provided in the operating room or other treatment area.

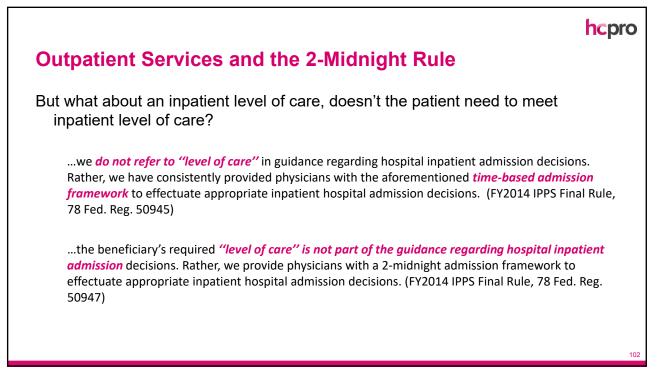


Outpatient Services and the 2-Midnight Rule

But this has been CMS' message from the start

...if the beneficiary has already *passed 1 midnight as an outpatient observation patient* or in routine recovery following outpatient surgery, the physician should consider the 2-midnight benchmark met if he or she expects the beneficiary to *require an additional midnight in the hospital*. This means that the decision to admit becomes easier as the time approaches the second midnight, and beneficiaries in medically necessary hospitalizations *should not pass a second midnight prior to the admission order being written*. (FY2014 IPPS Final Rule, 78 Fed. Reg. 50946)

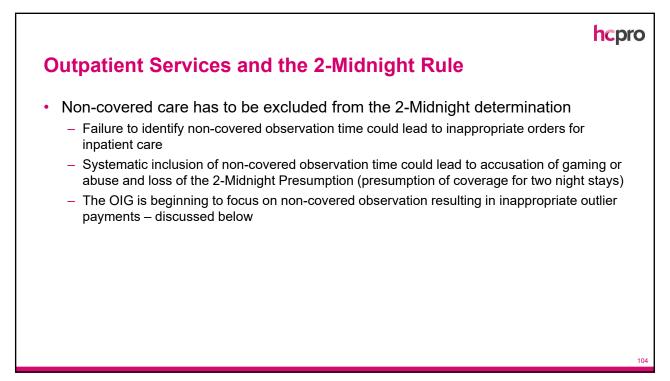
...Because we expect that this revision *should virtually eliminate the use of extended observation*, we also anticipate it will concurrently limit beneficiary cost-sharing for outpatient services. (FY2014 IPPS Final Rule, 78 Fed. Reg. 50946)



Outpatient Services and the 2-Midnight Rule

So where does that leave us?

- Covered outpatient services (such as observation, ED and outpatient procedures) should be counted towards the two-midnight rule
 - Documentation must show the services as covered, hospital level of care
 - Observation can be problematic because of patients receiving non-covered/custodial care
- The patient *never needs to meet an inpatient level of care*, as specified by third party criteria, to meet the two-midnight benchmark for Medicare
- Part A payment is appropriate (and inpatient admission) based solely on a medically necessary outpatient / observation level of care that last two midnights
 - Remember that an inpatient admission order is required to bill inpatient Part A



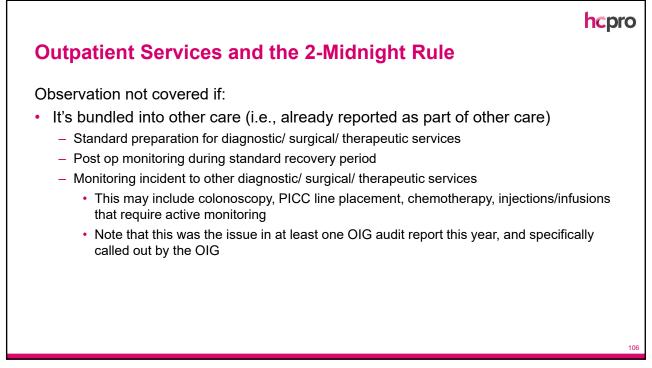
Outpatient Services and the 2-Midnight Rule

Observation not covered if:

- It is provided for the convenience of the patient/family/physician
 - Patients waiting for a ride, waiting for a transfer or waiting because of delays in care may fall in this category

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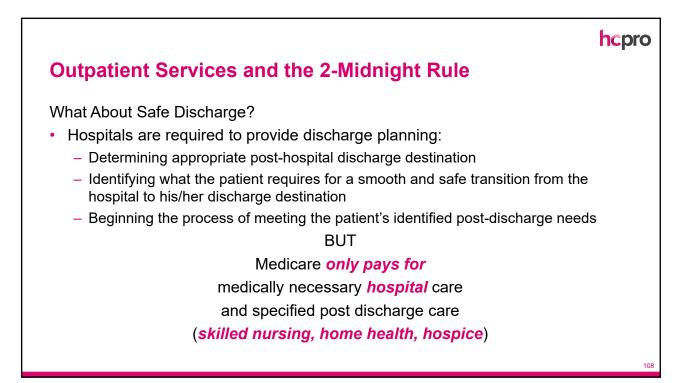
 Manual guidance seems to indicate that care provided to avoid inconvenience that affects the patient's health may be considered in determining care provided toward 2-midnight benchmark



