New Provider-Based/HOPD Requirements: How to Prepare

July 16, 2026

Healthcare Consulting

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Agenda

1. **Where We've Been**
2. **Where We Are**
   - *Consolidated Appropriations Act, 2026* (CAA 26)
     - CMS 2027 OPPS Proposed Rule
       - CAA 26 Section 6225 Requirements
       - Implementation of §6225
       - Attestation Documentation
       - CMS Verification & Oversight
3. **The Future: A Challenging Environment**
4. **Compliance Strategies: How to Prepare**

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Where We’ve Been

Where We've Been

Provider-Based Designation: Under Attack

- MedPAC
- Space Sharing
- Physician Supervision
- Introduction to "Site-Neutral"

On-Campus vs. Off-Campus
Measure “As the Crow Flies”

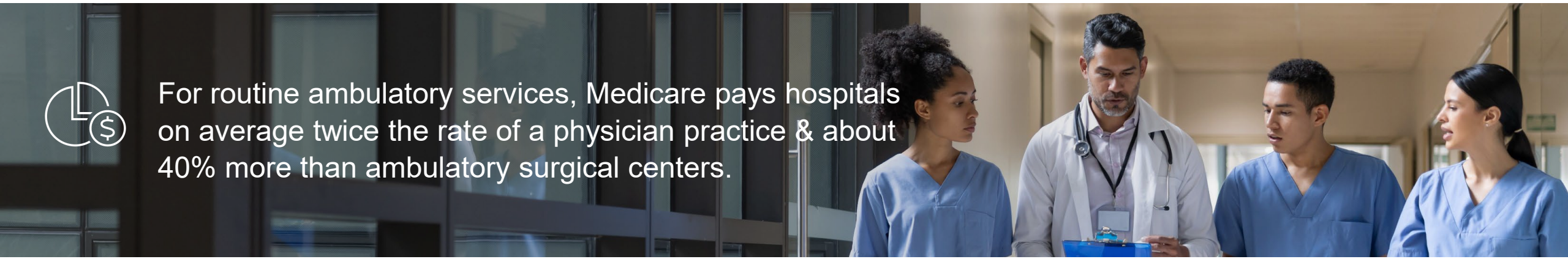
On-campus locations are:

- Buildings or structures within 250 yards of the main building
- CMS regional office has discretion to determine on-campus on a case-by-case basis
- Joint ventures must be located on the main campus of a provider who is a partial owner

Off-campus locations are:

- Not on the main campus or 250 yards from the main building or a “remote location” of the hospital
- Must be located within a 35-mile radius from the main building
- Alternative test, if unable to meet the 35-mile rule within the same state as the hospital:
  - DSH adjustment factor >11.75% & has agreement with local government to provide indigent care, or
  - 75% of clinic patients served reside in the same ZIP code as at least 75% of hospital patients served

Where We've Been



Site-Neutral Advocates:

- Medicare should pay the same amount for the same services
- Leads directly to higher costs for patients (coinsurance)
- Reduce wasteful spending
- Goals:
  - Eliminate differentials
  - No exceptions
  - Lower payment rates
- Encourages hospitals to acquire physician practices, leading to higher cost

Site-Neutral Opposition:

- Cost of following hospital accreditation standards:
  - Infection control
  - Quality
  - Life safety
  - HIPAA
  - Emergency preparedness
- Adversely affects patients' access to services by reducing hospital revenues, especially in rural and low-income populations

