

# Delivery System Reform Compliance Challenge Specifics

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# Agenda

- Survey of APM participation
- Interest in APM program integrity issues
  - OIG
  - GAO
  - Quality Payment Program
- Models of interest
  - Medicare Shared Savings Program
  - Oncology Care Model
  - Bundled Payments for Care Improvement Advanced
  - Medicare Diabetes Prevention Program
  - Emergency Triage, Treat, and Transport (ET3) Model

# Survey of APM Participation

- Model participation?
- Compliance challenges at your organization?
  - How do I keep up with changes to existing models?
  - CMS issues too much subregulatory guidance
  - The Participation Agreements are 100+ pages; I forget the requirements
  - How do I keep up with all of the new models?

# Interest in APM Participation – OIG December 2017 Report

“With regard to emerging challenges, we found that CMS has not yet developed a comprehensive program integrity plan for the [Quality Payment Program]. Appropriate oversight—particularly to ensure the accuracy of clinician-submitted data—is critical to prevent improper QPP payment adjustments. Although CMS included oversight provisions in the QPP final rule for 2017 and has initiated oversight planning, it still needs to clearly designate leadership responsibility for QPP program integrity and develop a plan to prevent and address fraud and improper payments.”

# Interest in APM Participation – OIG (cont'd)

## 2018 Top Management and Performance Challenges

- In testing value-based care models, CMS must continue to focus on program integrity risks, incorporate safeguards to reduce them, and promptly correct identified issues. This is especially important for models that introduce new payment incentives, which might lead to new fraud schemes, and for models for which waivers of payment, coverage, or fraud and abuse laws may have been issued.
- Where applicable, CMS must clearly define actionable and meaningful quality measures, ensuring their reliability and accuracy. CMS and other agencies currently using quality measurements should further align these efforts to reduce unnecessary provider burden.
- Moving forward, HHS will need to ensure that any metrics are effective, evidence-based measures for quality improvement.

# Interest in APM Participation – GAO 2016 Report

**Figure 7: Challenges That Can Be Mitigated by Partner Organizations Managing Compliance with Requirements of Value-based Payment Models for Small and Rural Physician Practices**

SERVICE	CHALLENGES MITIGATED
Manage compliance with requirements of value-based payment models	<ul style="list-style-type: none"><li>• Difficulties with staying abreast of regulatory changes and managing compliance with multiple requirements of value-based payment models.</li><li>• Difficulties with understanding and managing compliance with the terms and conditions of waivers related to various fraud and abuse laws.</li></ul>
EXAMPLES	
<ul style="list-style-type: none"><li>• A partner organization can liaison with CMS and prepare and submit CMS-required documentation on behalf of providers.</li><li>• A partner organization can provide guidance on waivers relevant to the value-based payment model.</li></ul>	

Source: GAO analysis of literature and stakeholder interviews. | GAO-17-55

If the government isn't there yet, is there hope for my organization? Or me???



# Quality Payment Program Incentives **Advanced** Alternative Payment Model Participation

- 5 percent bonus (**time-limited**)
- Model-specific rewards
- Exclusion from Merit-Based Incentive Payment System (MIPS)
- Higher fee schedule updates following the expiration of the 5% bonus



# Medicare Shared Savings Program

- Desire to move ACOs to two-sided risk
- BASIC Track Level E = former Track 1+ Model
  - 1<sup>st</sup> dollar savings up to 50% based on quality performance (NTE 10% updated benchmark)
  - 1<sup>st</sup> dollar losses at a rate of 30% NTE percentage of revenue specified in the revenue-based nominal amount standard under QPP capped at 1 percentage point higher than the benchmark nominal risk amount (8% of ACO participant revenue 2019-2020, capped at 4% of updated benchmark)



# Medicare Shared Savings Program (cont'd)

- Annual choice of beneficiary assignment methodology
- Qualifies as an Advanced APM
- Regulatory relief
  - Fraud and abuse waivers
    - Care coordination
    - Transportation
    - Innovative physician compensation arrangements
  - Option for Beneficiary Incentive Program
  - Expanded telehealth options (PY2020)
  - SNF 3-Day Rule Waiver

