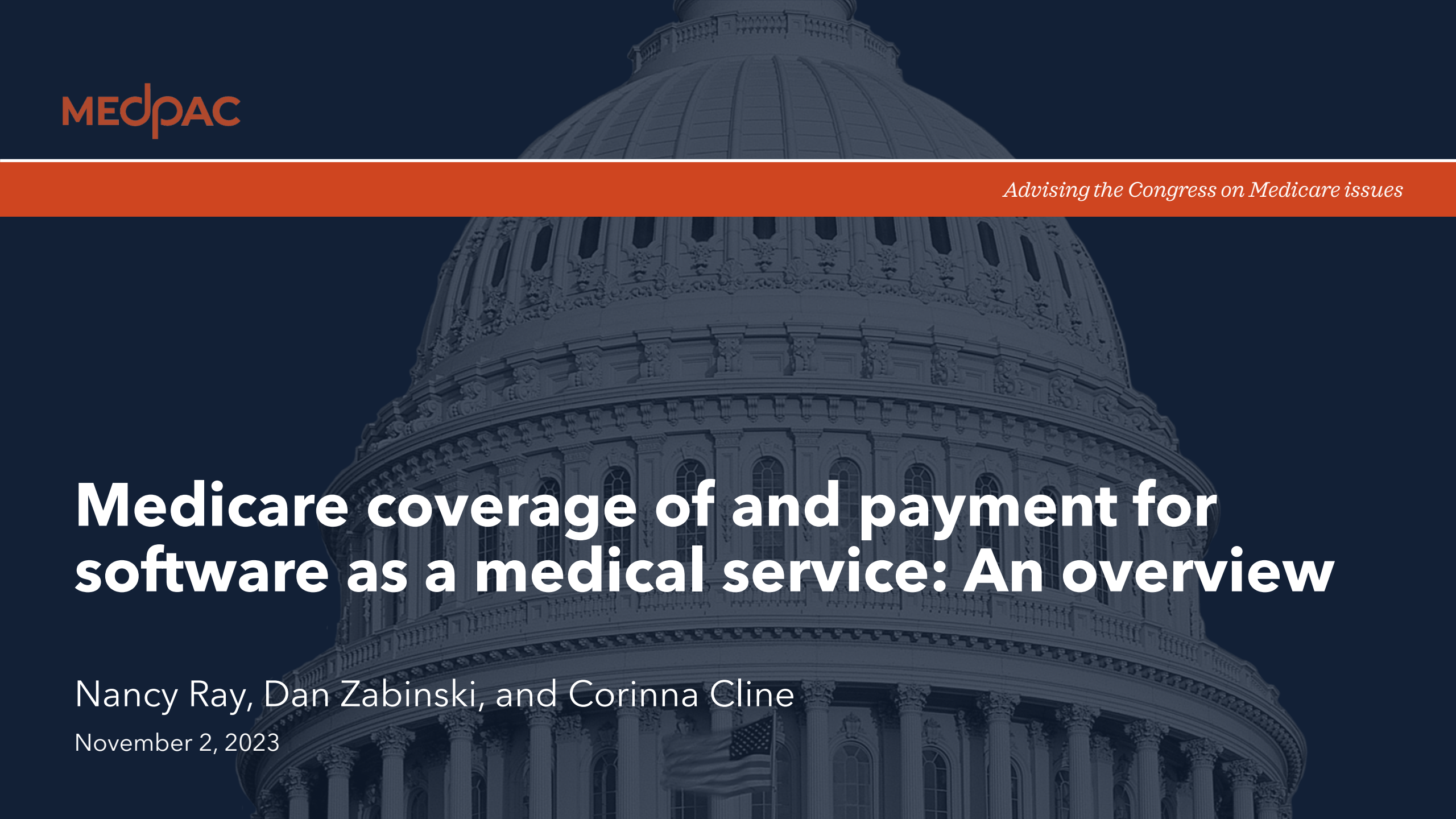
MEDPAC

Advising the Congress on Medicare issues



Medicare coverage of and payment for software as a medical service: An overview

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Presentation roadmap

1. Definition and characteristics of SaaS and PDTs
2. Statutory requirements for Medicare coverage
3. Payment for software as a medical service in Medicare's payment systems
4. Principles for payment in FFS Medicare
5. Discussion

Note: SaaS (software as a service), PDT (prescription digital therapeutic), FFS (fee-for-service).