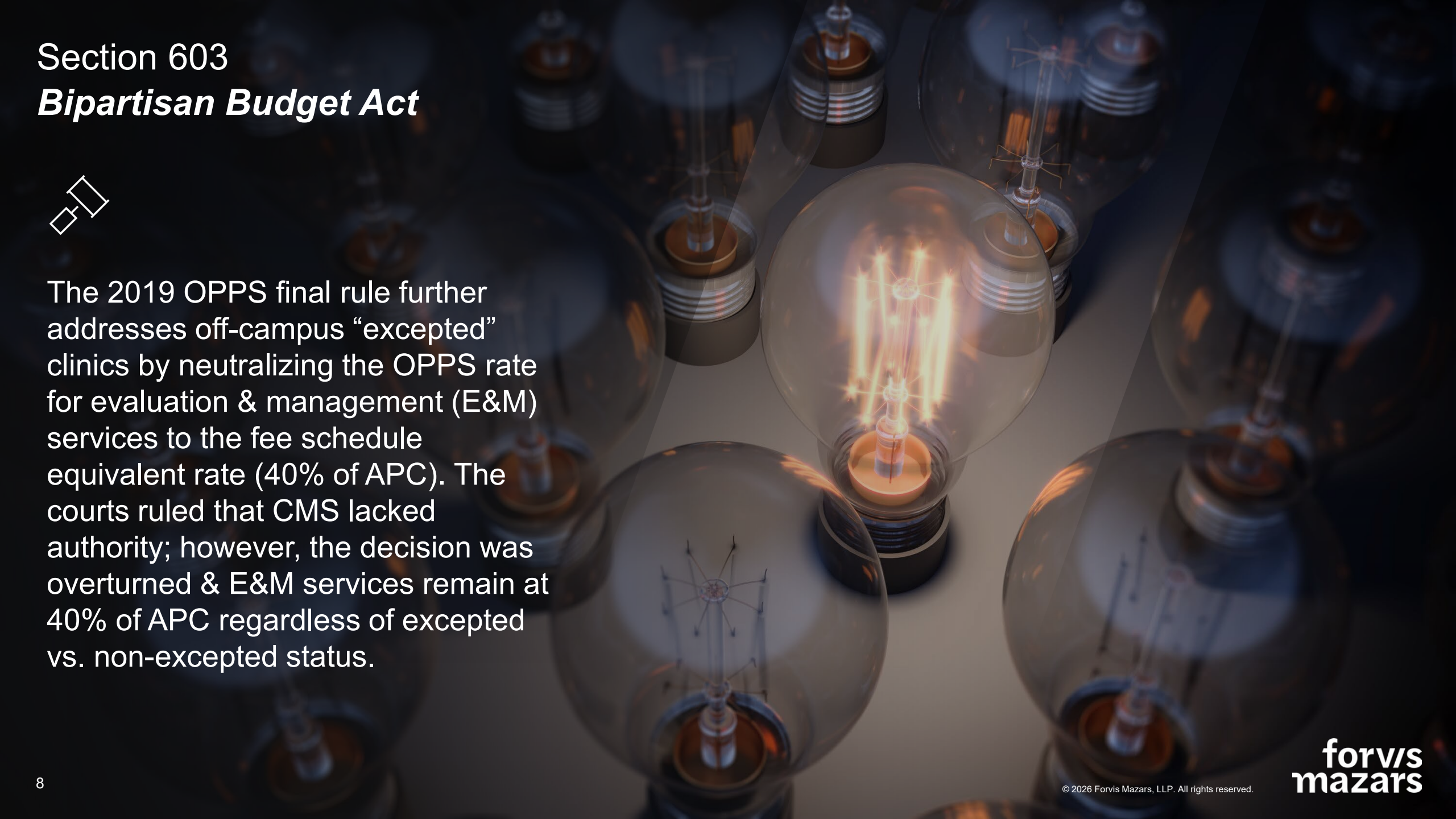
Section 603
Bipartisan Budget Act

Effective January 1, 2017

Items & services furnished by a non-excepted off-campus provider-based department (PBD) are not eligible for payment under the hospital Outpatient Prospective Payment System (OPPS) & are instead paid under the Medicare Physician Fee Schedule (PFS). Excepted items & services are items & services furnished after January 1, 2017:

- By a dedicated emergency department (2019 final rule further addresses freestanding EDs with modifier "ER")
- By an off-campus PBD that was billing for covered outpatient provider department (OPD) services furnished prior to November 2, 2015, *i.e.*, the date of enactment of §603 of the *Bipartisan Budget Act of 2015*, that has not impermissibly relocated or changed ownership
- By an off-campus PBD that qualifies for an exception under §16001 or §16002 of the *21st Century Cures Act*
- In a PBD that is "on the campus," or within 250 yards of the hospital or a remote location of the hospital

Section 603
Bipartisan Budget Act



The 2019 OPPS final rule further addresses off-campus “excepted” clinics by neutralizing the OPPS rate for evaluation & management (E&M) services to the fee schedule equivalent rate (40% of APC). The courts ruled that CMS lacked authority; however, the decision was overturned & E&M services remain at 40% of APC regardless of excepted vs. non-excepted status.