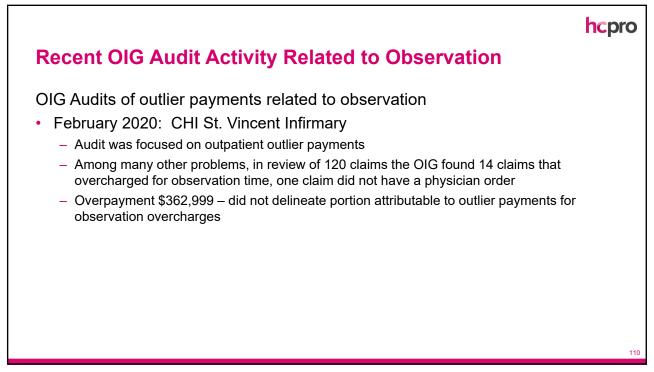
Outpatient Services and the 2-Midnight Rule

Observation not covered if:

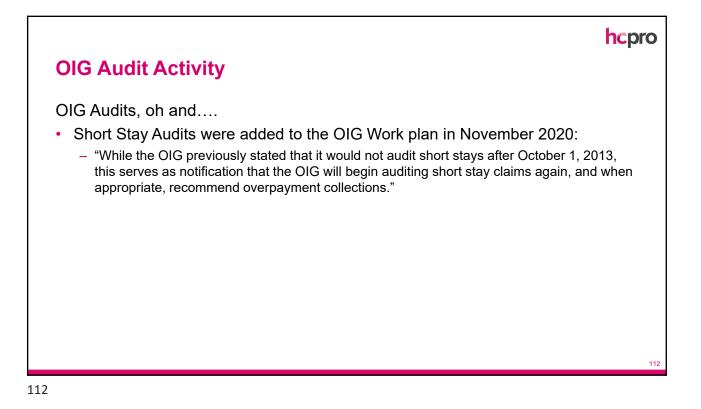
- It is not reasonable and necessary (i.e., not medically necessary at a hospital)
 - Patients with placement issues or no safe discharge may fall in this category
 - Consider providing the patient an ABN
 - More than 48 hours generally considered not medically necessary but CMS implemented MUE of 72 hours?
 - If 48 hours are *medically necessary* patient should have been admitted *under the 2-midnight benchmark*



hcpro Outpatient Services and the 2-Midnight Rule What does that mean? Hospitals have a responsibility to plan for and make a safe discharge for the patient *BUT* Medicare doesn't have to pay for it



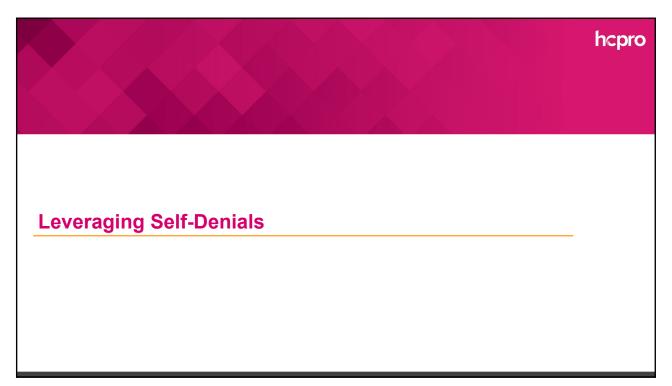
Accent Old Audit Activity Related to Observation Old Audits of outlier payments related to observation September 2020: Baylor, Scott and White – College Station Audit focused on outpatient outlier payments 30 claims found with overcharged observation time: 24 claims where observation was charged instead of extended recovery; 6 claims where observation was billed while other outpatient services were being performed "College Station stated that it does not perform utilization review for observation services less than 24 hours." Overpayments \$189,276 – did not delineate portion attributable to observation

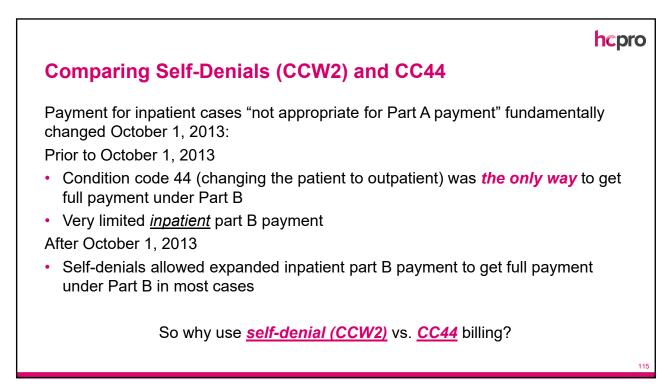


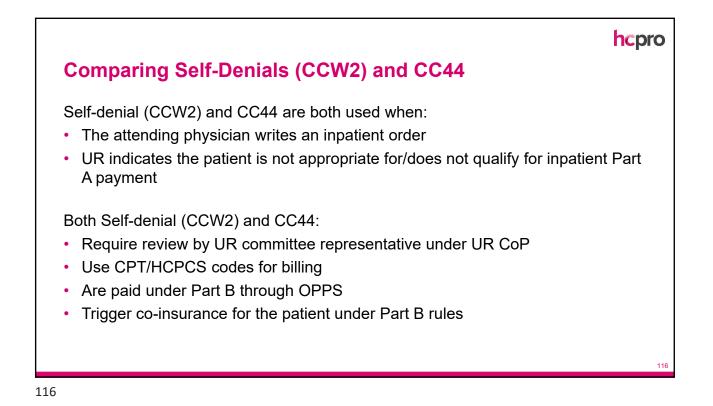
OIG Audit Activity

And that's scary because...

