Year in Review

AHLA Institute on Medicare & Medicaid Payment Issues 2024

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Agenda

- New policy initiatives
- New reimbursement programs
- Key hospital, physician and other federal provider / supplier payment rules from 2024
- Developments in Enforcement
- Continued efforts to increase transparency in health care

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New Policy Initiatives

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Health Equity and Health-Related Social Needs

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Advancing Health Equity

CMS Framework for Health Equity 2022 – 2032: 5 Priorities

- Expand standardized data collection, reporting, and analysis
- Assess causes of disparities and work to close gaps within CMS
- Build capacity to reduce disparities with healthcare organizations and the workforce
- Advance language access, health literacy, and culturally tailored services
- Increase accessibility to health care services and coverage

https://www.cms.gov/priorities/health-equity/minority-health/equity-programs/framework

CMS will hold its 2nd health equity conference in May 2024.

Health Equity Metrics

Measurement

- Health equity measurement initially introduced to Inpatient Quality Reporting in 2023
- 2024: further standardize equity measures and improve data collection
- Use reported SDOH ICD-10 codes to analyze severity of illness, complexity of services, and resource consumption
- Account for geographic as well as individual patient characteristics to support rural health

Payment adjustments:

- Hospital value-based purchasing adds to hospitals' total performance scores based on quality metrics and dual eligible patient population
- 2024 IPPS Final Rule includes SDOH codes related to homelessness as a complication/comorbidity for inpatient DRGs
- Medicare Shared Savings Program payment adjustment for ACOs serving more low-income patients
- Medicare Advantage Health Equity Index reward
- Value-Based Insurance Design model tests whether more flexibility in MA benefit design can better serve patients with chronic conditions and address health-related social needs

New Care Management Services
Physician Fee Schedule

Community Health Integration (CHI)

- Addresses SDOHs that are barriers to the patient's treatment
- By trained staff such as social workers, nurse case managers, or community health workers with certain competencies
- After an initial E&M or AWV with a physician/NPP
- Coinsurance – verbal consent required

Principal Illness Navigation (PIN)

- Focuses on social aspects of care not covered by more clinically focused care management
- Trained/certified patient navigators or peer support specialists help patients through a high-risk disease expected to last at least 3 months
- Initiating visit with a physician, NPP, or psychologist
- Patient may or may not have SDOH needs
- Coinsurance – verbal consent required

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New Care Management Services
Physician Fee Schedule

SDOH risk assessment (HCPCS G0136)

- Using a standardized tool including food, housing, utilities, and transportation at a minimum
- In conjunction with an E&M or psych eval visit when the physician/APC *has reason to believe* unmet SDOH needs are interfering with treatment
- Can be performed via telehealth
- Screening only (such as a pre-visit questionnaire) is not billable
- No more than every 6 months

Caregiver Training Services (CTS)

- Group or individual sessions for family/friends who provide unpaid assistance to people with chronic or disabling conditions (patient not required to be present)
- Part of patient's treatment plan or rehab plan of care
- Coinsurance – verbal consent required
- Not eligible for telehealth

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Behavioral Health Focus

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Behavioral Health Care

- CMS behavioral health strategy focuses on:
  - SUD prevention, treatment, recovery
  - Pain management
  - Improving mental health services
- Medicaid mobile crisis intervention programs approved for 15 states (as of 2/2/24)
  - Authorized by the American Rescue Plan of 2021 as rehabilitative mental health and substance use disorder (SUD) services
  - Multidisciplinary team goes to the person in crisis to offer de-escalation, stabilization, and connections to treatment and social support
- Innovation in Behavioral Health model announced Jan. 2024
  - "No wrong door" approach to meeting patients' physical and behavioral health needs

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Behavioral Health Professionals

New Professional Enrollment Categories

- Licensed Marriage and Family Therapists (LMFTs)
- Mental Health Counselors = Licensed Professional Clinical Counselors in CA
  - Also includes addiction counselors who meet educational requirements
- Comparable to Licensed Clinical Social Workers
- 75% of PFS rate in ambulatory settings
- Included in facility payment for IOP, PHP
- May participate in hospice interdisciplinary teams and as RHC clinicians

Health Behavior Assessment and Intervention (HBAI)

- 9 codes used for psychological assessment and treatment, when the primary diagnosis is a medical condition
- Evaluation of patient's responses to a medical condition, including coping strategies, motivation, and adherence to treatment
- Individual, group, or family services

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Outpatient Behavioral Health Services

Intensive Outpatient Programs (IOP)

- Consolidated Appropriations Act, 2023 provisions created a new benefit category for intensive outpatient program services for individuals with acute behavioral health needs.
- Patient needs at least 9 hours per week of treatment
- Requires physician certification every 60 days and treatment plan
- Can be furnished in RHCs, FQHCs, and Opioid Treatment Programs as well as hospitals and community mental health centers
- CMS treats Substance Use Disorders as diagnoses for medical necessity (in addition to traditional psychiatric diagnoses), but does not cover the SUD-specific CPT codes as IOP/PHP services
- IOP paid in addition to the OTP weekly bundle for naloxone/methadone treatment

Partial Hospitalization Program (PHP) update

- Patient needs at least 20 hours per week of treatment
- As an alternative to inpatient psychiatric care
- Requires physician certification every 60 days and treatment plan
- Added group therapy, psychological testing as primary behavioral health services
- 2 levels of per-diem payment in 2024
- 3 services per day (or fewer on days when the patient is unable to complete treatment)
- 4 or more services per day

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Mental Health Parity Proposed Rule

HHS, DOL, Treasury proposal would:

- Enhance and standardize enforcement of the Mental Health Parity and Addiction Equity Act (2008)
- Implement Consolidated Appropriations Act, 2021 requirement for payers to analyze, document, and use non-qualitative treatment limits (NQTLs), such as prior authorizations, for behavioral health services
- Require collection of outcome data on patient access to services
- Clarify that eating disorders and autism spectrum disorders are considered mental health conditions for MHPAEA enforcement

Substance Use Disorder Developments

SAMHSA Final Rule on Treatment for Opioid Use Disorder

- On Feb. 2, SAMHSA issued final rule intended to expand access to treatment for opioid use disorder (OUD), including permanently easing restrictions on take-home doses of methadone and the use of telehealth when initiating buprenorphine.
- Updates accreditation, certification and treatment standards for providing OUD medications, including making permanent certain flexibilities put in place during the COVID-19 public health emergency.
- Adds evidence-based practices such as split dosing, telehealth, and harm reduction activities, while removing stigmatizing language such as "detoxification."
- Other provisions include modifying the definition of an OTP treatment practitioner to include any provider who is appropriately licensed by a state to prescribe or dispense approved medications; updating admission criteria, as required by statute, to remove significant barriers to entry, such as the one-year requirement for OUD, while also defining the scope and purpose of the "initial" and "periodic medical examinations"; and codifying the use of online/electronic forms.

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New reimbursement programs

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New Payment Models: Introduction and Making Care Primary Model

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Value-Based Legislative Changes on the Horizon?

- Value in Health Care Act (H.R. 5013)
  - Bipartisan support; referred to Health Subcommittee (Jul. 2023)
  - Would continue 5% APM incentive payment for two years
  - Would receive 50% revenue threshold physician in value-based models must meet to qualify for bonuses
  - Would give HHS authority to increase revenue threshold, but no more than 5% in any single year
  - Authorizes CMS to establish lower APM participation thresholds for episode models and other types of APMs
  - Eliminating revenue-based distinctions for ACOs (affects certain rural and safety net providers' share in the savings).
  - Creates more transparent process to set financial spending targets
  - Establishes voluntary, full-risk track for ACOs
  - Provides technical assistance for clinicians new to APMs
  - Studies ways to increase parity between APMs in traditional Medicare and Medicare Advantage
- Strengthening Innovation in Medicare and Medicaid Act (H.R. 6732)
  - Calls for study of APMs, various higher-level changes
  - Introduced in Dec. 2023; referred to Health Subcommittee

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Making Care Primary Model

- On Jun. 8, 2023, CMS unveiled a new primary care model—the Making Care Primary ("MCP") Model
- Being tested in eight states through their Medicaid programs: CO, MA, MN, NJ, NM, NY, NC and WA
  - Will include three tracks with enhanced payments and run for 10.5 years from July 1, 2024 to December 31, 2034
  - Track 1 participants (building infrastructure to support care transformation)
  - Track 2 participants (implementing advanced primary care)
  - Track 3 participants (optimizing care and partnerships)
- Model is aimed at ensuring patients receive primary care that:
  - Is integrated and coordinated
  - Creates a pathway for primary care organizations and practices (such as rural, independent and safety net providers) to enter into value-based arrangements
  - Improves the quality of care while reducing spending