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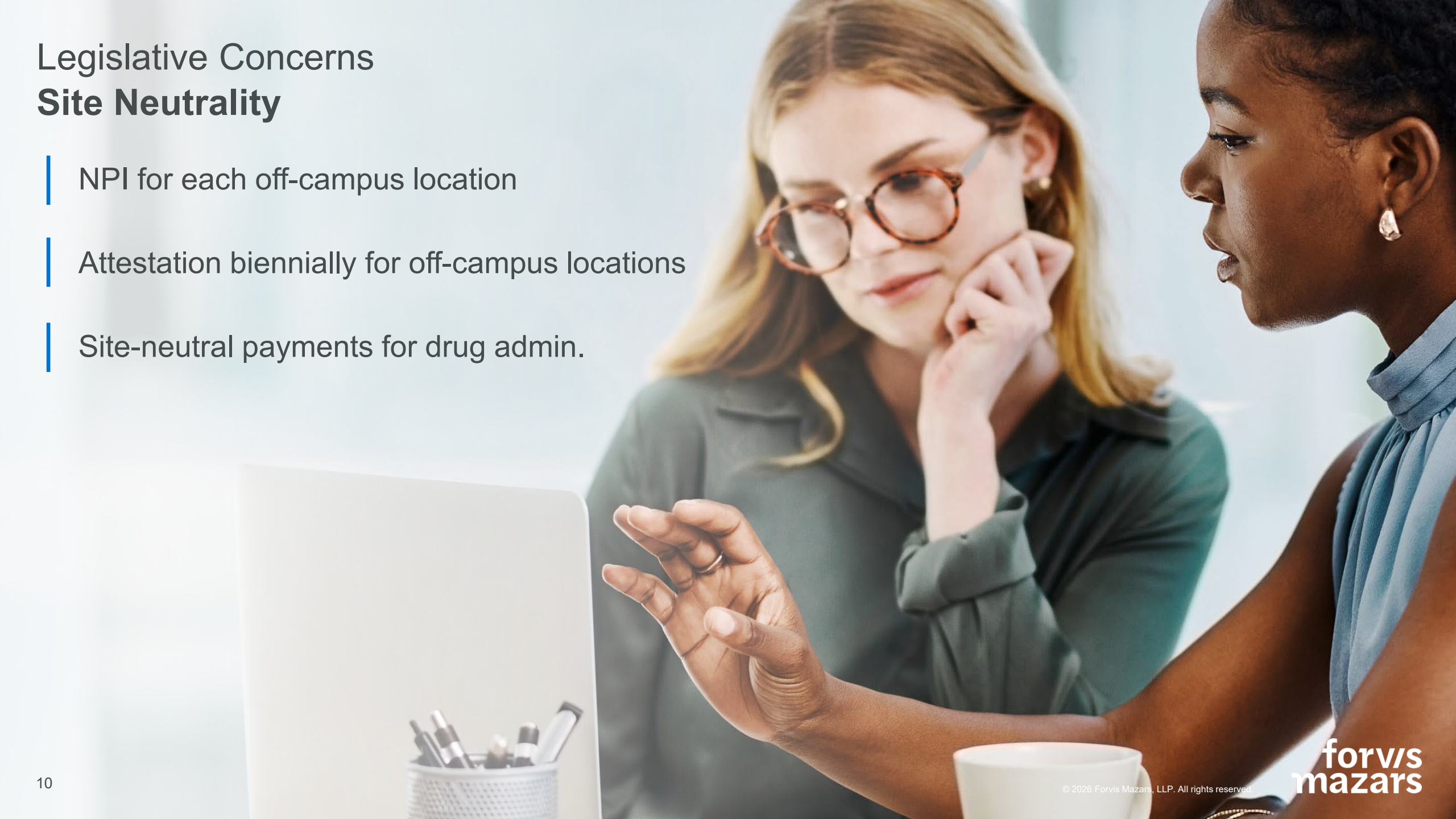
Medicare Provider-Based Reimbursement

Off-Campus Locations

- **Subject to site-neutral payment rules**
- **More than 250 yards, less than 35 miles from main hospital**
  - 35-mile rule does not apply to RHCs
- **Excepted locations: HOPDs established prior to November 2, 2015**
  - Paid 100% of OPPS for procedures
  - Paid 40% of OPPS for E&M codes (equivalent to PFS)
  - Specific to location: service changes acceptable, with limitations
  - OPPS final rule: Rural SCH excepted locations will be paid at 100% of OPPS for E&M codes
- **Non-excepted locations**
  - Regulatory intent: Paid at PFS for procedures & E&M codes
  - Operationalized as: Reduced payment to 40% of APC payment (MPFS relative adjuster)
  - New offsite locations (after November 2, 2015)

Legislative Concerns
Site Neutrality

- NPI for each off-campus location
- Attestation biennially for off-campus locations
- Site-neutral payments for drug admin.



Where We Are

CAA 26
§6225 Requirements

What Changes

- Medicare payment for off-campus outpatient departments will require:
  - A separate NPI per off-campus department
  - Provider-based compliance attestation
  - Ongoing reattestation to maintain eligibility: CMS timelines

When

- Effective January 1, 2028

Why It Matters

- **Failure to comply may jeopardize Medicare OPPS payment**
- CMS will enforce through audits & site & desk reviews
- HHS OIG will evaluate CMS oversight & report to Congress by 2030

Implications

- Direct Medicare revenue risk
- Increased regulatory scrutiny
- Requires strong governance over:
  - Provider-based status compliance
  - Billing/NPI structure
  - Compliance readiness

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American Hospital Association (AHA) Pre-Regulatory Letter to CMS