# Medicare Shared Savings Program (cont'd)

## Beneficiary Incentive Program

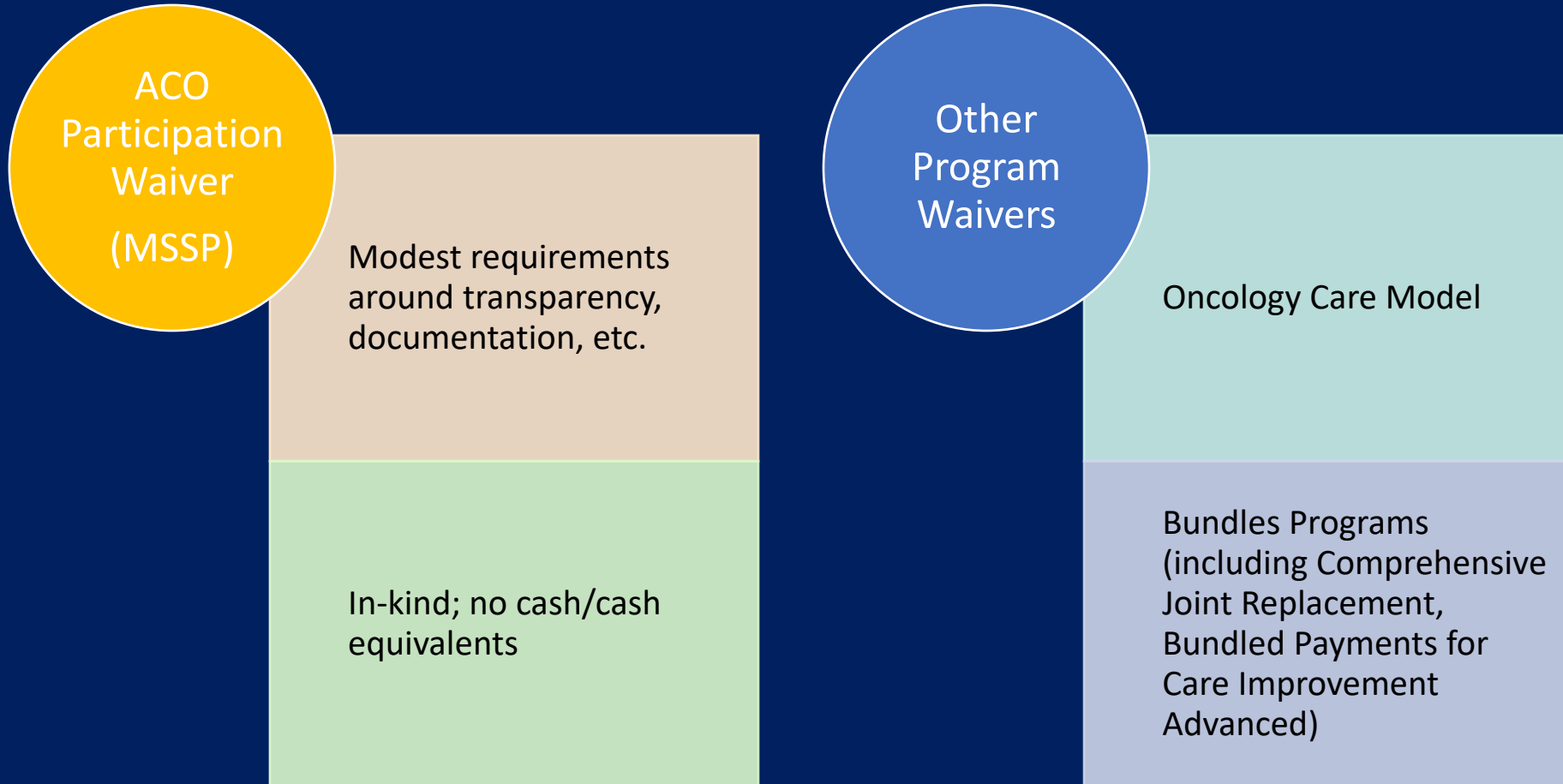
- Election to establish program July 1, 2019 must operate for an initial period of 18 months
  - Business commitment
- Significant compliance requirements
  - ACO must furnish the incentive payments – NOT the participant TINs
  - Incentive payments only for qualifying services (NTE \$20/qualifying service)
  - Only in the form of a check, debit card, or “traceable cash equivalent”
  - No cost shifting
  - Notice requirements
  - Must be provided no later than 30 days after a qualifying service is furnished
    - If beneficiary refuses payment → documentation of refusal
  - Public reporting requirements (stringent tracking)