Making Care Primary Model

- Track 1
  - Participants research and plan an approach to implement advanced primary care services, including: risk-stratifying their population; reviewing data / building out workflows; identifying staff for chronic disease management; and conducting health-related social needs screening and referral.
  - Payment for primary care remains FFS; CMS provides additional financial support to help participants build advanced care delivery capabilities.
- Track 2
  - Participants build upon work completed in Track 1 by: partnering with social service providers and specialists; implementing care management services; and systematically screening for behavioral health conditions.
  - Payment for primary care shifts partially to prospective, population-based payments. Additional financial support as participants build capabilities. Participants eligible to earn increased payments for improving outcomes and achieving savings.
- Track 3
  - Participants expand upon Track 1 and 2 requirements by: using quality improvement frameworks to optimize and improve workflows; address silos to improve care integration; enhance social service and specialty partnerships; and deepen connections to community resources.
  - Payment for primary care shifts to fully prospective, population-based payment. Additional financial support to sustain care delivery activities. Participants can earn increased payments for improving health outcomes and achieving savings.

Making Care Primary Model

MCP Payment Types By Track

Prospective Primary Care Payment (PPCP)

Track 1 | Track 2 | Track 3

- Replaces fee-for-service revenue for primary care services for beneficiaries attributed to MCP
- Will reflect participants' historical primary care billing for the first three model years; CMS will introduce a methodology that bases a portion of the PPCP on regional spend trends[1] for Track 3 participants

Enhanced Services Payment (ESP)

Track 1 | Track 2 | Track 3

- Risk-adjusted per beneficiary[2] per month (PBPM) payment to participants in Tracks 1, 2, and 3 in addition to payment for typical primary care services; decreases by track as participants build capacity
- Supports ongoing care management activities, such as chronic disease management and health-related social needs (HRSN) screenings

Performance Incentive Payment (PIP)

Track 1 | Track 2 | Track 3

- Upside risk only bonus payment based on quality utilization, and cost; bonus potential increases by track
- Assessed every year

Upfront Infrastructure Payment (UIP)

Track 1 | Track 2 | Track 3

- Infrastructure payment that is only available to Track 1 participants new to VBC arrangements and meet a low revenue threshold, or do not have an e-consult platform[3]
- Eligible participants may receive $72,500 in a lump sum payment at the start of Year 1 and an additional $72,500 at the start of Year 2

UIP Use Categories:

- Increased Staffing
- Social Determinants of Health (SDOH) Strategies
- Health Care Clinician Infrastructure

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Making Care Primary Model

- Following types of organizations that provide primary care may apply:
  - Solo primary care practices
  - Indian Health Programs
  - FQHCs
  - Group practices
  - Health systems
  - CAHs
- Certain entities ineligible (rural health clinics, concierge practices, grandfathered tribal FQHCs, primary care first practices and ACO Reach participant providers active as of May 31, 2023)
- Organizations cannot concurrently participate in MSSP and MCP
- Additional eligibility criteria outlined in RFA
- MCP components designed to improve health equity:
  - Some payments will be adjusted by clinical indicators and social risk.
  - Participants will be required to develop a strategic plan for how they will identify disparities and reduce them.
  - Participants will be required to implement HRSN screening and referrals.
  - Participants will be allowed to reduce cost-sharing for patients in need.
  - CMS will measure the percentage of patients screened for HRSNs
  - CMS will collect data on certain demographic information and HRSNs to evaluate health disparities in MCP communities.

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New Oncology Model: EOM

Enhancing Oncology Model: EOM

- Enhancing Oncology Model ("EOM")—aimed at improving cancer care for Medicare patients and lowering health care costs—began on Jul. 3, 2023
  - EOM intended to make cancer care more affordable and accessible for Medicare beneficiaries
  - Aims to hold oncology practices accountable for total costs of care
  - Aligns with the Biden Administration's Cancer Moonshot goals – decreasing the cancer death rate by at least 50% over 25 years
  - Performance period began in Jul. 2023 and ends in Jun. 2028
- Based on CMS experience with 2015's Oncology Care Model
  - Ran from Jul. 1, 2016—Jun. 20, 2022
- EOM includes 67 physician oncology group practices
  - Includes more than 600 sites of care across 47 states nationally and over 3,000 individual practitioners
  - Approximately 15% of the sites are located in rural/small town areas
- Also includes 3 payers (BCBSSC, BCBSTN, CVS Health / Aetna)

Enhancing Oncology Model

- Under EOM, participating oncology practices will take on financial and performance accountability for episodes of care surrounding systemic chemotherapy administration to patients with common cancer types.
- Two-part payment structure for EOM participants
- Participants responsible for the total cost of care during a 6-month episode.
  - Depending on total episode expenditures and quality performance, EOM participants have the potential to earn a performance-based payment (PBP) or owe CMS a performance-based recoupment (PBR).
  - PBP and PBR amounts will be adjusted based on actual quality performance.
- EOM participants will also have the option to bill a Monthly Enhanced Oncology Services (MEOS) payment per beneficiary per month for the provision of Enhanced Services to EOM beneficiaries during each 6-month episode.
  - EOM includes an additional MEOS payment for dually eligible beneficiaries, acknowledging the greater resources that may be needed to care for complex and underserved communities.

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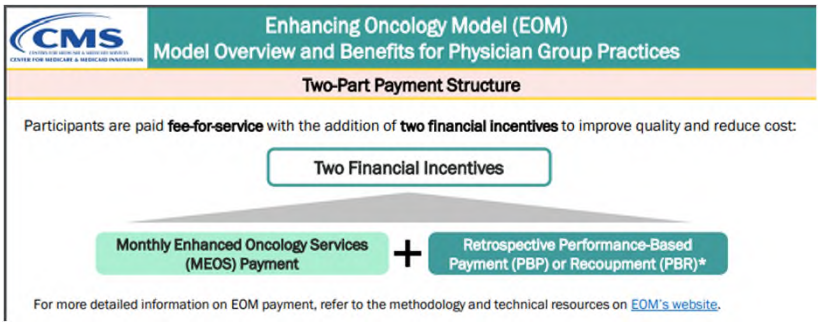
Enhancing Oncology Model: Payment Structure



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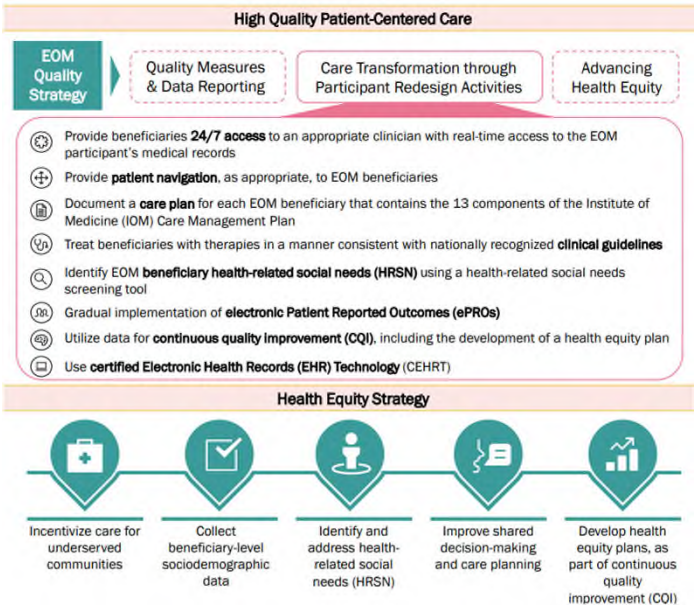

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Dementia Care Payment Model: GUIDE

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New Dementia Care Payment Model: GUIDE

- On Jul. 31, 2023, CMS announced a new eight-year, voluntary payment model called the Guiding an Improved Dementia Experience ("GUIDE") Model for Medicare providers and suppliers to offer a combination of care coordination for beneficiaries with dementia and support services for their caregivers.
  - Aimed at improving care for beneficiaries with dementia, helping them remain in their homes, and reducing the strain on unpaid caregivers
- Under the Model, participants must maintain an interdisciplinary care team, including:
  - Clinician with dementia proficiency
  - Trained care navigator who connects beneficiaries and caregivers with support services
- Beneficiaries receiving care will be placed in one of five tiers depending on the disease stage and caregiver status – and payment will increase by tier:
  - New safety net providers will be eligible for a one-time, lump sum infrastructure payment
  - All participants will receive a monthly, per beneficiary amount for providing care management and coordination
  - Participants may bill for respite services up to an annual cap, for caregivers of beneficiaries with moderate to severe dementia

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GUIDE Model

BENEFICIARY TIERS

People with Medicare who receive care from model participants will be placed in one of five "tiers," based on a combination of their disease stage and caregiver status. Beneficiary needs, and correspondingly, care intensity and payment, increase by tier.