AHA Key Concerns

- Separate NPIs are administratively complex & unnecessary (CMS already identifies service location via claims/enrollment data)
- Mandatory attestations risk significant provider & MAC burden
- Current MAC-by-MAC variation increases complexity & inefficiency
- NPIs affect multiple systems (EHR, billing, credentialing, pharmacy, registries)

AHA Recommendations to CMS

- No pre-2028 provider-based determinations required; only attestation submission by deadline
- CMS should accept any attestation approved prior to February 3, 2026 (the enactment date of CAA 26) as the provider's initial attestation
- Standardize attestation process nationally (checkbox-based, minimal documentation)
- Limit attestations to one initial + one subsequent (per statute)
  - Require reattesting only for material change (change in ownership)
  - No site visits/audits unless evidence of material misrepresentation or concealment of fact by provider
- Expedited NPI issuance (within one week of application)
- Clarify separate NPIs do not alter hospital control over PB operations (billing, governance, integration)

CMS 2027 OPPS Proposed Rule
Implementation of CAA 26 §6225

Definition of Off-Campus Outpatient Department

- A provider-based department
- Is not located on the main hospital campus
- Is not within the campus distance limits applicable to a remote location as defined under §413.65

Exclusions

- Only applies to hospitals and services paid under OPPS
- Excludes:
  - Critical Access Hospitals
  - Indian Health Service & Tribal Facilities
  - RHCs & FQHCs

Remote Location

- CMS distinguishes it as an off-campus location*
- Departments within 250 yards are considered on-campus

*CMS included ambiguous wording regarding "remote locations". Clarification in the final rule would be helpful to continue to designate as a multi-campus facility.

Proposed Attestation Requirements

Initial Attestation

- Main provider must submit an initial attestation for each off-campus outpatient department
- Proposed rule states multiple times that NPI for each location should be obtained prior to submission & enrollment information updated in PECOS
- Departments furnishing services prior to January 1, 2028 must submit an initial attestation between January 1, 2026 & December 31, 2027
- Departments furnishing services ***after*** January 1, 2028 must submit within the two years before services are billed
- Practical deadline is well before January 1, 2028
- Departments that have submitted an attestation between January 1, 2026 & December 31, 2027 will meet filing requirements before January 1, 2028 & may continue to bill even if CMS has not yet issued a formal determination
- CMS is seeking comment on initial mandatory attestations for locations that have received a determination prior to January 1, 2026

Subsequent Attestation

- CMS proposes ongoing reattestations
- Maximum not to exceed five years
- 2028 rulemaking will address subsequent attestation details

Standardized CMS Attestation Process

Major Operational Change

- CMS proposes replacing MAC-specific templates with:
  - Standardized National Attestation Form
  - Centralized electronic submission system

Anticipated Benefits

- Consistency across MAC jurisdictions
- Reduced administrative burden
- More efficient review process
- Less duplicative documentation

The current MAC attestation processes may continue until the new system is implemented.

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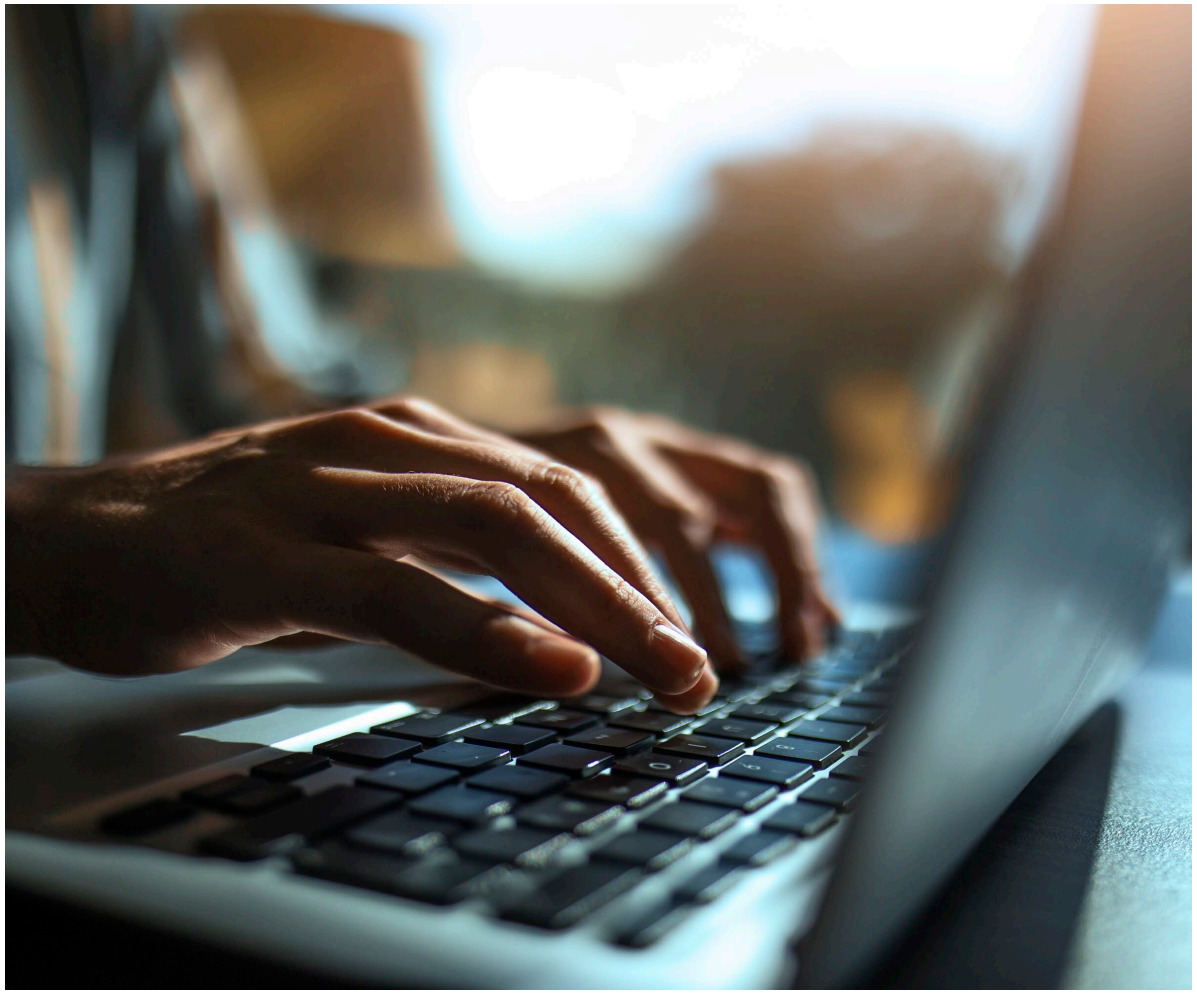
Attestation
Basic Content

