2026 Medicare Physician Fee Schedule (MPFS) Final Rule Updates

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Agenda & Objectives

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Agenda:

1. MPFS Conversion Factor
2. Rural Health Updates
3. Virtual Supervision
4. Telehealth Updates
5. Skin Substitutes
6. Changes to the Quality Payment Program (QPP)

Objectives

- Be able to state the conversion factor
- Provide 2 major policy changes
- Be able to state what has changed with virtual supervision
- Able to state changes to skin substitute payment
- Discuss changes to Telehealth for 2026

Source Authorities

- 2026 Final Published MPFS
  - https://www.govinfo.gov/content/pkg/FR-2025-11-28/pdf/2025-21458.pdf
- CMS Fact Sheets:
  - https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2026-medicare-physician-fee-schedule-final-rule-cms-1832-f
- National Payment Amount File 12/2025
  - https://www.cms.gov/files/zip/pfrev26a-updated-12-29-2025.zip
- Physician Fee Schedule Landing Page – CMS
  - https://www.cms.gov/medicare/payment/fee-schedules/physician

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The Mantra from CMS

Payment equity favoring independent and non-facility-based care, reduced reliance on facility-based payment advantages, and long-term support for team-based, technology-supported care models.

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2026 Conversion Factors (CF)

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2026 Conversion Factors (CF)

- For the first time, Medicare has implemented two separate conversion factors based on participation in Advanced Alternative Payment Models (APMs). Both factors include a temporary **2.5% increase** provided by the "One Big Beautiful Bill" Act passed by Congress.

Category	2026 Conversion Factor	Change from 2025 ($32.35)
Qualifying APM Participants (QPs)	**$33.57**	+3.77%
Non-Qualifying Participants	**$33.40**	+3.26%

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2026 Conversion Factors (CF) Qualifying APM Participants (QPs)

Category	2026 Conversion Factor	Change from 2025 ($32.35)
Qualifying APM Participants (QPs)	**$33.57**	+3.77%

- 0.75% statutory update for QPs per MACRA
- Temporary one year 2.5% increase from the “One Big Beautiful Bill”
- 0.49% budget-neutrality adjustment

2026 CF= 32.3465 x (1 + 0.0075) x (1 + 0.025) x (1 + 0.0049)
=32.3465 x 1.0075 x 1.025 x 1.0049 ≈ 33.5675 ≈ **33.57**

Overall percentage change= (1.0075 x 1.025 x 1.0049) – 1 ≈ 3.775% ≈ **3.77%**

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2026 Conversion Factors (CF) Non-Qualifying APM Participants (Non-QPs)

Category	2026 Conversion Factor	Change from 2025 ($32.35)
Non-Qualifying Participants	**$33.40**	+3.26%

- 0.25% statutory update for Non-QPs per MACRA
- Temporary one year 2.5% increase from the “One Big Beautiful Bill”
- 0.49% budget-neutrality adjustment

2026 CF= 32.3465 x (1 + 0.0025) x (1 + 0.025) x (1 + 0.0049)
=32.3465 x 1.0025 x 1.025 x 1.0049 ≈ 33.4009 ≈ **33.40**

Overall percentage change= (1.0025 x 1.025 x 1.0049) – 1 ≈ **3.26%**

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Key RVU Adjustments & New Policies

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Key RVU Adjustments & New Policies

While the conversion factor increased, several new adjustments will offset these gains for specific specialties:

- **Efficiency Adjustment (-2.5%):** CMS finalized a permanent policy to reduce work RVUs by **2.5%** for most **non-time-based codes** (e.g., procedures, radiology, and diagnostic tests). This reflects "efficiency gains" over time.
- Recalculated every 3 years

  – *Exemptions:* Time-based codes, E/M services, behavioral health, maternity, telehealth, and all brand-new codes for 2026 are excluded.