	TIER	CRITERIA
Beneficiaries **with** a caregiver	Low complexity	Mild dementia
	Moderate complexity	Moderate or severe dementia and low to moderate caregiver strain
	High complexity	Moderate or severe dementia and high caregiver strain
Beneficiaries **without** a caregiver	Low complexity	Mild dementia
	Moderate to high complexity	Moderate or severe dementia

MODEL BENEFICIARY ELIGIBILITY

The GUIDE Model's intended beneficiary population is community-dwelling Medicare fee-for-service beneficiaries, including beneficiaries dually eligible for Medicare and Medicaid, living with dementia. Eligible beneficiaries must meet the following criteria:

- ✓ Beneficiary has a diagnosis of dementia, as confirmed by clinician attestation.
- ✓ Have Medicare as their primary payer.

- ✓ Enrolled in Medicare Parts A and B (not enrolled in Medicare Advantage, including Special Needs Plans and PACE).
- ✓ Not enrolled in Medicare hospice benefit.
- ✓ Not residing in a long-term nursing home.

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GUIDE Model

- Two tracks: one for established programs and one for new programs.
  - Established programs must have an interdisciplinary care team, including a care navigator, use an EHR platform that meets the standards for Certified EHR Technology, and meet other care delivery requirements as outlined in the RFA.
  - New programs must not be operating a comprehensive community-based DCP at the time of model announcement and will have a one-year pre-implementation period to establish their programs.
- Model permits participants contracting with other Medicare providers / suppliers to meet care delivery requirements of GUIDE
- 5 Components:
  - **Defining a standardized approach to dementia care delivery for model participants** – includes staffing considerations, services for beneficiaries and their unpaid caregivers, and quality standards.
  - **Providing an alternative payment methodology to model participants** – CMS will provide a PMPB payment to support a team-based collaborative care approach.
  - **Addressing unpaid caregiver needs** – aims to address the burden experienced by unpaid caregivers by requiring model participants to provide caregiver training and support services, including 24/7 access to a support line, as well as connections to community-based providers.
  - **Respite services** – CMS will pay model participants for respite services (temporary services provided to a beneficiary in their home, at an adult day center, or at a facility that can provide 24-hour care for the purpose of giving the unpaid caregiver temporary breaks from their caregiving responsibilities).
  - **Screening for Health-Related Social Needs** – model participants will be required to screen beneficiaries for psychosocial needs and health-related social needs (HRSNs) and help navigate them to local, community-based organizations to address these needs.

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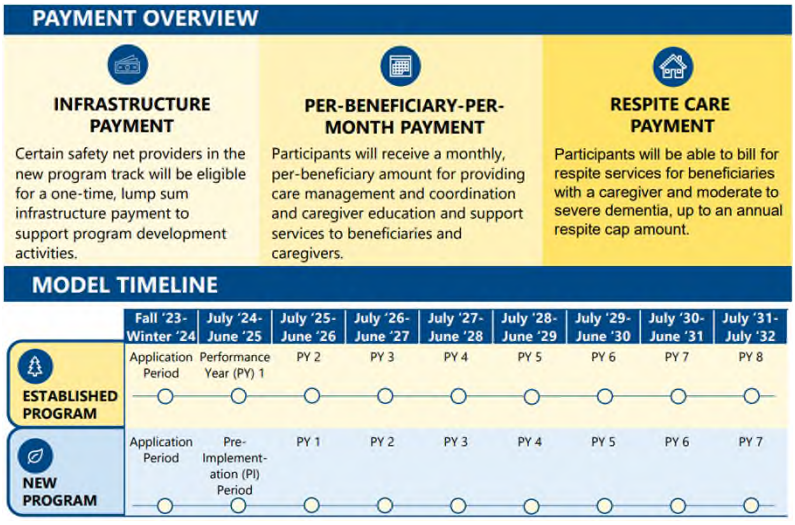
GUIDE Model



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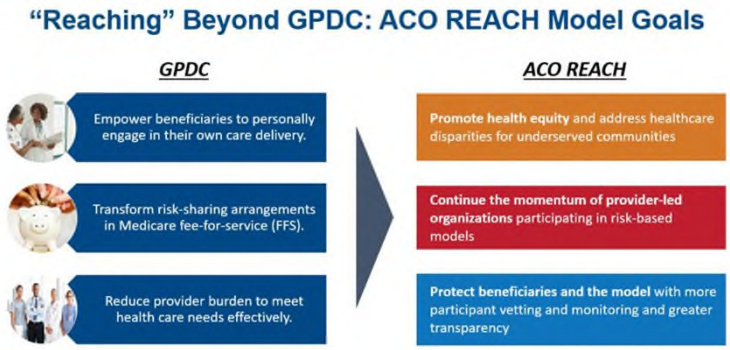
GUIDE Model

- GUIDE intended to improve health equity, including:
  - Requiring participating providers to implement HRSN screenings and referrals.
  - Offering financial and technical support for development of new dementia care programs targeted to underserved areas with less access to specialty dementia care.
  - Annual reporting by participants on progress towards health equity objectives, strategies, and targets.
  - Using data from the model to identify disparities and target improvement activities.
  - A health equity adjustment to the model's monthly care management payment to provide additional resources to care for underserved beneficiaries.

Updates to ACO REACH Model

Updates to ACO REACH Model

- Accountable Care Organization ("ACO") Realizing Equity, Access, and Community Health ("REACH") Model
  - Originally launched in February 2022 as a redesigned version of the Global and Direct Contracting Model (GPDC)



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ACO Reach Model

- First Performance Year of the redesigned model began on Jan. 1, 2023 and will run for four Performance Years: Performance Year 2023 (PY2023) through PY2026.
- Three types of participants
  - Standard ACOs
  - New Entrant ACOs
  - High Needs Population ACOs
- Two voluntary risk-sharing options:
  - Professional: A lower risk-sharing arrangement—50% savings/losses—with one payment option for participants: Primary Care Capitation Payment, a risk-adjusted monthly payment for primary care services provided by the ACO's participating providers.
  - Global: A higher risk sharing arrangement—100% savings/losses—with two payment options: Primary Care Capitation Payment (described above) or Total Care Capitation Payment, a risk-adjusted monthly payment for all covered services, including specialty care, provided by the ACO's participating providers.

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ACO Reach Model

- On Aug. 15, 2023, CMS announced a "coordinated set of changes" to the ACO REACH Model starting in 2024 performance year:
  - Changes are aimed at increasing predictability for model participants, protecting against inappropriate risk score growth, and further advancing health equity. Examples include:
  - Increasing predictability
    - Reduced escalation of beneficiary alignment minimum for new entrant ACOs and high needs population ACOs
    - Added 10% buffer on alignment minimums for all ACO types
    - Changed eligibility criteria for alignment to a high needs population ACO
    - Modification of financial guarantee policy (both for ACOs that have elected Provisional Financial Settlement and have fully paid Shared Losses (or received Shared Savings) (only required to update their financial guarantee to reflect the amount required for the current performance year) and ACOs that have selected Enhanced Primary Care Capitation and/or Advanced Payment Option (increased to 4%)
    - Modified Provisional Settlement to reflect 12 months of performance year experience (with 0 months of run-out), an update from 6 months of performance year experience (with 6 months of runout) previously.
    - Application of symmetric risk corridors to retrospective trend adjustment

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ACO Reach Model

- Other changes to ACO Reach for 2024 PY include:
  - Inappropriate risk score growth:
    - Revisions to risk adjustment methodology—Revised 2024 Part C risk adjustment model, being applied in Medicare Advantage program, will be applied to Standard and New Entrant ACOs.
    - PY2024 risk scores will be blended using 67% of the risk scores under the current 2020 risk adjustment model and 33% of the risk scores under the revised 2024 risk adjustment model.
  - Advancing health equity:
    - Revising composite measure used to identify underserved beneficiaries for the HEBA by incorporating two new variables (Low-Income Subsidy Status and State-Based Area Deprivation Index)
    - More continuous distribution of adjustment amounts under the HEBA such that the upward adjustment extends beyond the top decile of underserved beneficiaries and the downward adjustment is limited to the bottom three deciles.
      - Adjustments to ACO benchmarks in the modified policy will be $30 PBPM for beneficiaries with equity scores in the top decile, $20 PBPM for beneficiaries in the second decile, $10 PBPM for the third decile, $0 PBPM for the next four deciles, and -$10 PBPM for the bottom three deciles.
    - Expanded Nurse Practitioner and Physician Assistant Services Benefit Enhancement to certify and order pulmonary rehabilitation care plans