- Provider Information
  - Main provider name
  - Address
  - NPI
- Department Information
  - Department name
  - Address
  - NPI
- Compliance Certification
- Authorized Signature (must be the AO in PECOS for Medicare enrollment)
- If the primary contact is a consultant/outside representative, written authorization is required



Attestation
Documentation Requirements

- Providers must:
  - Maintain documentation supporting compliance
  - Furnish documentation upon CMS request
- Not all documentation will be required at initial submission
  - CMS may request documents:
    - During initial reviews
    - During audits
    - Following risk-based screening
    - During oversight activities
- CMS' goal is to reduce upfront documentation burden while preserving program integrity oversight
- The agency will use risk-based screening, targeted documentation reviews, & validation & audit activities to request additional information

Attestation
Documentation Requirements

Targeted Review

- Providers are required to maintain supporting documentation
- Only requested when warranted due to
  - Main providers generally operate departments consistently
  - Reviewing a representative sample can validate overall compliance

CMS Expects

- Reduced provider burden
- More efficient oversight
- Continued program integrity safeguards

Key takeaway: more oversight

Attestation
Location Documentation Requirements

Future system may auto-verify:

- Campus location requirements
- Distance requirements

When is additional documentation required?

- Distance cannot be verified electronically
- Department exceeds 35-mile distance standard
- Exceptions under §413.65(e)(3) must be demonstrated

Attestation
Licensure Documentation Requirements

Must be prepared to show:

- Department operated under the same license as the main provider or
- State law does not require a separate license

What additional evidence may be required?

- State licenses
- Licensing correspondence
- Regulatory approvals: department adds to license

Attestation
Public Awareness Requirements

Must be prepared to show:

- The department is part of the main provider
- Upon entering, a patient is aware they are entering the main provider

What additional evidence may be required?

- Signage
- Website
- Public-facing collateral
- How calls are answered

Attestation
Clinical Integration Documentation Requirements

Must be prepared to demonstrate that:

- Department practitioners hold privileges at the main provider
- Main provider exercises oversight & monitoring
- Inpatient & outpatient services are integrated
- Patients have access to the full range of hospital services

What additional documentation may be required?

- Medical staff bylaws & list of practitioners with privilege category
- Organizational charts
- Referral reports showing service integration between the main provider & the department
- Access to care & nondiscrimination policies
- Accreditation compliance letter

Attestation

Financial Integration Documentation Requirements

Must be prepared to demonstrate that:

- Department revenues & expenses are integrated into hospital trial balance
- Department does not maintain a separate general ledger
- Department does not maintain an independent trial balance

What additional documentation may be required?

- Detailed trial balance with department revenues & expenses embedded
- Chart of accounts showing same as above

Attestation
HOPD Documentation Requirements

Must be prepared to demonstrate compliance with:

- EMTALA requirements
- Anti-dumping requirements
- Site-of-service billing requirements
- Medicare beneficiary estimated financial responsibility notifications

What additional documentation may be required?