Software as a medical service

- SaaS: Algorithm-driven software that assists clinicians in making clinical assessments
  - e.g., AI-driven software that analyzes images of the eye taken by a retinal camera to diagnose diabetic retinopathy
- PDTs: Software applications delivered on beneficiaries' personal devices that treat an illness or injury
  - e.g., cognitive behavioral therapy to treat insomnia

Note: AI (artificial intelligence), FDA (Food and Drug Administration), PDT (prescription digital therapeutic), SaaS (software as a service).

Characteristics of SaaS and PDTs

- Software that is used or prescribed by clinicians for one or more medical purposes *without being part of a hardware medical device*
  - The FDA refers to such medical software as *Software as a Medical Device* (SaMD)
- The FDA approves (clears) most SaaS and PDTs:
  - As Class II devices (moderate to high risk)
  - Under the 510(k) or De Novo device approval pathways

Note: FDA (Food and Drug Administration), SaaS (software as a service), PDT (prescription digital therapeutic).

Statutory requirements for Medicare coverage

- Item or service (including SaaS and PDTs):
  - Is approved or cleared by the FDA*
  - Fits into a covered Medicare benefit category
  - Meets other statutory requirements including being reasonable and necessary for the treatment of an illness or injury
- Since 2018, Medicare has covered and paid for SaaS
- Medicare does not cover most PDTs because:
  - Such software does not fit into an existing Medicare benefit category
  - Such software is not consistent with Medicare's definition of durable medical equipment

*In most cases, an FDA-regulated product (e.g., prescription drugs and devices) must receive marketing authorization for at least one indication to be eligible for consideration of Medicare coverage.
Note: FDA (Food and Drug Administration), SaaS (software as a service), PDT (prescription digital therapeutic).

Software as a medical service in the hospital outpatient prospective payment system (OPPS)

- SaMS in the form of SaaS is covered under the OPPS
- OPPS covered service: Falls in a Medicare benefit category, has a HCPCS (billing) code, safe to provide in HOPD setting
- Under the OPPS, CMS determines whether a covered service is separately payable or packaged
  - Separately payable: Relatively costly or reason for visit
  - Packaged: Adjunctive to or supportive of a separately payable service

Note: SaMS (software as a medical service), SaaS (software as a service), OPPS (outpatient prospective payment system), HCPCS (Healthcare Common Procedure Coding System), HOPD (hospital outpatient department).

Payment status of SaaS in the OPPS

- OPPS has 10 HCPCS codes for covered SaaS
  - Example: HeartFlow analyzes data from CT scans for patients with symptoms of coronary artery disease
- The covered SaaS devices have some attributes that suggest they should be packaged and other attributes that suggest they should be separately payable
- CMS: Generally chose separately payable status for SaaS
  - In 2022, 3 of 10 covered SaaS devices were packaged; remaining 7 SaaS devices were separately payable
  - In 2023, all 10 SaaS devices are separately payable (never packaged)

Note: SaaS (software as a service), OPPS (outpatient prospective payment system), HCPCS (Healthcare Common Procedure Coding System), CT (computed tomography).

As of 2022, volume and spending on SaaS have been low in OPPS

- In 2022, of the 7 separately payable SaaS devices, only one, HeartFlow, had appreciable volume (8,665 uses) and spending ($8.4 million)
- LiverMultiScan and Cleerly Labs had volume of less than 100 uses and spending of less than $50,000
- The other separately payable SaaS devices had no volume or spending

Note: SaaS (software as a service), OPPS (outpatient prospective payment system).

Payment for SaMS in the Medicare physician fee schedule

- The 10 SaaS devices covered under the OPPS are also covered under the Medicare physician fee schedule (PFS)
- PFS has less packaging than the OPPS; all 10 SaaS devices have always been separately payable under PFS
- CMS has had difficulty setting the practice expense portion of the PFS payment rates for most of these SaaS devices
- Therefore, 2023 PFS payments for eight of these SaaS devices are set by Medicare's administrative contractors (rather than by CMS), generally on a case-by-case basis

Note: SaMS (software as a medical service), SaaS (software as a service), OPPS (outpatient prospective payment system).