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Innovation in Behavioral Health Model

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Innovation in Behavioral Health Model

- On Jan. 18, 2024, HHS announced a new program—the Innovation in Behavioral Health ("IBH") Model—to test approaches for addressing behavioral and physical health of individuals covered by Medicare / Medicaid
  - Model will be tested by CMMI for eight years
  - CMS will issue awards to Medicaid agencies in up to 8 states to implement the model
  - Practice participants will be community-based behavioral health practices, including community mental health centers, opioid treatment programs, safety net providers and public / private practices will individuals can receive outpatient mental health and / or SUD services
  - Model will launch in fall 2024, and CMS will release a Notice of Funding for the Model in Spring 2024
- Goal of IBH is to improve the overall quality of care and outcomes for adults with mental health conditions and/or substance use disorder by connecting them with supports to manage their care

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Innovation in Behavioral Health Model

- IBH Model has 4 pillars
  - Care Integration: Behavioral health practice participants will screen, assess, refer, and treat patients, as needed, for the services they require.
  - Care Management: Interprofessional care team, led by the behavioral health practice participant, will identify, and as appropriate address, the multi-faceted needs of patients and provide ongoing care management.
  - Health Equity: Behavioral health practice participants will conduct screenings for HRSNs and refer patients to appropriate community-based services. Participating practices will be required to develop health equity plan (HEP). HEP should stipulate how the practice participant will address disparities that impact their service populations.
  - Health Information Technology: Expansion of health IT capacity through targeted investments in interoperability and tools (including EHRs) will allow participants to improve quality reporting and data sharing.
- States can apply as whole state or selected region. Practice Participants
  - Licensed by the state awardee to deliver behavioral services, either mental health and/or substance use disorders
  - Meet all state-specific Medicaid provider enrollment requirements
  - Eligible for Medicaid reimbursement
  - Serve adult Medicaid beneficiaries (age 18 or older) with moderate to severe behavioral health conditions
  - Provide mental health and/or substance use disorder services at the outpatient level of care

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Innovation in Behavioral Health Model

- Health equity component
  - Practice participants are required to create HEP using a needs assessment of the population they serve.
    - HEP should detail steps that practice participants will take to address the population needs and stipulate how participanta will address disparities that disproportionately impact their service populations.
  - Model will require practice participants to annually screen and monitor patients for underlying and/or unmet HRSNs and make necessary referrals to other health care providers or local safety-net services
- Payment
  - Model includes a pre-implementation period (model years 1-3). During this period, states and practice participants will receive funding to develop and implement model activities and capacity building. During year 1, states will conduct outreach and recruit behavioral health practice participants:
    - Practice participants will receive funding to support necessary upgrades to health IT / EHRs, as well as practice transformation activities, and staffing to implement the model.
    - Participants who elect to participate in the Medicare payment model may also be eligible for additional funding to support model activities.
  - By start of year 4, states will implement a Medicaid payment model that supports practice participants in implementing the care delivery framework. Participants in selected states who participate in the additional Medicare payment model will receive a PBPM payment to support their implementation of the care delivery framework.
  - Payments will be further supplemented with additional performance-based payments during the implementation period (model years 4-8).

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Medicare Shared Savings Program

Medicare Shared Savings Program Growth

2022 Report

- Saved $1.8B
- Covered 11M beneficiaries
- Over 500,000 participating physicians and other clinicians
- 63% of ACOs earned shared savings

2024 Progress

- 480 participating MSSP ACOs
- $20M advance investment payments to support care for underserved populations
- 245 participants in ACO REACH and Kidney Care Choices models
- 13.7M Traditional Medicare beneficiaries aligned

Medicare Shared Savings Program

2024 Changes

- Health equity measures and a health equity adjustment that rewards excellent care delivered to underserved communities
- Expand advance investment payments as a permanent program to encourage providers in rural and underserved areas to participate
- Align more patients who see NPPs for primary care to improve equity and access
- Give new ACOs more time to transition to downside risk
- Technical changes to encourage participation by ACOs with medically complex, high-cost patient populations
- CMS hopes to increase MSSP participation by 10 – 20%

Key hospital, physician and other federal provider / supplier payment rules from 2024

340B Program Updates

HRSA Ends 340B Offsite Facility Registration COVID-19 Waiver

- During the COVID-19 Public Health Emergency, HRSA waived its enforcement of the requirement that an offsite, outpatient facility be listed as reimbursable on the hospital's Medicare Cost Report and be registered with OPAIS in order to use 340B drugs
  - Covered entities argued that this created long delays in actually receiving the drugs because OPAIS registration is conducted quarterly and Medicare Cost Report are filed annually
  - In the meantime, other drug discounts were not available
- In May 2023, the COVID-19 PHE officially ended
- In Oct. 2023, HRSA announced that the waiver for 340B hospital offsite facility registration requirements would end
  - Covered entities given 90-day period to come into compliance
  - HRSA determined that the waiver policy hampered compliance verification and auditing

Definition of "Patient" for 340B Purposes

- In November 2023, a South Carolina federal district court rejected HRSA's definition of "patient" as used in 340B program
  - Plaintiff Genesis Health Care, a FQHC, argued that HRSA's interpretation of an eligible "patient" was unduly restrictive
  - Case arose from HRSA audit. In audit enforcement letter, HRSA asserted that 340B eligibility available only for patients whose prescriptions originated from care provided by the covered entity
  - Genesis had been being removed from the 340B Program because the government determined Genesis was dispensing a high volume of 340B drugs to individuals who were not 340B "patients"
  - HRSA decision led to lawsuit by Genesis
  - After Genesis filed suit, HRSA reversed the audit's findings but Genesis appealed regardless

Definition of "Patient" for 340B Purposes

- Court held that the only requirement under the statute for 340B eligibility is for the individual to be a "patient" of a "covered entity
  - The prescription for a 340B drug does not need to originate from a health care encounter with the covered entity, as long as the individual has an ongoing patient relationship with the covered entity
  - Ongoing relationship not defined
  - Court provides that "[i]f there is a desire to restrict the 340B Program and limit the ability of 'covered entities' to remain profitable in the face of prescription drug price increases, Congress is the appropriate entity to take the necessary action. It is not the role of HRSA to legislate and limit the 340B program by restricting the definition of the term 'patient,' thereby frustrating the ability of the 340B statute to accomplish its purpose."

$9 Billion to be Returned to 340B Hospitals

- On Nov. 2, 2023, CMS issued a final rule to remedy underpayments made to 340B hospitals
  - Underpayments were attributed to changes to the OPPS held to be unlawful by the Supreme Court in *American Hospital Association v. Becerra* (142 S. Ct. 1896 (2022))
  - Supreme Court had held that the payment rates to 340B hospitals were invalid because prior to implementing the rates in 2018, HHS failed to conduct a survey of hospitals' acquisition costs
  - Approximately 1,700 340B hospitals were affected
- CMS finalized a policy to give affected providers a one-time lump sum payment
  - CMS estimates that for 2018 through 2022, certain OPPS providers received $10.6 billion less in 340B drug payments then they would have without the 340B policy
  - However, affected providers already received $1.6 billion through reprocessed claims for 340B drugs from Jan. 1, 2022 through Sep. 27, 2022
  - CMS will offset these payments prospectively. Will occur through reduction in OPPS conversion factor by a negative 0.5% adjustment each year beginning in 2026. Will take approximately 16 years to recoup amount.

SUSTAIN 340B Act

- The Supporting Underserved and Strengthening Transparency, Accountability and Integrity Now and for the Future of 340B Act
- Bipartisan support in Senate
- Proposes a number of changes to 340B program, including:
  - Covered entities can use contract pharmacies in accordance with HRSA's 2010 guidance; arrangements must be registered annually; HHS must issue regulations related contract pharmacy arrangements; additional CMP authorities against manufacturers.
  - Senators acknowledge lack of clarity exists on how "patient" should be defined under 340B program; solicits feedback on appropriate manner for defining that term.
  - Guidelines on child sites, including that child sites must be wholly-owned by and clinically / financially integrated with covered entity; must provide care consistent with covered entities' policies.
  - Covered entities required to report specific information about their use of 340B program in cost reports.
  - Expanded program integrity (audits, contract only with vendors who agree to make certain reports to HHS, expanded use of financial assistance policies).
  - Use of national clearinghouse to prevent duplicate discounts between 340B and Medicaid.