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Changes to Site of Service: PE Reduction

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Changes to Site of Service: Practice Expense (PE) Reduction

- **Indirect Practice Expense (PE) Shift:** CMS changed how it allocates indirect costs for services performed in facilities (hospitals/ASCs).
  - **The Change:** Indirect PE RVUs for facility-based services are now reduced to **50%** of the non-facility rate.
  - **The Impact:** This creates a significant **site-of-service differential**, boosting payments for office-based practices while cutting payments for facility-based specialists (e.g., Hospitalists, Surgeons, and Interventional Radiologists).
    - Facility-based physician services are expected to see an average payment decrease of ~7%, due exclusively to this change in PE methodology
    - Non-facility services are projected to enjoy a ~4% increase, since indirect costs are reallocated away from facility-based settings.

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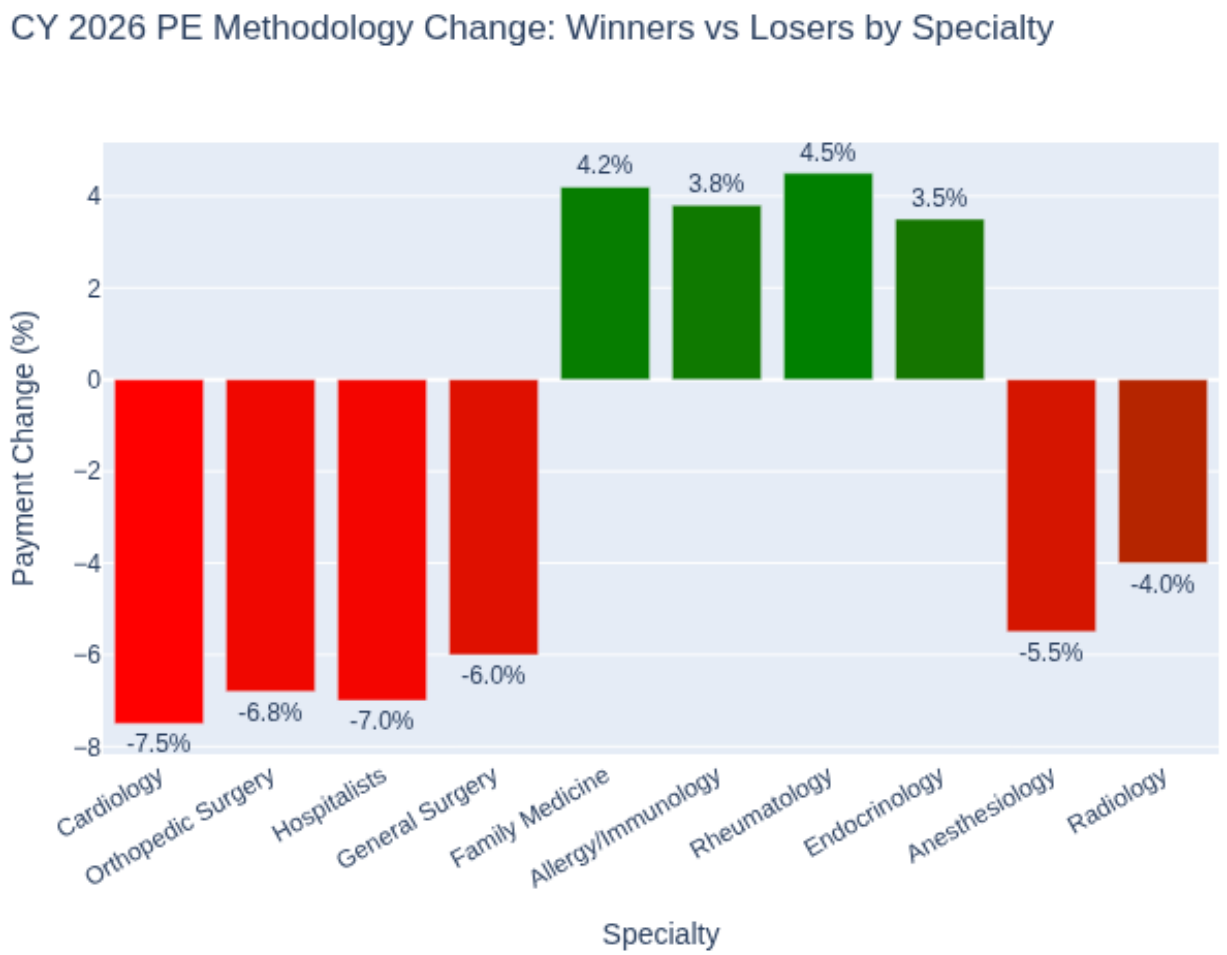
Changes to Site of Service: Practice Expense (PE) Reduction