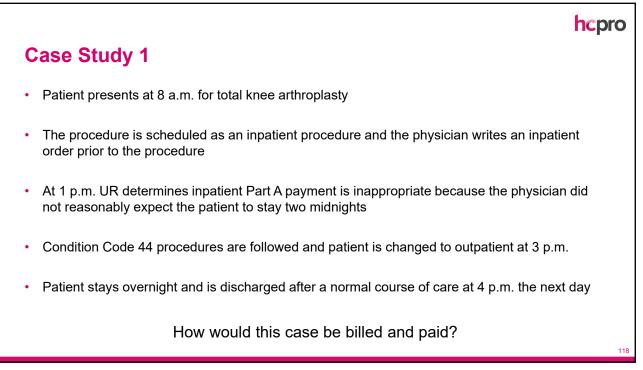
- December 2020: Providence Medical Center
 - General compliance audit
 - Found 13 claims alleged to not comply with 2-midnight rule
 - Hospital response:
 - Cases met 2-Midnight Presumption
 - · Cases were 2 midnights in length complying with the 2-midnight rule
 - Contractor incorrectly applied a standard of the "inpatient care is indicated when a patient can only be safely managed in an inpatient setting"
 - OIG's response:
 - We are not bound by the 2-Midnight Presumption
 - The contractor "*assured us* that its determinations were based on the regulatory requirements"







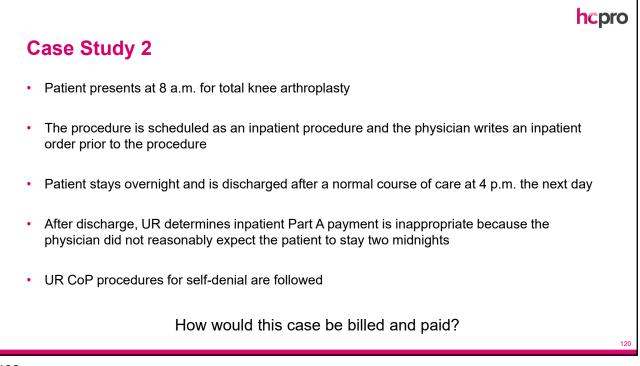
			hcpro
Comparing Se	If-Denials (CCW2) and (CC44	
What is the differ	ence between self-denial (CCV	V2) and CC44?	
	Self-Denial (CCW2)	CC44	
UR Determination	Any time <u>after</u> discharge	Before discharge	
Notice	Within two days of determination	Before discharge	
Patient status	Outpatient (TOB 13X) and/or Inpatient (TOB 12X)	Outpatient (TOB 13X)	
Attending Physician	Concurrence <u>not required</u> , only offer opportunity to give input	Concurrence <u>required</u>	
Payable	All covered services (except some nursing ancillary services for some hospitals/cases – more later)	All covered services	117



Case Study 1

How would this case be billed and paid?

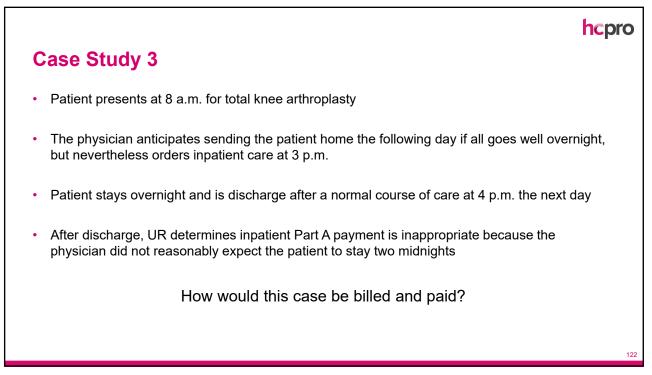
• The total knee arthroplasty is billed on an outpatient claim (TOB 131) with CC44 and paid OPPS rate (\$12,593)



Case Study 2

How would this case be billed and paid?

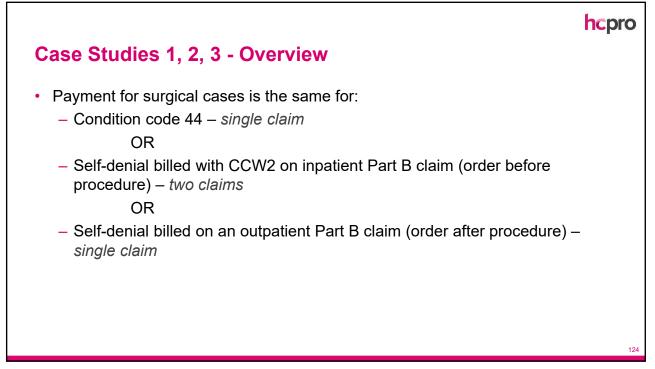
• The total knee arthroplasty is billed on an inpatient Part B claim (TOB 121) with CCW2 and paid OPPS rate (\$12,593)



Case Study 3

How would this case be billed and paid?

- The total knee arthroplasty is billed on a regular outpatient claim (TOB 131) and paid OPPS rate (\$12,593)
 - No Condition Code 44 or W2 because the pacemaker was provided on an outpatient basis and is being billed on an outpatient basis
- If any billable services occurred after 3 p.m. on first day, the hospital could bill them on an inpatient Part B claim (TOB 121) (after first filing the provider liable claim (TOB 110))
 - Caution: The C-APC payment for total knee arthroplasty is an encounterbased payment (i.e., payment for the full encounter) – a separate inpatient Part B claim could lead to inappropriate additional payment/patient coinsurance



Case Study 4 Patient presents to ED at 5 a.m. and is placed in observation at 8 a.m. Physician orders inpatient status at 8 p.m. that night Patient is discharged at 12 p.m. the next day

before discharge (CC44) or after discharge (CCW2)?