Proposed Rule Addressing Medicaid Drug Pricing Includes 340B Change

- Misclassification of Drugs, Program Administration and Program Integrity Updates Under Medicaid Drug Rebate Program
  - Issued May 26, 2023. Comment period closed Jul. 25, 2023
- Medicaid managed care plans use Medicaid-specific BINs and PCNs instead of the same BINs / PCNs being used for both commercial and Medicaid managed care plans
  - Medicaid managed care beneficiary insurance cards to include Medicaid-specific information
  - Goal is to avoid duplicate discounts under the 340B program
- Numerous other proposed changes related to Medicaid drug pricing, including:
  - Transparency in PBM pricing
  - Revise the determination of Medicaid "best price" to specify for manufacturers that cumulative discounts, rebates, or other arrangements must be "stacked" (aggregated) to generate a final price realized by the manufacturer for a particular unit of a COD, including discounts, rebates or other arrangements provided to different best price eligible entities.
  - Definition of covered outpatient drug
  - Definition of vaccine

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Accreditation Conflicts

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Proposed Rule on Oversight of Accrediting Organizations

- On Feb. 15, 2024 CMS issued proposed rule intended to strengthen oversight of accrediting organizations (AOs)
- Comment period runs through Apr. 15, 2024
- Changes in NPRM affect all AOs except those that accredit clinical labs and noncertified suppliers (ADI, HIT, DSMT, DMEPOS)
- Impetus for rule includes several concerns identified by CMS in recent years:
  - Providers and suppliers that have been terminated from Medicare / Medicaid but retain accreditation despite significant quality and safety concerns;
  - AOs provide fee-based consulting services to the providers and suppliers they accredit, potentially affecting the integrity of the onsite survey process and decreasing public trust by creating conflicts of interest;
  - Inconsistent survey results due to differing AO standards or practices (such as AOs notifying facilities of the date of their onsite surveys in advance contrary to CMS policies).

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Proposed Rule on Oversight of Accrediting Organizations

- Proposed rule would make a number of changes, including:
  - Holding AOs accountable to the same standards as State SAs, that also conduct surveys on behalf of CMS.
  - Placing certain limitations on the fee-based consulting services AOs provide to the health care facilities they accredit.
  - Prohibiting AO owners, surveyors, and other employees, and as well as their immediate family members that have an interest in or relationship with a health care facility accredited by the AO from participating in surveys, having input into the survey results and involvement in pre- or post-survey activities of that facility, or from having access to survey records related to that facility.
  - Addressing potential and actual conflicts of interest by requiring AOs to report specific information to CMS about how they will monitor, prevent, and handle conflicts of interest and fee-based consulting services they provide.
  - Requiring AOs with poor performance to submit a publicly reported correction plan to CMS.
  - Improving consistency and standardization in surveys nationwide by more closely aligning AO survey activity requirements and staff training with those of SAs.

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Lab Developed Tests

Background on Lab Developed Tests (LDTs)

- What is an LDT? One definition:
  - In vitro diagnostic test that is intended designed, manufactured and used within a single site CLIA-certified laboratory that meets the requirements for high complexity testing
- Compared to commercially marketed lab tests (manufactured by medical device companies and sold to providers)
  - Need to be cleared by FDA through premarket notification / premarket approval process
- 1976 Medical Device Amendments Act granted FDA jurisdiction over commercially distributed test kits as in-vitro diagnostic devices
- FDA has claimed that statute gives agency jurisdiction over LDTs
- Agency has historically exercised enforcement discretion over LDTs
- Some labs and various other parties have asserted LDTs are clinical services (not medical products) and thus not within scope of FDA authority

FDA Issues Proposed Rule for Regulating LDTs

- The FDA issued a proposed rule (88 Fed. Reg. 68006) on Oct. 3, 2023 aimed at settling the agency's long-disputed authority to regulate in vitro diagnostic products ("IVDs") manufactured within a single laboratory
- Proposed rule would specify that laboratory developed tests ("LDTs") are medical devices under the Federal Food, Drug, and Cosmetic Act, and are thus subject to FDA regulation
  - In a press release published on Sep. 29, 2023, the FDA stated that this proposed rule is coupled with a policy under which the agency intends to provide greater oversight of LDTs, through a phaseout of its general enforcement discretion approach to LDTs.
  - FDA Commissioner Robert M. Califf, M.S. stated that a catalyst for this enforcement was an increase in using LDTs for larger and more diverse populations: "70% of today's medical decisions depend on laboratory test results. Given the role these tests play in modern medical care, their accuracy and validity have a significant impact on public health."

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Proposed Rule on LDTs

- Rulemaking would amend the definition of "in vitro diagnostic products" in FDA regulations (21 C.F.R. 809.3) to make clear that IVDs are devices are the FD&C Act, "including when the manufacturer of these products is a laboratory"
- Agency proposes a phaseout of FDA's general enforcement discretion approach that is designed to increase oversight
- Comment period was 60 days; ended on Dec. 4, 2023
- As of Mar. 4, 2024, FDA LDT rulemaking is pending before White House Office of Information and Regulatory Affairs
- Typically last step before final rule published in Federal Register

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Phaseout of LDT Enforcement Discretion

Phases	Time from publication of final phaseout policy	Phaseout general enforcement discretion form specific FDA requirements:
Stage 1	1 year	MDR requirements and correction and removal reporting requirements
Stage 2	2 years	Requirements other than MDR, correction and removal reporting QS and premarket review requirements
Stage 3	3 years	QS requirements
Stage 4	3.5 years, but not before Oct. 1, 2027	Premarket review requirements for high-risk IVDs
Stage 5	4 years, but not before Apr. 1, 2028	Premarket review requirements for moderate risk and low risk IVDs (that require premarket submissions)

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Categories of Tests Excluded from General Enforcement Discretion Approach

- For these categories of tests, FDA has generally expected applicable requirements to be met. Approach is not changing:
  - Tests intended as blood donor screening or human cells, tissues and cellular and tissue-based products (HCT/Ps) donor screening tests required for infectious disease testing or for determination of blood group and Rh factors
  - Tests intended for emergencies, potential emergencies or material threats declared under Section 564 of FD&C Act
  - Direct-to-consumer tests intended for consumer use (without meaningful involvement by a licensed health care professional)

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Categories of Tests Not Affected by Phaseout Policy

- "1976-Type LDTs": LDTs with the following characteristics, which provide the greatest risk mitigation among the characteristics that were commonly associated with LDTs offered in 1976
  - Use of manual techniques (without automation) performed by lab personnel with specialized expertise
  - Use of components legally marketed for clinical use; and
  - Design, manufacture, and use within a single CLIA-certified lab that meets requirements under CLIA for high complexity testing
- Forensic tests (intended solely for law enforcement purposes)
- Human leukocyte antigen (HLA) tests: HLA LDTs for transplantation used in histocompatibility labs that meet the regulatory requirements under CLIA to perform high complexity testing, when used in connection with organ, stem cell and tissue transplantation to perform HLA allele typing, for HLA antibody screening and monitoring or for conducting real and virtual HLA crossmatch tests
- Public health surveillance tests: intended solely for use on systematically collected samples for analysis and interpretation of health data in connection with disease prevention and control (and test results are not reported to patients or their healthcare providers)

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Status of VALID Act

- Verifying Accurate, Leading-edge IVCT Development ("VALID") Act
  - Introduced in 2020 and 2021. Included in legislation reauthorizing FDA user fee program, but stripped from bill in Sept. 2022.
  - Would create new test product category, in vitro clinical tests ("IVCTs") and give FDA authority to approve IVCTs. Risk-based framework for IVCT regulation.