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Notable Specialty Impacts

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Notable Specialty Impacts

The redistribution of Practice Expense (PE) funds creates "winners and losers" in this rule:

- **Primary Care & Office-Based:** Family Medicine, Internal Medicine, and Rheumatology are expected to see a net increase (approx. **3-6%**) due to the PE shift toward non-facility settings.
- **Facility-Based Specialists:** Many specialties will see net cuts despite the higher conversion factor:
  - **Infectious Disease:** ~81% of physicians face cuts of 5% or more.
  - **Interventional Radiology:** Estimated **-7% impact** for facility-based services.
  - **Oncology:** Some practices face cuts between 10% and 20%.

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Rural Health Updates

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Rural Health Updates: All-Inclusive Rate (AIR)

- Independent and provider-based RHCs in hospitals with ≥50 beds:
  - All-inclusive per-visit payment limit: $165
- Specified provider-based RHCs (in hospitals <50 beds, enrolled before Dec 31, 2020)
  - Reimbursement limited to the greater of:
    - CY 2025 payment limit plus 2.7% MEI, or
    - The $165 statutory rate
- Additional IOP (Intensive Outpatient Program) payment rates for 2026:
  - 3 or fewer services/day: $319.38
  - 4 or more services/day: $418.45

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Rural Health Updates: General Bundle Codes

CMS is finalizing the shift away from broad, all-encompassing codes in favor of individual reporting:

- **G0511 Sunset:** The general care management bundle code (G0511 [Rural health clinic or federally qualified health center (RHC or FQHC) only, general care management, 20 minutes or more of clinical staff time for chronic care management services or behavioral health integration services directed by an RHC or FQHC practitioner (physician, NP, PA, or CNM), per calendar month]) has officially sunset.
- RHCs and FQHCs must now bill individual Chronic Care Management (CCM) and Principal Care Management (PCM) codes separately.

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Rural Health Updates: General Bundle Codes

CMS is finalizing the shift away from broad, all-encompassing codes in favor of individual reporting:

- **G0512 Unbundling:** Starting **January 1, 2026**, CMS is unbundling the Psychiatric Collaborative Care Model (CoCM). Instead of the single G0512 code, you will report the specific component codes: **99492, 99493, and 99494.**
  - **99492**
    - [1ST PSYCHIATRIC COLLAB CARE MGMT 1ST 70 MINS]
  - **99493**
    - [SBSQ PSYCHIATRIC COLLAB CARE MGMT 1ST 60 MINS]
  - **99494**
    - [1ST/SBSQ PSYCH COLLAB CARE MGMT EA ADDL 30 MINS]

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Rural Health Updates: General Bundle Codes

CMS is finalizing the shift away from broad, all-encompassing codes in favor of individual reporting:

- **G0071 Unbundling:** The code for virtual check-ins and remote evaluations (G0071) is also unbundled. You will now report **G2010** (remote evaluation of images/video) and **G2250** (virtual check-in) individually.
  - **G2010**
    - [Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment]
  - **G2250**
    - [Remote assessment of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment]

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Rural Health Updates: Advanced Primary Care Management (APCM)

CMS has introduced new **APCM add-on codes** for RHCs and FQHCs to encourage integrated behavioral health:

- **Optional Add-ons:** You can now bill optional codes (**G0568, G0569, and G0570**) alongside APCM services.

- **Behavioral Health Integration:** These codes move away from strict "minute-tracking" and instead focus on the availability of integrated behavioral health services and the development of individualized treatment plans.