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Case Study Payment is the s	4 same in both cas	es:		hcp
			After discharge (CCW2): UR conducted post discharge	
	Billed	Paid	Billed Paid	
ED VISIT	131/CC44	\$2283*	131	\$2283*
OBSERVATION	131/CC44 14 hours** (8 a.m. – 8 p.m., 10 a.m. – 12 p.m.)	As part of the Observation C-APC	131 12 hours (8 a.m. – 8 p.m.)	As part of the Observation C-APC

Case Study 5 Patient presents to ED at 5 a.m. and is placed in observation at 8 a.m. Physician orders inpatient status at 1 p.m. that afternoon Patient is discharged at 12 p.m. the next day Mow would this case be billed and paid if UR review occurs before discharge (CC44) or after discharge (CCW2)?

Case Study 5 Payment is the sa		es:		hcp
			After discharge (CCW2): UR conducted post discharge	
	Billed	Paid	Billed	Paid
ED VISIT	131/CC44	\$73 – \$522*	131	\$73 – \$522*
OBSERVATION	131/CC44 7 hours (8 a.m. – 1 p.m., 10 a.m. – 12 p.m.)	As part of the ED Visit	131 5 hours (8 a.m. – 1 p.m.)	As part of the ED Visit

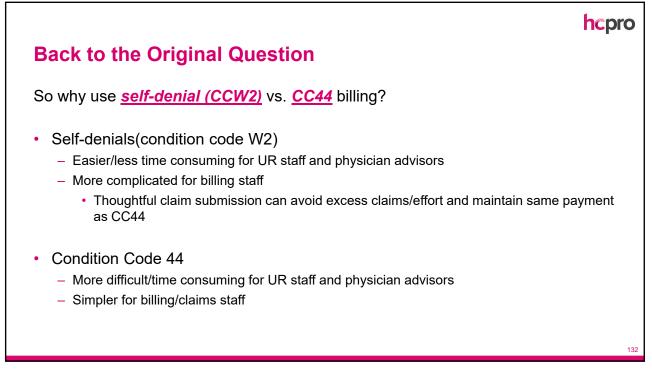
Case Study 6 Patient presents to ED at 5 a.m. and is placed in observation at 8 a.m. Physician orders inpatient status at 3 p.m. that afternoon Patient is discharged at 12 p.m. the next day How would this case be billed and paid if UR review occurs before discharge (CC44) or after discharge (CCW2)?

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Case Study 6 Payment is the sa	me in both cas	es:		hcp
			After discharge (CCW2): UR conducted post discharge	
	Billed	Paid	Billed	Paid
ED VISIT	131/CC44	\$2283*	131	\$73 – \$522
OBSERVATION	131/CC44 9 hours** (8 a.m. – 3 p.m.,	As part of the Observation C-APC	131 7 hours (8 a.m. – 3 p.m.)	As part of the ED visit

Case Studies 4, 5, 6 - Overview

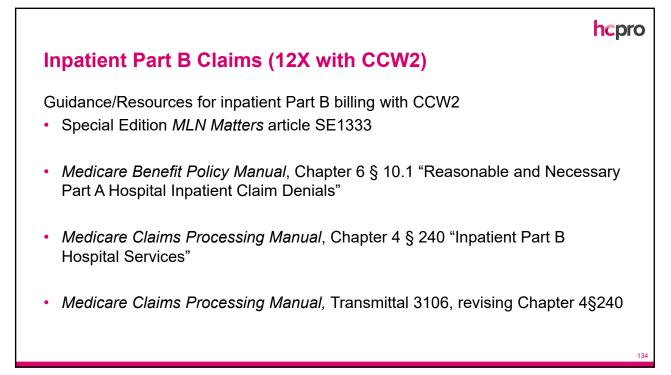
- Payment difference between self-denial (CCW2) and CC44 for medical cases is difficult to predict, dependent on:
 - Hours of observation before inpatient order is written
 - Hours of observation after UR determination/change in status
 - · Assuming observation can be combined on a single line
 - Differences in billable services
 - Differences in payable/packaged services when billed on a single claim vs. two claims