Test Category	Summary of Definition	Approval Process
High-Risk Tests	Inaccurate results likely to cause death, serious harm, other serious negative outcomes; no sufficient mitigating measures	Subject to FDA premarket review
Moderate-Risk Tests	Inaccurate results cause non-life threatening or medically reversible injury or treatment delay (or qualifies as high-risk but sufficient mitigating measures exist)	Brought to market through voluntary technology certification program requiring companies to demonstrate appropriate internal test validation processes
Low-Risk Test	Inaccurate result cause minimal or immediately reversible harm (or sufficient mitigating measures exist so that test meets above standard)	Exempt from premarket review

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Status of VALID Act & Other Legislation

- VALID Act introduced in House of Representatives (Mar. 2023)
  - Referred to Subcommittee on Health (Apr. 2023). No action since.
- What about the VITAL Act?
  - Verified Innovative Testing in American Laboratories Act of 2021
  - Would transfer all aspects of regulation over LDTs to HHS / CLIA
  - Specifically removes authority from FDA
  - CMS directed to hold hearings (within 90 days of legislation passing) related to updating CLIA regulations to reflect new oversight over LDTs
  - HHS directed to issue report to Congress within 6 months of passage
  - No progress on legislation in 2022
  - Legislation not reintroduced in 2023

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Transitional Coverage of Emerging Technologies

- Faster pathway to coverage for "Breakthrough Devices"
- Uses national coverage determination (NCD), and coverage with evidence development (CED) processes to expedite Medicare coverage of certain Food and Drug Administration-approved technologies to treat life-threatening or irreversible debilitating medical conditions.

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Physician-Owned Hospitals (POHs)
IPPS Final Rule

- Stark whole hospital and rural provider exceptions
- ACA sec. 6001(a)(3) froze the number of operating rooms, procedure rooms, and beds for POHs in 2010
- IPPS 2024 rule revises process for POHs to request exceptions (42 CFR sec. 411.363)
- Eligibility as an "applicable hospital" or a high Medicaid facility
- Determining the baseline size of the facility
- Data and information required for expansion exception requests
  - CMS seeks "more robust" community input
- Reinstating certain restrictions on expansion requests for high Medicaid facilities

Patient Status Appeals

- Proposed rule for patients to appeal being reclassified from inpatient to outpatient/observation (12/27/2023)
  - https://edit.cms.gov/files/document/medicare-appeal-rights-certain-changes-patient-status-factsheet.pdf
- Creates appeals procedures to implement the court order in Alexander v. Azar, 613 F. Supp. 3d 559 (D. Conn. 2020), aff'd sub nom., Barrows v. Becerra, 24 F.4th 116 (2d Cir. 2022).
  - https://www.govinfo.gov/content/pkg/FR-2023-12-27/pdf/2023-28152.pdf
- Expedited process for eligible beneficiaries to appeal while they are still in the hospital
- Standard appeals for patients to file appeals after leaving the hospital
- Retrospective process for beneficiaries with hospital admissions on or after 1/1/2009

Telehealth & Virtual Care

- Consolidated Appropriations Act, 2023 extended telehealth services for patients in their homes covered under the Physician Fee Schedule to 12/31/24
- Includes selected services performed by hospital staff but paid under the PFS, such as physical therapy
- Expanded services
  - Health and Well-Being coaching (0591T, 0592T, 0593T) – temporary coverage through 2024
  - SDOH health risk assessment (G0136)
  - Diabetes Self-Management Training (G0108 – G0109)
- Federal legislation needed to extend coverage into 2025
  - Except for behavioral health services and traditional facility-based telehealth for rural areas
  - Requirement for periodic in-person visits for behavioral health patients on hold until 2025

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Virtual Supervision

Direct supervision by physicians and Non-Physician Practitioners (NPPs)

- In physician practice and hospital outpatient settings
- Includes NPP supervision of *cardiac rehab and pulmonary rehab*
- Virtual presence of the physician/NPP through audio-video real-time communications technology (excludes audio-only)
- Approved through 12/31/24, but CMS likely to extend
  - No indications that remote supervision increases risks to quality or patient safety

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Remote Physiologic Monitoring (RPM) & Remote Therapeutic Monitoring (RTM)

- RPM = monitoring of vital signs and other indicators
- RTM = monitoring therapy adherence, response to treatment
- Monthly fees for monitoring patients via technology and communicating with them
- Collect data at least 16 of 30 days
- Allowed during global surgical period for clinicians other than the proceduralist
- CPT rules prohibit reporting both in the same month
- Can be billed with care management codes as long as time is not counted twice

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Evaluation & Management Services

E&M Complexity Add-On Code G2211

- Add on to office/outpatient visits for "*complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition.*"
- Focus is on longitudinal relationships between patients and physicians
- Not billable with minor procedures and E&M + modifier 25
- CMS expects G2211 to be reported with many office visits – 38% to 54 %

Split/Shared Visits

- Same-day E&M facility services by physicians and APCs in the same group
- Visit billed by the professional who performs medical decision making or more than 50% of the time
- Usual incident to rules apply to office visits that involve physicians and APCs

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Developments in enforcement

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Supreme Court Clarifies the FCA Scienter Element (Schutte)

- Supreme Court unanimously ruled that liability under the FCA depends on the defendant's **subjective belief** about whether a claim was false.
- Supreme Court rejected the 7th Circuit's application of the objective scienter standard from ***Safeco Insurance Co. of America v. Burr***, 551 U.S. 47 (2007).
- Court will review what the defendant believed "at the time they submitted their claims," and not what an objectively reasonable person may have known or believed or "post hoc interpretations that might have rendered their claims accurate."
- Requisite scienter under the FCA may be established by showing that defendants: (1) actually knew that their claims were false; (2) were aware of a substantial risk that their claims were false and intentionally avoided learning whether they were accurate; or (3) were aware of such a substantial and unjustifiable risk that the claims were false but still submitted the claims.

United States ex rel. Schutte v. SuperValu Inc., 598 U.S. 739 (2023)

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Supreme Court's Ruling on the Government's Authority to Seek Dismissal of a *Qui Tam* (Polansky)

- Supreme Court clarifies the standard under which the government can intervene and dismiss FCA actions.
  - Affirms that the government has broad dismissal authority.
- In Polansky, the government had declined to intervene while the case was under seal but filed a motion to dismiss after deciding the burdens of the suit outweighed its potential value.
  - Supreme Court held that the government may move to dismiss when it has ***first intervened in the action*** – "so long as it intervened sometime in the litigation, whether at the outset or afterward."
  - Rejects the government's contention that it may move to dismiss an FCA action even if it has never intervened.
- Courts should assess dismissal pursuant to Federal Rule of Civil Procedure 41 – where a defendant has not served an answer or MSJ, the plaintiff need only file a notice of dismissal. Otherwise, dismissal requires a court order.

United States ex rel. Polansky v. Executive Health Resources, Inc., 599 U.S. 419 (2023)

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DOJ's FCA Recovery Statistics for 2023

- Record year for DOJ
- 543 settlements/judgments
- Self-initiated investigations way up (from 305 to 500)
- Third highest number of new qui tams filed
- Continued emphasis and recoveries related to alleged health care fraud
- <$1.8B in health care recoveries

	2022	2023	Increase
Settlements	351	543	55%
Recoveries	$2.2B	$2.68B	20%

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Lab Settlements

- Genomic Health - $32.5 million settlement by lab providing genomic-based clinical diagnostic cancer tests
  - Failed to invoice hospitals for services or writing off unpaid fees
  - Billed for tests ordered within 14 days of a patient's discharge from a hospital in violation of Medicare regulations
- Genotox Laboratories - $6 million settlement by reference lab providing urine drug tests
  - Paid commissions to sales representatives or marketing firms
  - Submitted claims for tests that were not medically necessary or not covered

COVID-19 Settlements

- United Memorial Medical Center - $2 million settlement by medical center
  - Submitted false claims for cost outlier payments, retained overpayments, and double-billed for COVID-19 tests.
  - Submitted claims for COVID-19 tests despite being reimbursed for those services by the State of Texas/City of Houston.
- Total Access Urgent Care - $9 million settlement by urgent care clinics
  - Submitted claims for physician E&M services performed by non-physicians
  - Self-disclosed upcoding of COVID-19 testing claims.
- CRH Healthcare - $1.6 million by physician group
  - Upcoded E&M levels and COVID-19 tests

Beware of Increase Stark Enforcement?

- *United States ex rel. Goldsholl v. Covenant Healthcare System, et al.*, No. 12-15422 (E.D. Mich.) – Regional hospital system and 2 physicians paid over $69 million in 3 related settlements to resolve allegations that they shared improper financial relationships with 8 referring physicians and investment groups that failed to satisfy Stark Law/AKS exceptions.
- *U.S. ex rel. Pinto v. Cardiac Imaging, Inc., et al.*, No. 18-cv-2674 (S.D. Tex.) – Cardiac imaging provider and its CEO agreed to pay $85,480,000 to resolve allegations that they violated the AKS and Stark Law by paying referring cardiologists excessive fees ($500 per hour) to supervise PET scans.