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Rural Health Updates: Advanced Primary Care Management (APCM)

- **G0568**
  - [Int psych care mng, 1 cal mo]
- **G0569**
  - [Subs psych care mng, subs mo]
- **G0570**
  - [Care manage serv, pr cal mo]

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Rural Health Update:

- **Virtual Direct Supervision:** CMS has **permanently** adopted the policy allowing "direct supervision" to be met via real-time audio/video technology. This is a huge win for rural clinics where a supervising physician may not be physically on-site every day.

- **HCPCS G2025 Extension:** RHCs and FQHCs can continue to use **G2025** *[Payment for a telehealth distant site service provided by a rural health clinic (RHC) or federally qualified health center (FQHC) only]* for non-behavioral health telehealth visits through **December 31, 2026**. The payment rate for G2025 in 2026 is **$97.53**.

- **Originating Site Fee:** The facility fee for being an originating site has increased to **$31.85** for 2026.

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Rural Health Updates: Remote Monitoring

- RHCs and FQHCs can now report **Remote Patient Monitoring (RPM)** and **Remote Therapeutic Monitoring (RTM)** codes separately in the same month they report APCM, provided the requirements for both are met. This allows for significantly higher revenue capture for patients with chronic conditions.

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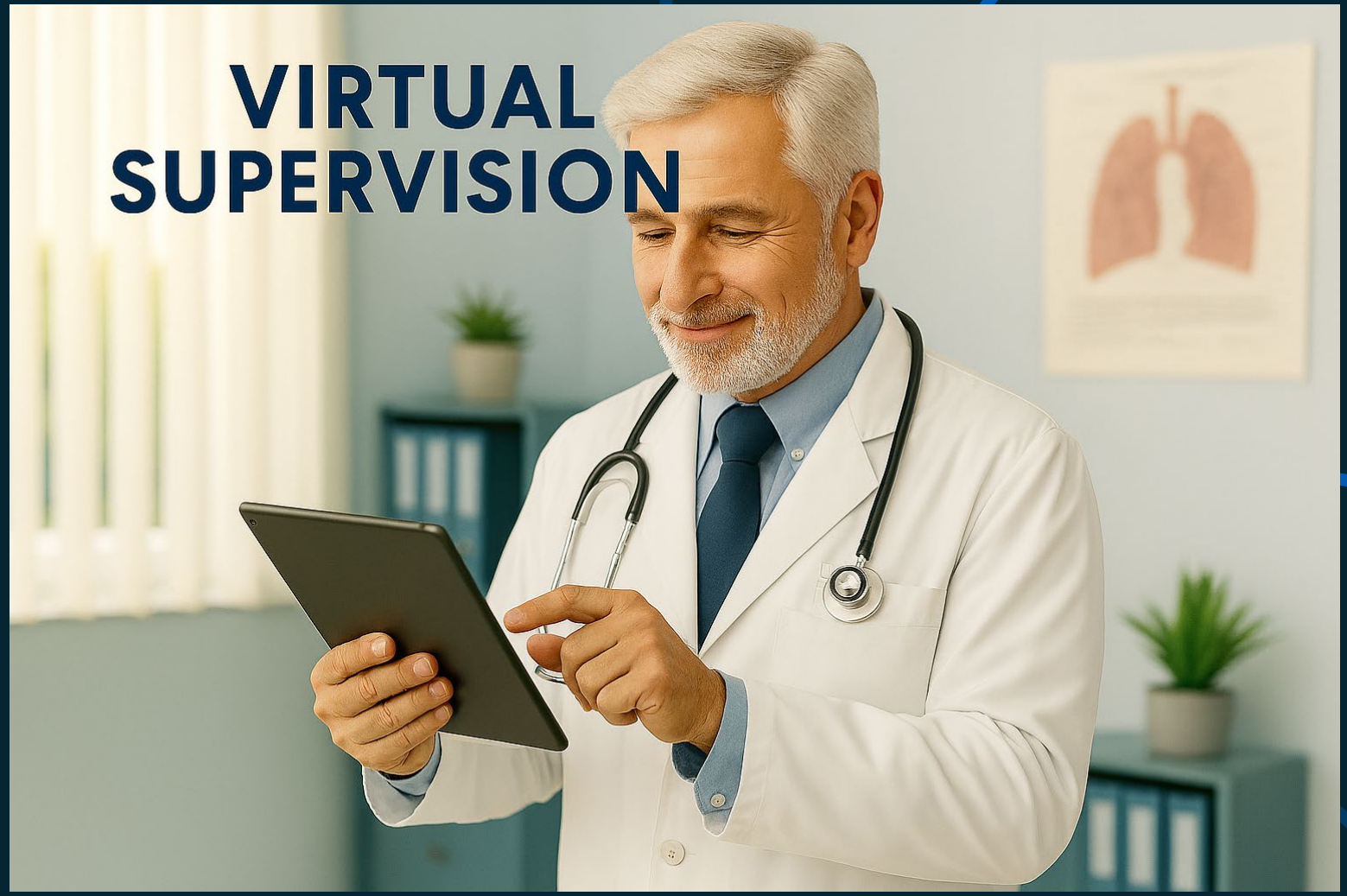