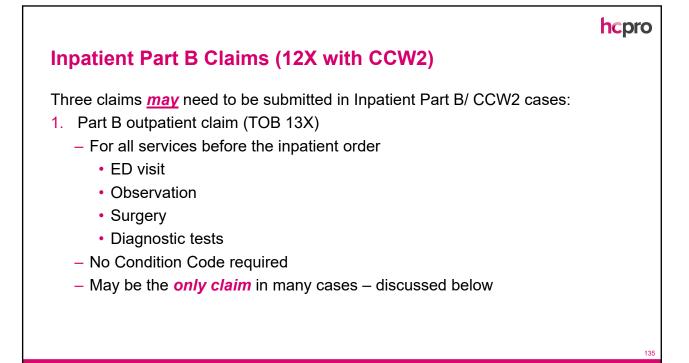


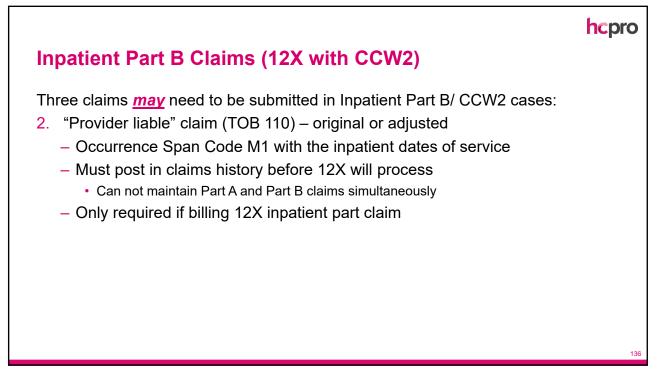
Three types of Inpatient Part B

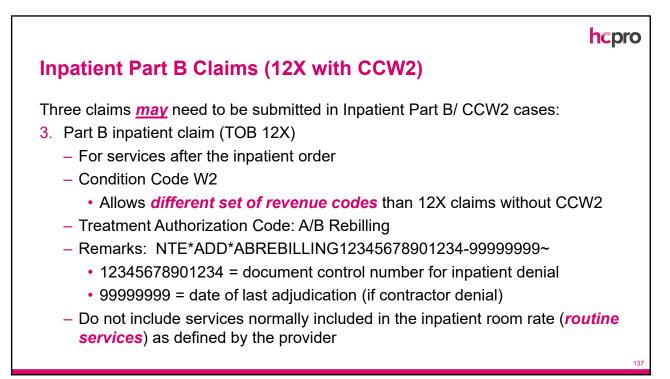
There are three situations where Inpatient Part B billing is used, which can cause confusion:

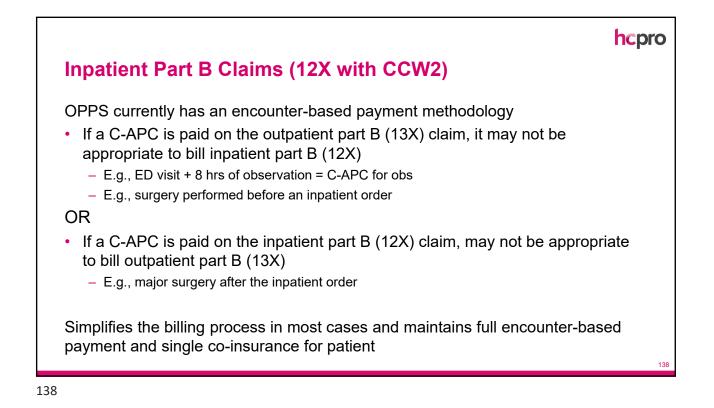
- Admission not reasonable and necessary for part A payment (TOB 12X with CCW2)
 - Payment for all service normally payable on outpatient Part B claim, including surgery, except those requiring outpatient status (ED, Obs) which are billable on TOB 131
- No eligibility for Part A or exhaustion of Part A benefits (TOB 12X no CCW2)
 - Very limited payment available for diagnostics, therapy, other selected services
 No payment for surgery
- Preventative services (TOB 12X no CCW2)
 - There is no Part A benefit for preventative services so they are billed to Part B







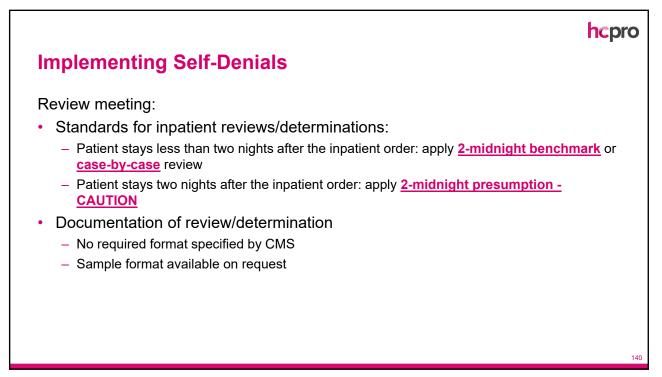


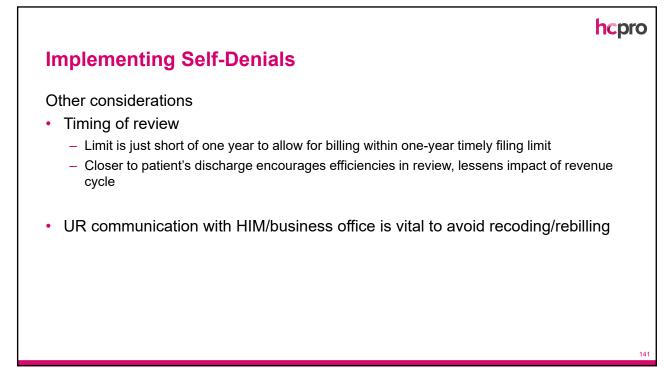


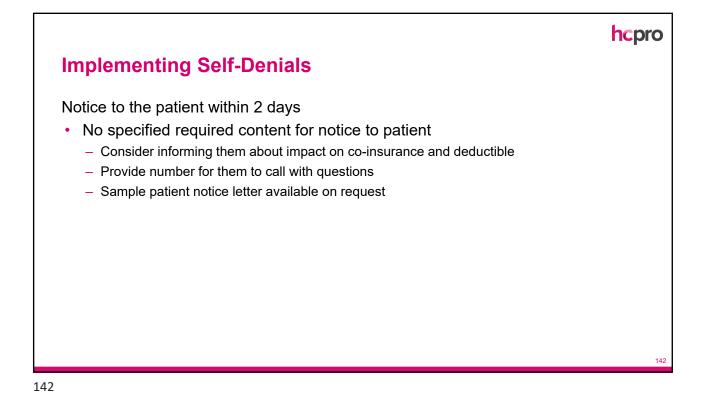
Implementing Self-Denials

Steps for self-denial reviews

- UR staff identifies a case for review
 - Notifies HIM and business office to hold coding/billing
 - The case is added to agenda for periodic review meeting (i.e. weekly, bi-weekly, semi-weekly) with UR physician
 - Attending physician is notified/invited to provide their views
- Review meeting occurs where determination is finalized
- Notice of determination is sent to
 - HIM/business office
 - Patient
 - Attending physician
- Sample policy available on request