# Medicare Shared Savings Program (cont'd)

## Beneficiary Incentive Program



# Medicare Shared Savings Program (cont'd)



# Medicare Shared Savings Program (cont'd)

## Waivers (Duke ConnectedCare)

- On Dec 19, 2013, DCC's Board of Managers approved a pre-participation waiver for start-up expenses in an operating budget that were funded by Duke University Health System (DUHS). The arrangement provided in-kind staffing from DUHS for MSSP application and start up activities, and funding of legal and consulting services, and membership and meetings of the National Association of ACOs.
- On January 13, 2015, DCC's Board of Managers approved a participation waiver for operating budgets for fiscal years 2014 and 2015 funded by DUHS. The funding provided for operating and capital expenses related to personnel, services, goods, and facilities to support improved care coordination, beneficiary and provider communications and engagement, and analytics services.
- On April 14, 2015, the DCC Board of Managers approved a participation waiver for the fiscal year 2016 operating budget funded by DUHS. The funding provided for operating and capital expenses related to personnel, services, goods, and facilities to support improved care coordination, beneficiary and provider communications and engagement, and analytics services.
- On April 9, 2016, the DCC Board of Managers approved a participation waiver for the fiscal year 2017 operating budget funded by DUHS. The funding provides for operating and capital expenses related to personnel, services, goods, and facilities to support improved care coordination, beneficiary and provider communications and engagement, and analytics services.
- On May 11, 2017, the DCC Board of Managers approved a participation waiver for the fiscal year 2018 operating budget funded by DUHS. The funding provides for operating and capital expenses related to personnel, services, goods, and facilities to support improved care coordination, beneficiary and provider communications and engagement, and analytics services.
- On May 10, 2018, the DCC Board of Managers approved a participation waiver for the fiscal year 2019 operating budget funded by DUHS. The funding provides for operating and capital expenses related to personnel, services, goods, and facilities to support improved care coordination, beneficiary and provider communications and engagement, and analytics services.

# Medicare Shared Savings Program (cont'd)

## Waivers (UC San Diego)

- Pursuant to the Final Rule, UC San Diego Health Accountable Care Network (UCSDH ACO) seeks waiver protection for the arrangement described below ("EHR Subsidy Arrangement"):

The EHR Subsidy Arrangement became effective January 1, 2018. The parties to each subsidy arrangement include UC San Diego Health and the UCSDH ACO on the one hand, and the eligible UCSDH ACO Participant practice on the other. The EHR Subsidy Arrangement has two components—an upfront, one time implementation services component, and an ongoing licensing, maintenance and support component. Under the EHR Subsidy Arrangement, certain UCSDH ACO Participant practices will be given subsidized access to the UCSD Health EPIC Community Connect Platform.

- The EHR Subsidy Arrangement is designed to facilitate the widespread adoption of EHR technology by UCSDH ACO Participant providers who provide medical care to patients assigned to the UCSDH ACO in order to enhance and improve the efficiency, effectiveness and quality care provided to such individuals.

# Medicare Shared Savings Program (cont'd)

## Waivers (McLeod Health (SC))

- The board of McLeod Health Network, LLC (“the ACO”), has made a good faith determination that the following arrangements are reasonably related to the purposes of the Medicare Shared Savings Program (MSSP) (and the Triple Aim of better health for individuals, better health for populations, and lowered growth in expenditures) and is publically disclosing such arrangements in accordance with the requirements of the MSSP.
- Assistance with MSSP Quality Measure Tracking and Reporting.

The ACO will provide support to independent practices with the goal of meeting requirements for reporting on the MSSP’s quality and cost measures. Specifically, the ACO may support independent practices with:

- The creation of reports in their EMR related to the ACO’s quality program
  - Quality data extraction from their EMR to support the ACO’s quality program
  - EMR workflow improvement specifically related to quality metric tracking related to the ACO’s quality program
  - Training on workflow for capturing quality metrics in the ACO’s quality program
  - Advancing Care Information attestation support to improve the ACO’s collective performance
  - Correspondence with EMR vendor for purposes of creating reports and extracting quality data for the ACO’s quality program
- Outpatient Case Management

The ACO will provide outpatient case management for a limited period of time to beneficiaries who are considered high risk for healthcare complications as determined by an appropriate algorithm. This effort will achieve triple aim results through enhanced care coordination with the goal of reducing the incidence of healthcare complications.