- EMTALA policy
- Examples of CMS Form 1500
- Policy & form that provides notice of estimated financial responsibility to the Medicare beneficiary

Attestation

Ownership & Control Documentation Requirements

Must be prepared to demonstrate that:

- Department is 100% owned by the main provider
- Main provider maintains final authority over:
  - Administrative decisions
  - Personnel policies
  - Medical staff appointments

What additional documentation may be required?

- Organization charts
- Narrative attestations from leadership
- Human resource polices
- Medical staff bylaws
- Hospital bylaws

Attestation
Administration Integration Documentation Requirements

Must be prepared to demonstrate that:

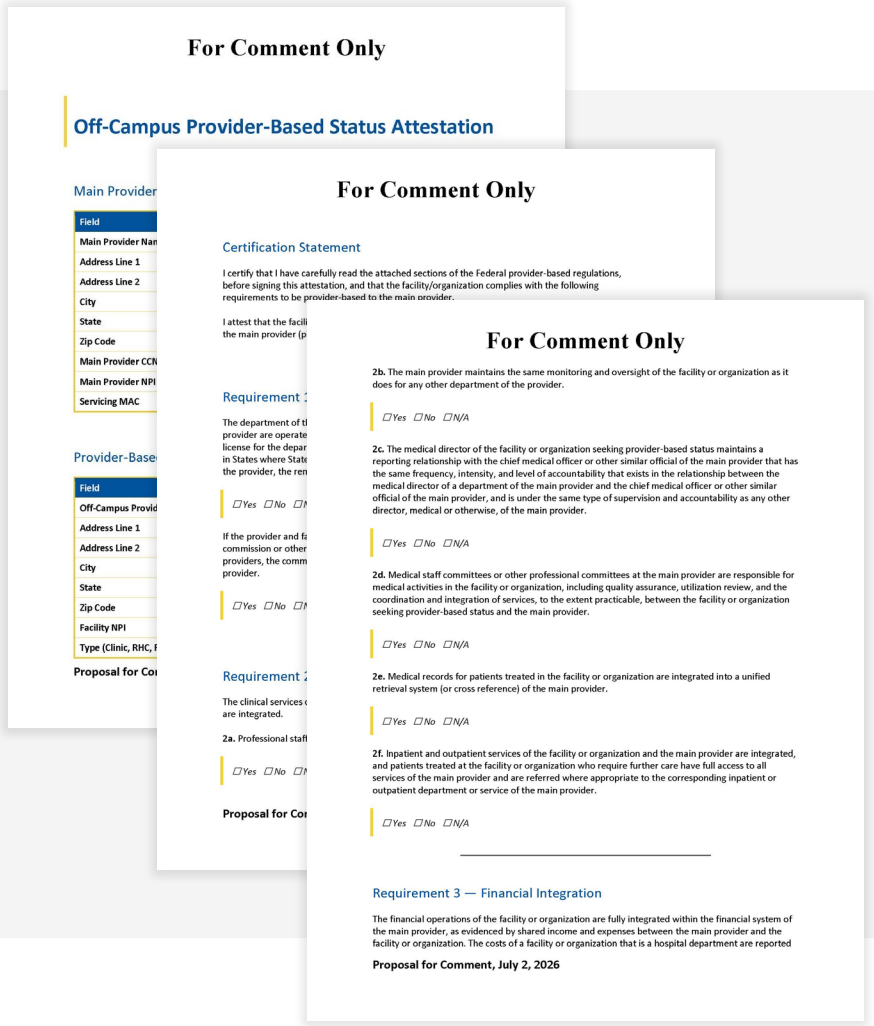
- Administrative functions are integrated with the hospital
- Reporting structures flow to hospital leadership
- Department operates within hospital governance structure

What additional documentation may be required?

- Organization charts
- Reporting relationships
- Governance documents
- Management oversight records

CMS Draft Attestation

Scan to see the draft attestation form from CMS.



CMS Verification & Oversight

§1833(t)(23)(B)(i) requires CMS to establish a process to verify compliance with provider-based requirements to prevent inappropriate Medicare payments

Proposed Compliance Monitoring Tools

- Site visits
- Remote audits
- Investigations
- Additional documentation requests
- Program integrity contractors
- Future technology-enabled reviews

CMS Verification & Oversight
Risk-Based Model

CMS proposes a multitiered, risk-based review process.