Payment for SaMS in the inpatient prospective payment systems

- Under inpatient prospective payment systems (IPPS), technology like SaMS is usually bundled into the payment rate for the applicable MS-DRG
- Manufacturers of new technology can apply for a new-technology add-on payment (NTAP), which provides payments in addition to the MS-DRG payment for two to three years

Note: SaMS (software as a medical service), MS-DRG (Medicare severity-diagnosis related group).

Criteria for NTAP status

- Usually, a new technology must meet three criteria for NTAP status:
  - Not substantially similar to existing technology (new)
  - High cost in relation to the payment rate of the applicable MS-DRG
  - Represents substantial clinical improvement
- However, if the FDA designates the technology as Breakthrough, the new technology must meet only the cost criterion for NTAP status
- Six SaMS devices have received NTAP status
  - Two SaMS devices, ContaCT and Caption Guidance, no longer have NTAP status
  - Four SaMS devices began NTAP status in fiscal year 2024; all have Breakthrough status

Note: NTAP (new technology add-on payment), MS-DRG (Medicare severity-diagnosis related group), SaMS (software as a medical service), FDA (Food and Drug Administration). A device is granted Breakthrough status if the FDA determines that the device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions and meets at least one of the following: represents breakthrough technology; no approved or cleared alternatives exist; offers significant advantages over existing approved or cleared alternatives; or device availability is in the best interest of patients.

Payment for SaMS in the durable medical equipment (DME) fee schedule

- DME: Medical equipment prescribed by a clinician, that meet five criteria, and are needed at a patient's home
- PDTs are the type of SaMS applicable to the DME system
- Medicare covers software embedded in a device if it meets the DME criteria; for example:
  - Covered: Software and devices used together to generate speech for those with severe impediments
  - Covered: PDTs in which the software and medical device are integral to each other
  - Not covered: PDTs in which software is solely usable on personal devices

Note: SaMS (software as a medical service), PDT (prescription digital therapeutics).

Discussion

Principles for payment in FFS Medicare

- Ensure beneficiary access to high-quality services
- Utilize payment approaches that:
  - Promote provider efficiency and delivery of high-quality care
  - Spur price competition among manufacturers of similar products
  - Create incentives for the development of software that leads to substantial clinical improvement with an appropriate reward for innovation and affordability for beneficiaries and taxpayers

Note: FFS (fee-for-service).

Discussion: How should Medicare ensure that covered services improve beneficiaries' health outcomes?

- Some devices that pose low- to moderate-risk rely on evidence showing that they are substantially equivalent to existing devices for FDA market authorization
- Medicare could require that a manufacturer of a SaaS/PDT provide evidence that its product results in a clinically meaningful improvement for Medicare beneficiaries compared with the standard of care
- Alternatively, a coverage with evidence development policy could be used for new software that lacks evidence showing it has a positive effect for Medicare beneficiaries

Note: FDA (Food and Drug Administration), SaaS (software as a service), PDT (prescription digital therapeutic).

Discussion: How should Medicare generally pay for covered SaMS that is separate from the device?

- MedPAC has long supported larger payment bundles because they give providers opportunities to be flexible in the provision of care and incentives to use the most cost-efficient methods
- Paying separately for items and services (including medical software):
  - Undermines the integrity of payment bundles
  - Limits the competitive forces that generate price reductions among like services
  - Can lead to overuse (to the extent clinically possible)
  - Shifts financial pressure from providers to Medicare