Increased Scrutiny Surrounding the OTC COVID-19 Testing Demonstration

- In August 2023, OIG announced a work plan to evaluate the OTC COVID-19 Test Demonstration.
  - The Demonstration ran between April 4, 2022, to the end of the PHE.
  - Eligible providers could distribute up to 8 U.S. FDA-approved or authorized OTC COVID-19 tests per calendar month to each beneficiary.
- CMS set a fixed national payment rate of $12 per OTC COVID-19 test.
- CMS disbursed $1.1 billion for about 101 million OTC COVID-19 tests to 8 million Medicare beneficiaries.
- On April 20, 2023, the DOJ announced criminal charges against 18 defendants across 9 federal districts for involvement in pandemic-related fraud schemes, including the distribution of unsolicited OTC COVID-19 tests.
- CMS took adverse administrative actions against 28 medical providers for their alleged roles in COVID-19 related schemes.

HHS-OIG's General Compliance Program Guidance

November 2023: HHS-OIG released guide highlighting 7 elements of an effective compliance program:

1. Written policies and procedures;
2. Compliance leadership and oversight;
3. Training and education;
4. Effective lines of communication with the Compliance Officer and disclosure programs;
5. Enforcing standards: consequences and incentives;
6. Risk assessment, auditing, and monitoring; and,
7. Responding to detected offenses and developing corrective action initiatives.

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Medicare Advantage

Increased Scrutiny from Congress and the Press

Utilization Management

- CMS clarifies (again) that the 2-midnight benchmark applies to MA, but the 2-midnight presumption for medical review/audits does not
- PY 2024 MA Final Rule details when and how MAOs can develop UM policies that supplement Original Medicare coverage rules
- Transparency requirements for UM criteria
- January 2024: Final rule on electronic information exchange and authorization processes
- Downstream impact on delegated provider organizations

Marketing and Communications

- Increased scrutiny of MAOs and "third-party marketing organizations" (TPMOs)
- Marketing redefined as any information shared with potential members that mentions the benefits of MA, even if not discussing a specific MA product or specific benefits

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Medicare Advantage

Risk Adjustment Data Validation Program Final Rule

- Extrapolation of audit findings beginning with PY 2018
- No specific audit or extrapolation methodology
- Statistical modeling and data analytics to focus on MAO contracts at highest risk of improper payments
- No fee for service adjustor

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Continued efforts to increase transparency in health care

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Federal Pricing Transparency Rule for Hospitals

- In a supplement to the 2020 OPPS Final Rule, published November 27, 2019, CMS added 45 CFR Section 180, which became effective 1/1/2021.
- Updated under 2022 OPPS Final Rule effective Jan. 1, 2022.
- Updated under 2024 OPPS Final Rule effective Jan. 1, 2024 (staggered implementation).
- All hospitals (federal owned and operated hospitals are deemed to be in compliance) must make public:
  - A **machine-readable** file (MRF) containing a list of all standard charges for **all items and services**, and
  - A **consumer-friendly list** of standard charges for **shoppable services**.

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Court Challenges

- A three-judge panel of the US Court of Appeals of the District of Columbia Circuit on December 29, 2020 rejected the appeal of a lower court's upholding of CMS hospital price transparency requirements on de novo review, and affirmed the district court's grant of summary judgment to the Secretary.
  - This was the American Hospital Association's appeal of an earlier court challenge.
  - Originally filed in June 2020, and the AHA urged enforcement discretion.

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued October 15, 2020 Decided December 29, 2020

No. 20-5193

AMERICAN HOSPITAL ASSOCIATION, ET AL.,
APPELLANTS

v.

ALEX M. AZAR, II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES,
APPELLEE

Appeal from the United States District Court
for the District of Columbia
(No. 1:19-cv-03619)

http://www.steamboatinstitute.org/app/uploads/2020/12/Azarvs AHA_AppealsOpinion.pdf

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"Standard Charges" Definition

- Standard charges include five (5) types:
  - Gross charges
  - Payer-specific negotiated charges (clearly associated with the name of the third party payor and plan)
  - De-identified minimum negotiated charge
  - De-identified maximum negotiated charge
  - Discounted cash price
  - 45 CFR Section 180.20
- Specified data elements for standard charges for all items and services (there are 7) include charges by individual item or service for hospital inpatient and outpatient services and any code used by the hospital for accounting or billing for the item or service (CPT, HCPCS, DRG, NDC or other payer identifier.) 45 CFR Section 180.50 (b).

"Shoppable Services" Definition

- Shoppable services are at least 300 services which include as many of the 70 CMS-specified services as provided by the hospital, plus additional services to reach the 300. 45 CFR Section 180.60(a)(1).
- A hospital is deemed by CMS to meet the Shoppable Services requirement if it maintains an internet-based price estimator tool with certain attributes (such as allows consumers to obtain an estimate of the amount they will be obligated to pay.) 45 CFR Section 180.60(a)(2).
- Shoppable services include a **plain language** description and each **Ancillary Service** (an item or service the hospital customarily provides as a part of or in conjunction with a shoppable primary service.) 45 CFR Section 180.60(b).

Multiple Hospital Locations

- In certain cases, hospitals maintain multiple hospital campuses under a single hospital license.
- Each hospital location operating under a single hospital license that has a different set of standard charges much separately make public the standard charges applicable to that location. 45 CFR Section 180.50 (a)(2).
- This is ostensibly to ensure that regional costs are incorporated into pricing, but mostly just to make you mad.

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Compliance Challenges and Opportunities

- Compliance is highly inconsistent.
- Survey data from a PatientRightsAdvocate.org study published in July 2023 found that only 36% of 2,000 hospitals surveyed were posting complete pricing information.

https://www.patientrightsadvocate.org/july-semi-annual-compliance-report-2023

FORBES > INNOVATION > HEALTHCARE

Price Transparency: A Boon For Patients, A Bust For Hospitals?

Seth Joseph Contributor
I write about the intersection of health care, technology and policy

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May 31, 2023, 10:36am EDT

https://www.forbes.com/sites/sethjoseph/2023/05/31/price-transparency-a-boon-for-patients-a-bust-for-hospitals/?sh=6eb6442717ef

Report: Only quarter of hospitals analyzed complied with key price transparency rule

By **Robert King** - Feb 6, 2023 12:22pm

https://www.fiercehealthcare.com/providers/report-only-quarter-hospitals-analyzed-complied-key-price-transparency-rule

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CMS Enforcement and Hospital Compliance

- CMS conducted website assessments between September and November 2022 of 600 hospitals randomly sampled from the Homeland Infrastructure Foundation-Level Data.
- Of the 600 acute care hospitals sampled for the 2022 analysis, 493 (82%) posted a consumer-friendly display that met the consumer-friendly display website assessment criteria, 490 (82%) posted a machine-readable file that met the website assessment criteria, and 421 (70%) did both.
- As of September 2023, CMS had issued nearly 989 warning notices and over 631 requests for corrective action plans since the initial implementing regulation went into effect in 2021. Over 738 hospitals have addressed problems and have become compliant with the regulations, leading to closure of their cases.
- As of January 19, 2024, while CMS has issued monetary penalties to 14 hospitals since 2021 (3 remain under review), every other hospital that was reviewed has corrected its deficiencies.

CMS Enforcement and Hospital Compliance

- If found in non-compliance, CMS can:
  - Provide a written warning
  - Request a corrective action plan for a material violation
  - Impose a civil monetary penalties and publicize the penalty on a CMS website if failure to respond to a CAP.
    - 45 CFR Section 180.70

April 2023 Enforcement Changes

- CMS requires full compliance within 90 days from corrective action plan (CAP) request (previously allowed hospital to propose a CAP completion date).
- Automatically impose CMP for failure to submit CAP within 45 days and failure to comply with CAP within 90 days.
- Immediately request CAP for hospitals that make no attempt to satisfy requirements (previously sent warning letter)

2024 New Requirements

- Good faith efforts required.
- Specific technical requirements (txt file, footer link).
  - Facilitates automated access to hospital price data
- Machine readable files must follow CMS template layout and technical specifications to ensure consistency.
- Affirmation statement that MRF is true, accurate, and complete
- Revised data elements.
- Modifications to the way “Standard Charges” are described.
- System-wide approach for hospitals that are part of a health system
- Publicizing enforcement actions (not limited to CMPs)
- Staggered implementation (some effective 1/1/23, some 7/1/24).