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Proposed Changes to Virtual Supervision

- Modality: “real-time audio and visual interactive telecommunications” excluding audio-only.
- Scope limitation by global surgery indicator: would allow virtual direct supervision except for services with 010 or 090 global surgery indicators.
- Service categories specifically called out as in-scope (examples):
  - Incident-to services under 42 CFR § 410.26
  - Diagnostic tests under 42 CFR § 410.32
  - Pulmonary rehab under 42 CFR § 410.47
  - Cardiac rehab / intensive cardiac rehab under 42 CFR § 410.49
- CMS also asked for comments about whether services with a 000 global surgery indicator should be excluded for patient safety/quality reasons.

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Final Changes to Virtual Supervision

- The biggest “change” is that it’s now **final and permanent** beginning 1/1/2026, rather than expiring after 12/31/2025.
- Other specific final decisions are:
  - Modality: supervising presence may include virtual presence through audio/video real-time communications excluding audio-only.
  - Global surgery limitation retained: virtual direct supervision finalized for services without 010 or 090 global surgery indicators.
  - CMS guidance (Telehealth FAQ) clarifies “which services allow virtual direct supervision”

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Final Changes to Virtual Supervision

- Final policy applies to services where direct supervision is required that do not have a 010 or 090 global surgery indicator, and explicitly includes:
  - Most incident-to services (§ 410.26)
  - Many diagnostic tests (§ 410.32)
  - Pulmonary rehab (§ 410.47)
  - Cardiac rehab / intensive cardiac rehab (§ 410.49)
  - Certain hospital outpatient services (as provided under § 410.27(a)(1)(iv))
- CMS did focus in the rule on the needed changes for pulmonary and cardiac rehab specifically as well as some diagnostic tests
- This final rule will change elements of 42 CFR to codify the changes

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What Implication For Physicians

- Audio-only cannot satisfy direct supervision (even if audio-only may be allowed for certain telehealth services like behavioral health—different concept).
- You need a way to identify excluded codes (010/090 global surgery indicator) vs allowed codes;
  - CMS frames the policy at the “global surgery indicator” level rather than only by individual CPT/HCPCS codes.
- Expect compliance teams to focus on:
  - “direct supervision required” flags,
  - The service’s global surgery indicator,

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What Implication For Physicians

- ***Documenting availability via real-time audio/video***. (Modality boundary: Why CMS keeps saying audio/video (not audio-only) – this has to do with the concept of "direct supervision"
- For "direct supervision," the requirement ***isn't just communication*** — it's ***'immediate availability to furnish assistance and direction***'. CMS is treating video as part of being meaningfully "present."
- Documentation is going to have to reflect that during this visit the provider was immediately available to furnish assistance and direction – this becomes important when we discuss telehealth and resident supervision

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Telehealth & Supervision Updates

CMS has moved to make several pandemic-era flexibilities permanent or extended:

- **Direct Supervision:** CMS permanently adopted a definition that allows "direct supervision" via **real-time audio and visual technology** (telehealth) for most services.