# Medicare Shared Savings Program (cont'd)

## Waivers (Ohio Integrated Care Providers)

ACO Participant	Waiver Type
Maria Jamiolkowski, DO	Electronic Health Record
Medical Associates of Cambridge	Electronic Health Record
Medical Home Primary Care Center	Electronic Health Record
Morgan County Family Practice	Electronic Health Record
Nephrology Consultants	Electronic Health Record
Perry County Family Practice	Electronic Health Record
South Zanesville Family Medical Center	Electronic Health Record
T & T Forrestal Inc	Electronic Health Record
Thornville Family Medical Center	Electronic Health Record
Edward L Colby, DO, Inc.	Electronic Health Record
Medical Associates of Cambridge	Recruitment
Amjad Rass, DO, Inc.	Recruitment
Dr. Bradley C. Wilson, Inc.	Electronic Health Record
David W. Ray, DO, LLC	Electronic Health Record
Healthcare Associates of Zanesville, Inc.	Electronic Health Record
Medical Home Primary Care Center	Care Coordination
William Overholser, MD	Electronic Health Record
Perry County Family Practice	Care Coordination
South Zanesville Family Medical Center	Recruitment
Medical Home Primary Care Center	Recruitment
Healthcare Associates of Zanesville	Care Coordination

# Medicare Shared Savings Program (cont'd)

## Waivers (TC2 (GA))

- The TC2 (ACO) Board of Managers has duly authorized the arrangement below and made a bona fide determination that the arrangement is reasonably related to the purposes of the MSSP because the arrangement will promote accountability for the quality, cost and overall care for Medicare beneficiaries assigned to ACO. The descriptions of relevant arrangements are disclosed below for the purpose of the ACO availing itself of the protections afforded under the MSSP Waivers:

ACO Participation Waiver: Navicent Health, a participant in and member of the ACO, may make payments or contributions to the ACO to cover shared losses of the ACO for the performance year 2017.

# Medicare Shared Savings Program (cont'd)

## Waivers

- Many organizations are using waivers but are not compliant with the transparency requirement
  - Query: Does this expose those organizations to False Claims Act liability, including participant TINs?
  - Query: Is this a red flag for OIG?
- Difficult to believe that organizations would not be utilizing fraud and abuse waivers at all
  - Care coordination
  - Medication adherence
  - Broad use
- Anecdotally, absolutely no consistency in arrangements for which waiver protection is sought
  - Academic medical centers appear to have more arrangements listed
    - Size of ACO
    - Compliance with transparency requirement
- Some organizations list waivers that are not available at this time under MSSP
  - Telemedicine

# Oncology Care Model

- Ensure currency of Implementation Protocol
- Compliance with gainsharing waiver requirements
- Timely reporting program integrity issues
- Same TIN requirement for those “OCM Practitioners” providing “Chemotherapy Services”
  - Important to understand nuances in defined terms
- Upcoming optional CMS termination right
  - “If the Practice is a Non-Pooled OCM Participant, CMS **may** terminate this Agreement if the Practice does not earn a [performance-based payment] by the time of initial Reconciliation of the fourth Performance Period...”

# Bundled Payments for Care Improvement Advanced Model

- If gainsharing, compliance requirements for distributing gain
- Timely reporting to CMS of program integrity issues
- If utilizing home visits payment policy waiver, notice to CMS is required
- Notice to CMS if utilizing beneficiary incentive program

# Medicare Diabetes Prevention Program

“We also considered an alternative approach where existing Medicare providers and suppliers would have to submit a separate enrollment application (including any applicable enrollment application fee) and be separately screened to be eligible to bill for MDPP services. This alternative would enable all organizations furnishing MDPP services to have the same classification as MDPP suppliers and undergo the same application requirements. **Under this option, should an entity have an issue related to their MDPP enrollment, for example, falsely attesting to beneficiary weight loss, CMS would have discretion to apply revocation to its MDPP enrollment, rather than affecting their broader enrollment in Medicare.**” - *CY2017 PFS Final Rule*

# Medicare Diabetes Prevention Program (cont'd)

- Model involves structured intervention with the goal of preventing type 2 diabetes in individuals with an indication of prediabetes.
  - Payment for core sessions along with patient achievement
  - Subject to rulemaking
- Timely reporting to CMS of adverse legal actions and other required provider enrollment changes
  - Relatively new requirement in the PIM (including subsequent clarification): **Federal sanctions**
  - Keep coaches roster current!!!
    - Query: does CMS match effective date of change on enrollment in PECOS to check compliance?
- Develop and implement complaint resolution protocol
  - Documentation of all beneficiary contact
    - Name, MBI, summary of complaint, actions taken, etc...
- Administrative requirements
  - Name of business in public view
  - Appropriate signage