1

Level 1: Automated Validation

Applies to all submissions

2

Level 2: Targeted Documentation Review

Applies to higher-risk or inconsistent submissions

3

Level 3: Extended Compliance Review

Applies to selected providers based on risk indicators

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CMS Verification & Oversight
Initial Review Stage

Level 1: Automated Validation

Applies to all submissions

1

Process

- Verify completeness of attestation
- Confirm consistency with PECOS enrollment records
- Validate required attestation elements

Outcome

- Passes & moves forward for PB determination, **OR**
- Flagged for additional review

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CMS Verification & Oversight
Targeted Review

Level 2: Targeted Documentation Review

Applies to higher-risk or inconsistent submissions

2

Attestations may be flagged for:

- Missing information
- Inconsistencies
- Data anomalies
- Elevated compliance risk indicators

Additional documentation requested may include:

- Supporting documentation
- Additional explanation
- Further evidence supporting compliance with §413.65

CMS Verification & Oversight
Extended Compliance Review

Level 3: Extended Compliance Review

Applies to selected providers based on risk indicators

3

Attestations may receive enhanced review using risk-based methodologies:

- Remote audits
- Targeted documentation requests
- Compliance verification activities
- Detailed record review
- Data analytics investigations

CMS Verification & Oversight
Non-Response

CMS proposes that:

- Providers must respond within CMS-established timeframes, generally not to exceed 60 days
- Failure to provide documentation may result in:
  - Noncompliance determination
  - Denial of provider-based status
  - Potential payment recovery actions

Documentation readiness will be key to successfully maintaining PB designations.

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Site Neutrality Today
CMS Proposed Rule: Radiology

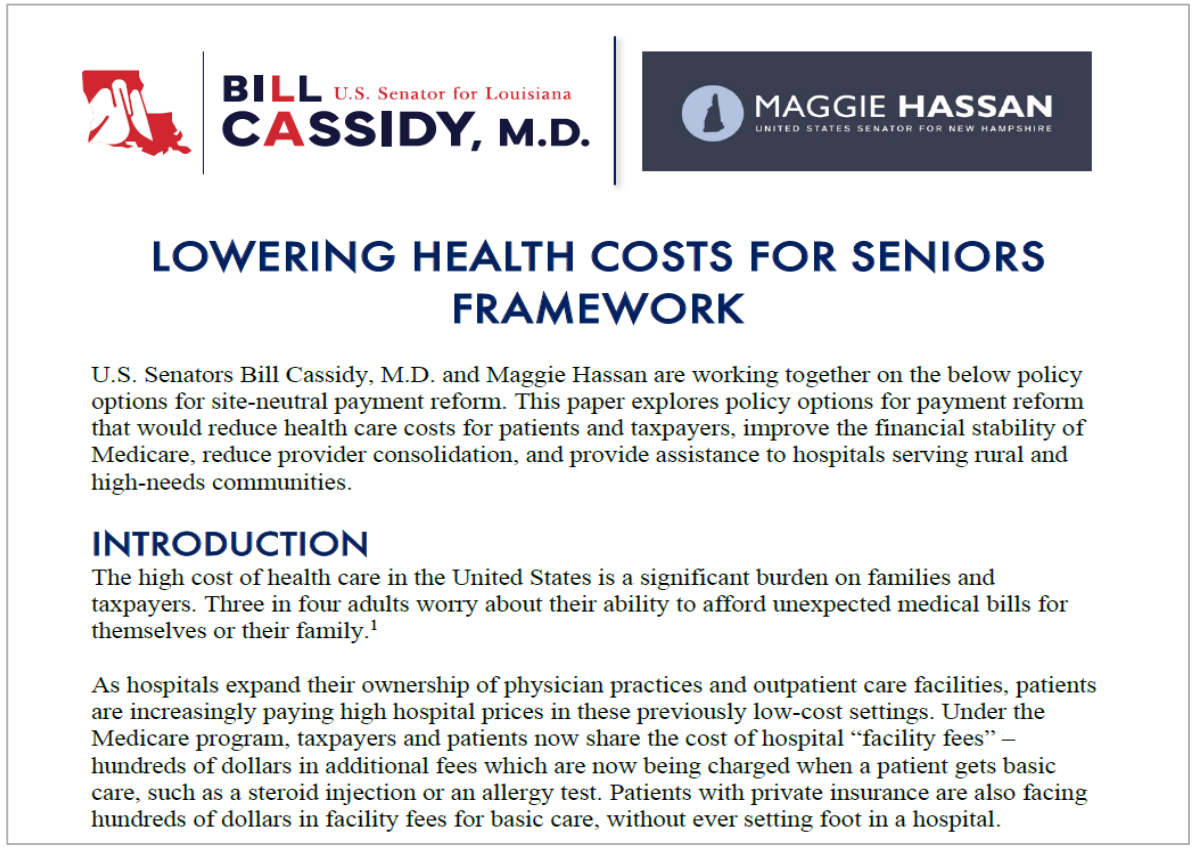
- For 2027, radiology services without contrast APCs in excepted off-campus HOPDs will be paid at 40% of the MPFS

- Exception: Sole Community Hospitals

The Future: A Challenging Environment

Site-Neutral Payments

Policies expanding site-neutral payments & encouraging care in lower-cost settings are likely.