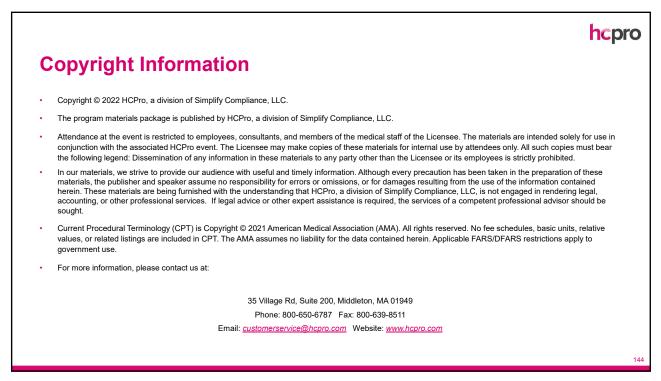






Thank you!

Questions?



hcpro boot camps

Attachment A				
Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority	
ZEMDRI [™] (Plazomicin) (Next-generation aminoglycoside antibiotic for multi-drug resistant gram-negative bacteria) Extended One Year	XW033G4 or XW043G4	\$4,083.75 (75% add-on limit)	83 Fed. Reg. 41326-34, 83 Fed. Reg. 49837; 84 Fed. Reg. 42190- 191; 85 Fed. Reg. 58613	
AndexXa [™] (Andexanet alfa) (Reversal of anti-coagulation of Xarelto and Eliquis or life-threatening or uncontrolled bleeding) Extended One Year	XW03372 or XW04372	\$18,281.25	83 Fed. Reg. 41355-62; 83 Fed. Reg. 49837; 84 Fed. Reg. 42193- 194; 85 Fed. Reg. 58614-615	
AZEDRA [®] (Ultratrace [®] iobenguane Iodine-131) Solution (treatment of iobenguane avid malignant and/or recurrent and/or unresectable metastatic pheochromocytoma and paraganglioma (PPGL) Continued from FY2021	XW033S5 or XW043S5	\$98,150	84 Fed. Reg. 42194-201; 85 Fed. Reg. 58615	
CABLIVI [®] (caplacizumab-yhdp) (inhibits microclot formation in acquired thrombotic thrombocystopenic purpura) Extended One Year	XW013W5 or XW033W5 or XW043W5	\$33,215	84 <i>Fed. Reg.</i> 42201-208; 85 <i>Fed.</i> <i>Reg.</i> 58615	
ELZONRIS [™] (tagraxofusp, SL-401) (targeted treatment of blastic plasmacytoid dendritic cell neoplasm) Extended One Year	XW033Q5 or XW043Q5	\$125,448.05 \$144,116.04	84 <i>Fed. Reg.</i> 42231-42237; 85 <i>Fed. Reg.</i> 58615- 616	
Balversa [™] (Erdafitinib) (second-line treatment for locally advanced or metastatic urothelial carcinoma) Continued from FY2021	XW0DWL5	\$3,563.23	84 Fed. Reg. 42237-242; 85 Fed. Reg. 58616	
SPRAVATO (Esketamine) (nasal spray for treatment-resistant depression) Extended One Year	XW097M5	\$1,014.79	84 <i>Fed. Reg.</i> 42247-256; 85 <i>Fed.</i> <i>Reg.</i> 58616-617	

Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
XOSPATA [®] (gilteritinib) (treatment of relapsed or refractory acute myeloid leukemia (AML)) Extended One Year	XW0DXV5	\$7,312.50	84 <i>Fed. Reg.</i> 42256-260; 85 <i>Fed.</i> <i>Reg.</i> 58617
JAKAFI [™] (Ruxolitinib) (oral kinase inhibitor treating acute graft-versus- host disease (GVHD)) Continued from FY2021	XW0DXT5	\$4,096.21 \$4475.38	84 <i>Fed. Reg.</i> 42265-273; 85 <i>Fed.</i> <i>Reg.</i> 58617-618
T2Bacteria [®] Panel (T2 Bacteria Test Panel) (aids in the diagnosis of bacteremia, a precursor for sepsis Extended One Year	XXE5XM5	\$97.50	84 <i>Fed. Reg.</i> 42278-288; 85 <i>Fed.</i> <i>Reg.</i> 58618
ContaCT (a radiological computer- assisted triage and notification software system, analyzing CTAs of the brain and notifying neurovascular specialists of suspected large vessel occlusions) Extended One Year	4A03X5D	\$1,040	85 <i>Fed. Reg.</i> 58625-636
Eluvia [™] Drug-Eluting Vascular Stent System (a drug-eluting stent for the treatment of lesions in the femoropopliteal arteries) Extended One Year	X27(H,J,K,L)385, X27(H,J,K,L)395, X27(H,J,K,L)3B5, X27(H,J,K,L)3C5,	\$3,646.50	85 <i>Fed. Reg.</i> 58645-658
Hemospray® Endoscopic Hemostat (for hemostasis of nonvariceal gastro- intestinal bleeding) Extended One Year	XW0G886, XW0H886	\$1,625.00	85 <i>Fed. Reg.</i> 58665-672
IMFINZI ® (durvalumab) and TECENTRIQ ® (atezolizumab) (programmed death-ligand 1 (PD-L1) blocking antibodies for the treatment of patients with extensive-stage small cell lung cancer) Extended One Year	XW03336, XW04336, XW033D6, XW043D6	\$6,875.90	85 <i>Fed. Reg.</i> 58672-684
Soliris ® (eculizumab) (for treatment of neuromyelitis optica spectrum disorder who are anti-aquaporin-4 antibody positive) Continued from FY2021	XW033C6, XW043C6	\$21,199.75	85 <i>Fed. Reg.</i> 58684-689
SpineJack ® System (an implantable fracture reduction system, for use in the reduction of painful osteoporotic vertebral compression fractures) Extended One Year	XNU0356, XNU4356	\$3,654.72	85 <i>Fed. Reg.</i> 58689-701

Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
BAROSTIM NEO ® System (for the improvement of symptoms of heart failure for patients who remain symptomatic despite treatment with guideline-directed medical therapy) Continued from FY2021	0JH60MZ, with 03HK3MZ or 03HL3MZ	\$22,750	85 <i>Fed. Reg.</i> 58716-58717
The Optimizer ® System (QFV) (for the treatment of chronic heart failure in patients with advanced symptoms with normal QRS duration and not indicated for cardiac resynchronication therapy) Continued from FY2021	0JH60AZ, 0JH63AZ, 0JH80AZ, 0JH83AZ	\$14,950	85 <i>Fed. Reg.</i> 58720-721
Cefiderocol (Fetroja) (a B-lactam antibiotic for the treatment of complicated urinary tract infections (cUTI) Continued from FY2021	XW03366, XW04366	\$7,919.86 (75% add-on limit)	85 <i>Fed. Reg.</i> 58721-723
NUZYRA® for injection (omadacycline) (a tetracycline class antibacterial for treatment of specific infections) Extended One Year	XW033B6, XW043B6	\$1,552.50 (75% add-on limit)	85 <i>Fed. Reg.</i> 58725-727
RECARBRIO [™] (a fixed dose combination of imipenem, a penem antibacterial; cilastatin, a renal dehydropeptidase inhibitor; and relebactam, a novel B-lactamase inhibitor (BLI) for complicated urinary tract infections (cUTI)) Continued from FY2021	XW033U5, XW043U5	\$3,532.78 (75% add-on limit)	85 <i>Fed. Reg.</i> 58727-729
XENLETA (a pleuromutilin antibacterial agent, a first treatment from a novel class of antibiotics for community- acquired bacterial pneumonia) Continued from FY2021	XW03366, XW04366, XW0DX66	\$1,275.75 (75% add-on limit)	85 <i>Fed. Reg.</i> 58729-732
ZERBAXA® (a combination of ceftolozane, a cephalosporin antibacterial; and tazobacam, a b- lactamase inhibitor (BLI) for treatment of specified infections) Continued from FY2021	XW03396, XW03496	\$1,836.98 (75% add-on limit)	85 <i>Fed. Reg.</i> 58732-733
RYBREVANT [™] (amivantamab, for the treatment of metastatic non-small cell lung cancer (NSCLC). New FY2022	XW033B7, or XW043B7	\$6,405.89	86 <i>Fed. Reg.</i> 44988-996

Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
COSELA [™] (trilaciclib, used to decrease the incidence of chemo-therapy- induced myelosuppression in adult patients administered prior to a certain treatment for extensive-stage small cell lung cancer((ES-SCLC) New for FY2022	XW03377, or XW04377	\$5,526.30	86 <i>Fed. Reg.</i> 45008-17
ABECMA [®] (idecabtagene vicleucel, a B- cell maturation antigen (BCMA)- directed genetically modified autologous chimeric antigen receptor (CAR)T-cell immunotherapy for relapsed or refractory multiple myeloma and is a 5 th line plus treatment) New for FY2022	XW033K7, or XW043K7	\$272,675.00*	86 <i>Fed. Reg.</i> 45028-35; * as corrected in 86 <i>Fed. Reg.</i> 58032
StrataGraft [™] Skin Tissue, a viable bioengineered, regenerative skin construct (BRSC) for treatment of severe thermal burns. New for FY2022	XHRPXF7	\$44,200.00	86 <i>Fed. Reg.</i> 45079-90
TECARTUS [®] (brexucabtagene autoleucel, a CD19 directed genetically modifier autologous T-cell immunotherapy for relapsed and refractory mantle cell lymphoma, a form of CAR-T. New for FY2022	XW033M7, or XW043M7	\$259,350*	86 <i>Fed. Reg.</i> 45090-104; * as corrected in 86 <i>Fed. Reg.</i> 58033
VEKLURY [®] (remdesivir, a nucleotide analog that inhibits viral RNA- dependent RNA polymerases, demonstrating activity countering viral pathogens such as SARS-CoV-2 (COVID-19)) New for FY2022	XW033E5, or XW043E5	\$2,028.00	86 <i>Fed. Reg.</i> 45104-116
ZEPZELCA (lurbinectedin, a marine derived, synthetic antineoplastic compound for treatment of metastatic small cell lung cancer (SCLC) with disease progression on chemotherapy) New for FY2022	XW03387, or XW04387	\$8,622.90	86 <i>Fed. Reg.</i> 45116-126
Aprevo [™] (an interbody fusion implant that stabilizes the lumbar spinal column and facilitates fusion during lumbar fusion procedures for spinal deformity, custom made from patient CT scans New for FY2022	XRG(A,B,C,D)0R7 XRG(A,B,C,D)3R7 XRG(A,B,C,D)4R7	\$40,950.00 *	86 <i>Fed. Reg.</i> 45127-133; * as corrected in 86 <i>Fed. Reg.</i> 67875

Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
aScope Duodeno (a sterile, single-use endoscope for endoscopy and endoscopic treatment of the upper gastrointestinal tract) New for FY2022	XFJB8A7, or XFJD8A7	\$1,715.59 ¹	86 <i>Fed. Reg.</i> 45133-135
EXALT [™] Model D Single-Use Duodenoscope (a single-use, flexible duodenoscope for diagnostic and therapeutic treatment of the pancreaticobiliary system during ERCP) New for FY2022	XFJB8A7, or XFJD8A7	\$1,715.59 ¹	86 <i>Fed. Reg.</i> 45138-140
Caption Guidance [™] (an artificial intelligence (AI) guided medical imaging acquisition software system for cardiac ultrasound images, providing real-time guidance during transthoracic echocardiography) New for FY2022	X2JAX47	\$1,868.10	86 <i>Fed. Reg.</i> 45135-138
Harmony [™] Transcatheter Pulmonary Valve System (a bioprosthetic heart valve from porcine pericardial tissue for treatment of congenital heart disease) New for FY2022	02RH38M	\$26,975.00	86 <i>Fed. Reg.</i> 45146-149
INTERCEPT Fibrinogen Complex (PRCFC) (a blood product for treatment of fibrinogen deficiency- related bleeding, including massive hemorrhage) New for FY2022	30233D1, or 30243D1 reported with ICD-10-CM codes D62*, D65, D68.2, D68.4* or D68.9*	\$2,535.00	86 <i>Fed. Reg.</i> 45149-150; * as corrected in 86 <i>Fed. Reg.</i> 67875
Shockwave C2 Intravascular Lithotripsy System (for lithotripsy- enabled, low-pressure dilation of calcified, stenotic de novo coronary arteries prior to stenting) New for FY2022	02F03ZZ, 02F13ZZ, 02F23ZZ, or 02F33ZZ	\$3,666.00	86 <i>Fed. Reg.</i> 45151-153

¹ The preamble text established a payment limit of \$1,715.59, however, the table on 86 *Fed. Reg.* 45585 shows a payment limit of \$1,715.58. The limit in the table appears to be an error based on other corrections in the correction notice of October 20, 2021 which corrected the amount in the table to match the amount discussed in the preamble text for other services, however, the amounts for aScope Duodeno and EXALT[™] Model D Single-Use Duodenoscope were not corrected.

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Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
CONTEPO [™] (fosfomycin) ² (an intravenous epoxide antibiotic for treatment of complicated urinary tract infections (cUTI), including acute pyelonephritis), if FDA marketing authorization by July 1, 2022 New for FY2022	XW033K5, or XW043K5	\$2,625.00 ³ (75% add-on limit)	86 <i>Fed. Reg.</i> 45154-155
FETROJA [®] (cefiderocol) (an injectable siderophore cephalosporin for hospital- acquired bacterial pneumonia/ ventilator- associated bacterial pneumonia New for FY2022	XW033A6, or XW043A6 * reported with ICD-10-CM codes Y95 and J14, J15.0, J15.1, J15.5, J15.6, or J15.8; OR J95.851 and B96.1, B96.20, B96.21, B96.22, B96.23, B96.29, B96.3, B96.5, or B96.89	\$8,579.84** (75% add-on limit)	86 Fed. Reg. 45156-157; * as corrected in 86 Fed. Reg. 67875; ** as corrected in 86 Fed. Reg. 58032
RECARBRIO [™] (imipenem, cilastatin, and relebactam) (a novel b-lactamase inhibitor for treatment of hospital acquired bacterial pneumonia/ ventilator associated bacterial pneumonia caused by susceptible Gram-negative bacteria) New for FY2022	XW033U5, or XW043U5 *reported with ICD-10-CM codes Y95 and J14, J15.0, J15.1, J15.5, J15.6, or J15.8 for HABP ; OR XW033A6 or XW043A6 reported with ICD-10-CM codes J95.851 and B96.1, B96.20, B96.21, B96.22, B96.23, B96.29, B96.3, B96.5, or B96.89 for VABP	\$9,577.00** (75% add-on limit)	86 <i>Fed. Reg.</i> 45157-159; * as corrected in 86 <i>Fed. Reg.</i> 58023; further corrected in 86 <i>Fed. Reg.</i> 67875; ** as corrected in 86 <i>Fed. Reg.</i> 58032

² Approval conditioned on FDA approval by July 1, 2022 and NTAP will begin the quarter following the date of FDA authorization.

³ Contepo[™] is a QIDP with payment limit of 75%. The preamble text for Contepo[™] established a payment limit of \$2,625.00, which is 75% of the cost per case of \$3,500, however the table on 86 *Fed. Reg.* 45585 shows a payment limit of \$2,275 or 65% of the calculated cost per case, which appears to be an error. The payment limit was corrected for two other newly added QIDP drugs with the same error, however, the amount for Contepo in the table was not corrected.