# ET3 Model

- CMS model to pay EMS Agencies to “Treat in Place” or transfer patients to “Alternative Destinations” as a means of decreasing ED utilization
- Available to ambulance suppliers and EMS agencies; hospitals participate as “Non-Participant Partners”
- Goal of multi-payer alignment



# ET3 Model (cont'd)

- High risk: newly enrolling home health agencies (HHAs) and newly enrolling DMEPOS suppliers;
- Moderate risk: ambulance service suppliers, community mental health centers, comprehensive outpatient rehabilitation facilities, hospice organizations, independent clinical laboratories, independent diagnostic testing facilities (IDTFs), physical therapists enrolling as individuals or group practices, portable x-ray suppliers, revalidating HHAs, and revalidating DMEPOS suppliers; and
- Limited risk: all other provider types.<sup>8</sup>

## ET3 Model (cont'd)

- Each Applicant must describe its relationship to each of its proposed Non-Participant Partners in response to this RFA, including a description of any and all legal and financial relationships.
  - No waivers issued with RFA (not unusual); arrangements between Participant and Non-Participant Partners must comply with the fraud and abuse laws.
  - For disclosed relationships, may want to ensure existing hospital-ambulance agreements are compliant with fraud and abuse laws.
- Implementation contractor will confirm any financial arrangements disclosed by each Participants and to identify the existence of any financial arrangements not disclosed (e.g., a single entity with ownership over both a participating ambulance service supplier and an alternative destination site with which the Participant partners.)

# Managing Compliance Challenges Across Programs

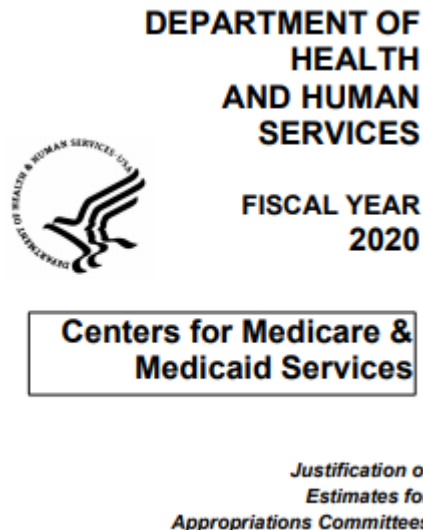
- Task someone with reviewing the Participation Agreement periodically
- Share subregulatory guidance with your attorneys
  - Counsel may not have access to important subregulatory guidance, including “ACO Spotlight”
- Consult with legal counsel prior to there being a crisis
  - Committee involvement
  - Regular 1:1 meetings
- Increasingly important to coordinate since Population Health initiatives have significant spillover into other operations
  - Example: Telehealth
  - Example: Care Management

# The Future – More of the same...

- April 22, 2019: New primary care models announced
  - Desire for commercial alignment
- April 25, 2019: State Medicaid Director Letter announcing opportunities for state partnerships to address needs of dual-eligible
  - Michigan: Capitated Financial Alignment
- Potential changes to fraud and abuse regulations will require participation in alternative payment models
  - Pending as of June 5: Modernizing and Clarifying the Physician Self-Referral Regulations (expected July 2019)
  - Pending as of June 5: Revisions to the Safe Harbors under the Anti-Kickback Statute and Beneficiary Inducements Civil Monetary Penalties Rules Regarding Beneficiary Inducement (expected July 2019)

# The Future (cont'd)

## FY2020 CMS Congressional Justifications



## MCR36: Shift Medicare Health Care Payments from Volume to Value

To achieve the goals of better care, smarter spending, and healthier people, the U.S. health care system must substantially reform its payment structure to incentivize quality health outcomes, and value, over volume. APMs and payment reforms that increasingly tie FFS payments to value are currently moving the health care system in the right direction. In order to continue the advancement of value-based care, **CMS aims to increase the adoption of APMs where participants take on downside risk** – that is, direct financial accountability for beneficiaries' costs and quality of care. Medicare is leading the way by publicly tracking and reporting payments **tied to APMs that are taking on downside risk**. CMS will use FY 2019 as a developmental year to establish a baseline and set future targets for FY 2020 and FY 2021.

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