BILL CASSIDY, M.D. U.S. Senator for Louisiana

MAGGIE HASSAN UNITED STATES SENATOR FOR NEW HAMPSHIRE

LOWERING HEALTH COSTS FOR SENIORS FRAMEWORK

U.S. Senators Bill Cassidy, M.D. and Maggie Hassan are working together on the below policy options for site-neutral payment reform. This paper explores policy options for payment reform that would reduce health care costs for patients and taxpayers, improve the financial stability of Medicare, reduce provider consolidation, and provide assistance to hospitals serving rural and high-needs communities.

INTRODUCTION

The high cost of health care in the United States is a significant burden on families and taxpayers. Three in four adults worry about their ability to afford unexpected medical bills for themselves or their family.[1]

As hospitals expand their ownership of physician practices and outpatient care facilities, patients are increasingly paying high hospital prices in these previously low-cost settings. Under the Medicare program, taxpayers and patients now share the cost of hospital "facility fees" – hundreds of dollars in additional fees which are now being charged when a patient gets basic care, such as a steroid injection or an allergy test. Patients with private insurance are also facing hundreds of dollars in facility fees for basic care, without ever setting foot in a hospital.

Potential Policy Actions

Legislation:

- Repeal §603 HOPD exemptions
- Site neutrality across HOPD, ASC, & MD office
- Funding to support rural/safety-net hospitals
- Eliminate IPO list

Administrative Action:

- Continued phasing out IPO list
- Continued Expansion of ASC Covered Procedures list

Source: "Lowering Health Costs for Seniors Framework," cassidy.senate.gov, November 1, 2024.

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Potential Future Risks: Site Neutrality

Service Category	Likelihood of Site-Neutral Expansion: Off-Campus (Grandfathered PBDs)	Likelihood of Site-Neutral Expansion: On-Campus HOPDs	Notes/Policy Drivers
Clinic Visits	**Completed**	**High – No change** CMS requested comment in 2026 OPPS rule	Established precedent; MedPAC & CBO cite as top savings source
Drug Administration/Infusion	**High – No change** CY 2026 rule applies PFS rate to *excepted off-campus* PBDs	**Moderate - No change** CMS RFI for future inclusion	CMS sees this as the next expansion area (excludes reimbursement for drug costs)
Diagnostic Imaging (CT/MRI/Ultrasound)	**Moderate – Non-contrast radiology services will be paid at 40% of APC**	**Moderately Low - No change**	MedPAC supports; CMS cautious due to access concerns; already partially addressed under imaging caps
Diagnostic Testing (Cardiac Echo, Labs, EEGs, etc.)	**Moderate – No change**	**Moderately Low - No change**	Low complexity services; may follow imaging reforms in later waves
Minor Surgical Procedures (Cataract, Cystoscopy, Arthroscopy, etc.)	**Moderate – No change**	**Moderately Low - No change**	Many are ASC-eligible; cost differences measurable

Potential Future Risks

Service Category	Likelihood of Site-Neutral Expansion: Off-Campus (Grandfathered PBDs)	Likelihood of Site-Neutral Expansion: On-Campus HOPDs	Notes/Policy Drivers
Major Outpatient Surgery (Total Joint, Spine, Cardiac Cath, etc.)	**Moderate – No change**	**Low - No change**	Higher complexity; safety still under study
Chemotherapy Services	**Moderate – No change**	**Low - No change**	High-cost drugs; political sensitivity; may be delayed
Radiation Therapy	**Moderate – No change**	**Low - No change**	Likely affected by parallel bundled payment pilots

Compliance Strategies: How to Prepare

Strategies to Consider

Preparation & Planning

- Prepare/update provider-based inventory (know which locations are implicated)
- Perform a gap assessment for compliance with requirements
- Work on corrective actions
- Begin compiling attestations
- NPI planning & timeline
  - Obtain NPIs
  - IT plan for NPI billing updates
  - Enrollment updates in PECOS
- Calculate impacts: potential future risks
  - Off-campus excepted: other procedures
  - On-campus
- Consider submitting comments on the proposed rule
- Advocacy
- Stay up to date: 2027 OPPS final rule

Strategies to Consider

CMS Shifting to Verification

- Maintain documentation before submitting attestation
- Stay audit-ready
- Demonstrate operational integration—not on paper and not merely ownership

Areas Where CMS May Focus

- Separate NPIs
- Ownership & governance
- Clinical integration
- Financial integration
- Beneficiary notice compliance
- Public awareness of hospital ownership

Additional Readiness
Calculating Impacts

Excepted Status Eliminated

Calculate impact for procedures

Drug Administration On-Campus Payments

Site Neutrality for 66 APCs

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Questions?

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