Civil Monetary Penalties

Civil Monetary Penalties

For every day a hospital is determined to be out of compliance:

- For a hospital with a number of beds equal to or less than 30, the maximum daily dollar civil monetary penalty amount to which it may be subject is $300, even if the hospital is in violation of multiple discrete requirements of this part.
- For a hospital with at least 31 and up to and including 550 beds, the maximum daily dollar civil monetary penalty amount to which it may be subject is the number of beds times $10, even if the hospital is in violation of multiple discrete requirements of this part.
- For a hospital with a number of beds greater than 550, the maximum daily dollar civil monetary penalty amount to which it may be subject is $5,500, even if the hospital is in violation of multiple discrete requirements of this part.

Hospital Name	CMP Amount	Date Action Taken
Northside Hospital Atlanta	$883,180.00	2022-06-07
Northside Hospital Cherokee	$214,320.00	2022-06-07
Frisbie Memorial Hospital	$102,660.00	2023-04-19
Kell West Regional Hospital *Under Review**	$117,260.00	2023-04-19
Falls Community Hospital &Clinic	$70,560.00	2023-07-20
Fulton County Hospital *Under Review**	$63,900.00	2023-07-20
Community First Medical Center *Under Review**	$847,740.00	2023-07-24
Hospital General Castaner	$101,400.00	2023-08-22
Samaritan Hospital - Albany Memorial Campus	$56,940.00	2023-08-22
Doctors' Center Hospital Bayamón	$102,200.00	2023-08-22
Doctors' Center Hospital Bayamón	$99,540.00	2023-08-23
Betsy Johnson Hospital	$979,000.00	2023-08-23
UF Health North	$325,710.00	2023-09-05
Holy Cross Hospital	$677,440.00	2023-09-05
Saint Elizabeths Hospital	$883,180.00	2022-06-07

State Pricing Transparency Laws

- Following the rollout of the federal pricing transparency regulations, states began to take action in a variety of forms:
  - Hospital pricing transparency laws that are more burdensome or different from the federal regulations.
  - Hospital pricing transparency laws implementing the exact same standards as the federal law but allowing for enforcement by the state licensing agency.
  - A focus on more specific details, like requirements to provide patients with accurate pricing estimates, itemized bills, or other pricing information.

Lower Costs, More Transparency Act

- H.R. 5378 passed in House of Representatives on December 11, 2023.
- If passed in Senate would be effective on January 1, 2026.
- Codifies hospital price transparency regulations into statute
- Increases maximum CMPs to $10 million/year (up from current $2 million) for large hospitals
- Eliminates option to meet the consumer-friendly display of shoppable services requirement using an online price estimator tool.

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The California Experience

Office of Health Care Affordability (OHCA)

- Similar to other state efforts – MA, ME, MD, OR, PA

Healthcare Expenditure Goals

- By mid-2024, OHCA will establish an initial healthcare expenditure goal for the year 2025 and standards for alternative payment methodologies.
- 2024 – 2025 – non-enforceable spending targets comparing year over year increases
- 2026 – first year of enforceable cost targets; OHCA to adopt quality and *equity* measures

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OHCA has three primary responsibilities:

Slow Health Care Spending Growth

- Collect, analyze, and publicly report data on total health care expenditures, and enforce spending targets set by the Health Care Affordability Board.
- ***Not limited to hospital services***

Promote High Value System Performance

- Measuring quality, equity, adoption of alternative payment models, investment in primary care and behavioral health, and workforce stability.

Assess Market Consolidation

- Through ***cost and market impact reviews***, OHCA will analyze transactions that are likely to significantly impact on
  - market competition
  - the state's ability to meet targets
  - affordability for consumers and purchasers.

Based on results of the review, OHCA will coordinate with other state agencies to address consolidation as appropriate.

No Surprises Act

No Surprises Act Dispute Resolution Process

- The Act offers an internal dispute resolution process to determine payment amounts in disputes between payors and providers
- This part of the Act has been in flux since Feb. 2022 due to litigation and difficulties with technology
  - IDR entities were instructed by CMS to pause processing disputes in Jul. 2023 due to two court decisions that vacated certain portions of the regulations
    - On Aug. 3, 2023, a Texas district court struck down rules increasing the administrative fee for participating in the arbitration process and prohibit the batching of related claims under that process ("TMA IV")
    - On Aug. 24, 2023, a Texas district court issued a decision vacating the rules for calculating qualified payment amounts under the IDR process ("TMA III")
    - Prior to this, in Feb. 2023, provisions governing the IDR process were vacated by a Texas District Court ("TMA II")

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No Surprises Act Dispute Resolution Process

- Processing disputes has since resumed, but the IDR online portal faces a backlog of billing disputes after the IDR's first year of operations resulted in fourteen times the amount of billing disputes were initiated in the portal
  - CMS expected 22,000 disputes but received 490,000 disputes
- As of Jun. 2023, about 61% of nearly 490,000 provider-payor payment disputes submitted to the portal remained unresolved
- CMS issued updated information in Feb. 2024
  - Volume of claims continues to far surpass projections
    - In the first 6 months of 2023, 136,111 reached IDR in the first quarter and 152,699 reached IDR in the second quarter
    - Total of 288,810 cases to reach IDR is 13 times higher than CMS' projections for the full calendar year
  - CMS data shows providers winning 77% of the time
  - The top 10 initiating parties represented approximately 78% of all disputes initiated in the first 6 months of 2023.
  - Many of the top initiating parties are large practice management companies or revenue cycle companies

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No Surprises Act Federal Independent Dispute Resolution Proposed Rule

- A proposed rule was released in Nov. 2023 to adjust certain timelines and steps for the federal IDR process, establish new "batching" criteria, and change the administrative fee structure
  - This proposed rule makes the IDR process compliant with the Texas Medical Association decisions ("TMA II", "TMA III", "TMA IV")
  - Multiple claims can be "batched" together and considered a single dispute if the items and services at issue in the claim are rendered by the same provider, paid for by the same payer and related to the treatment of a similar condition
    - Guidance released on Nov. 28, 2023 stated that "certified IDR entities have the sole responsibility for determining whether the items and services submitted as part of a batched dispute meet the statutory and remaining regulatory standards for a batched dispute."
  - Changes to the mandatory open negotiation process that precedes arbitration, including:
    - Requiring parties to conduct open negotiations through the online portal operated and maintained by CMS. Currently, the portal is used solely for the arbitration process following claim negotiation.
    - Requiring the initiating party to include additional information with its negotiation notices, including more details about the disputed items or services.
    - Requiring the non-initiating party to file a response within 15 business days of receiving the initiating party's open negotiation notice.

No Surprises Act Federal Independent Dispute Resolution Proposed Rule

- Proposed changes to rules governing arbitration process that kicks in following negotiation period:
  - Requiring the Notice of IDR Initiation to include additional information, most of which would be identical to the requirements for the open negotiation notice.
  - Requiring the non-initiating party to furnish a written response regarding claim eligibility within three business days of receiving the Notice of IDR Initiation.
  - Implementing a preliminary three-business-day selection window in which the parties could negotiate regarding IDRE selection, followed by a final selection window in which the IDRE would undergo conflicts screening.
- Also made changes to administrative fee structure for disputes initiated on or after Jan. 1, 2025
- The comment period on a proposed rule streamlining the IDR process (88 Fed. Reg. 75744) was reopened on Jan. 22, 2024 after initially being closed on Jan 2, 2024
  - Comment period ran through Feb. 5, 2024

No Surprises Act IDR Process Administrative Fee and Certified IDR Entity Fee Ranges Final Rule

- Depts. of Labor, Treasury and HHS issued final rule on Dec. 18 that outlines policies related to the IDR administrative fee
- New fee of $115 per party for disputes initiated on or after the effective date of the final rule.
  - Will remain in effect until departments propose and finalizes a different administrative fee amount in subsequent notice and comment rulemaking
- Certified IDR entity fees:
  - For disputes initiated on or after the effective date of the rule, the Departments are finalizing a certified IDR entity fee range of $200-$840 for single determinations and $268-$1,173 for batched determinations.
  - For batched determinations exceeding 25 dispute line items, the Departments are finalizing the proposal that certified IDR entities may set a fixed fee within the range of $75-$250 for each increment of 25 dispute line items included in the batched dispute, beginning with the 26th line item.
  - IDRE fees will be updated no more than once annually and only through notice and comment rulemaking.

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Discussion

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