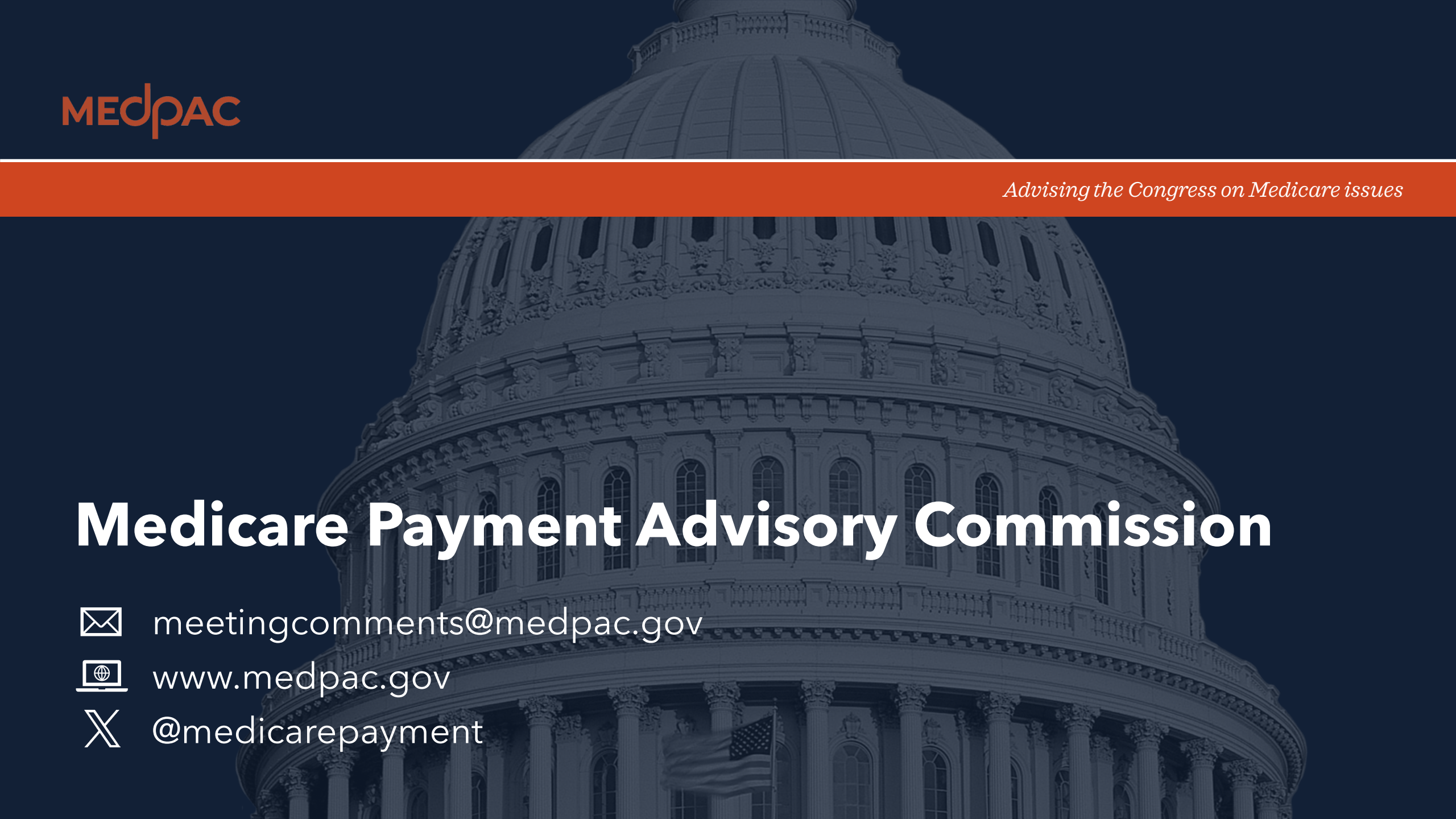
Note: SaMS (software as a medical service).

Discussion: How should Medicare set the payment rate for items and services paid for under fee schedules?

- Bundles/packaging generally not used under the fee schedules for clinician services and durable medical equipment
- Options for setting a payment rate:
  - The manufacturer's list price
  - A market-based price determined by the manufacturer's pricing decisions, which may not be related to the clinical value of the product
  - A new product's net clinical benefit compared with the standard of care
  - Accounting for efficiencies from the new technology when determining Medicare's payment rate

Discussion questions

- How should Medicare ensure that covered services improve beneficiaries' health outcomes?
- How should Medicare generally pay for covered medical software that is separate from the device?
- How should Medicare set the payment rate for items and services paid for under fee schedules?
- Questions about the material?



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