- **Telehealth Frequency Limits:** Frequency limitations for subsequent inpatient visits, nursing facility visits, and critical care consultations have been **permanently removed**.

- **Originating Site Fee:** The facility fee for telehealth originating sites increased to **$31.85** for 2026.

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2026 Proposed Approach

- Proposed:
  - CMS proposed to ***streamline how services are added*** to the Medicare Telehealth Services List by removing the “provisional vs permanent” distinction and focusing review on whether the service can be furnished using an interactive, two-way audio-video telecommunications system.
- Final:
  - The “gate” CMS emphasizes is increasingly: can the service be furnished via two-way audio/video?
  - The telehealth list continues to be updated through annual PFS rulemaking; the proposed rule text reiterates the request deadline process (e.g., CMS notes a February 10 submission deadline for consideration in the next year’s rulemaking).

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CMS 5 Steps to Determine Eligibility of CPT for Telehealth Inclusion

Step	Evaluation step / criterion	2025 approach	2026 approach
1	Statutory eligibility / authority	Threshold gate: service must be allowed under Medicare telehealth statute and applicable regulations.	Still a threshold gate: CMS continues to require statutory authority before adding services.
2	Can the service be furnished via real-time interactive audio/video?	Explicit criterion considered along with other category tests (e.g., similarity/evidence).	Becomes the dominant practical gatekeeper; emphasis on whether the service can be furnished using interactive, two-way A/V.
3	Clinical similarity to services already on the telehealth list (Category 1 logic)	Distinct evaluative step; supported permanent additions based on similarity to existing telehealth services.	No longer a separate step; folded into overall judgment primarily informed by A/V feasibility and evidence.
4	Evidence of safety/efficacy/quality when furnished via telehealth	Distinct evaluative step; used to support additions especially for non-similar services and PHE experience.	Still considered, but as part of a streamlined overall determination rather than a separate multi-category test.
5	Telehealth list category assignment (e.g., permanent vs provisional)	Separate step: CMS used categories (e.g., provisional/temporary vs permanent) and reassessment pathways.	Removed: CMS eliminates the provisional vs permanent distinction and applies a streamlined pathway.

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What Changed in The Process

Step	Evaluation step / criterion	Change type	Alleviated / streamlined?	What was alleviated
1	Statutory eligibility / authority	Unchanged	No	N/A
2	Can the service be furnished via real-time interactive audio/video?	Emphasized	Partially (consolidation)	Reduces need for separate 'similarity' step when A/V feasibility is clear.
3	Clinical similarity to services already on the telehealth list (Category 1 logic)	Consolidated	Yes	Removed standalone similarity requirement as a separate analytical hurdle.
4	Evidence of safety/efficacy/quality when furnished via telehealth	Consolidated	Yes	Reduced duplicative categorization and re-testing; evidence integrated into a single decision step.
5	Telehealth list category assignment (e.g., permanent vs provisional)	Eliminated	Yes (major)	Eliminated category mechanics and the extra administrative step of assigning/reviewing provisional vs permanent status.
	Annual request mechanics / timing (e.g., submission deadlines)	Mostly unchanged	No (process remains)	N/A

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Frequency Limits

- **Proposed**: CMS proposed to permanently remove telehealth frequency limits for:
  - subsequent inpatient visits
  - subsequent nursing facility visits
  - critical care consultations
- **Final:** CMS finalized the ***permanent removal***, effective January 1, 2026.

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Proposed & Final – Teaching

- **Proposed:**
  - CMS did not propose to extend the broad policy that allowed teaching physicians to be “virtually present” for services involving residents in all teaching settings (policy in effect through 12/31/2025). CMS proposed reverting to pre-PHE policy requiring physical presence during critical portions in metropolitan statistical areas (with the rural exception maintained).
- **Final:**
  - After receiving comments, CMS changed their approach from the proposed in several ways.
    1. Final - allowing teaching physicians to have a virtual presence in all teaching settings, but only when the service itself is furnished virtually as a Medicare telehealth service, and this is permanent

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Proposed & Final – Teaching

- **Final:**
  - After receiving comments, CMS changed their approach from the proposed in several ways.
    2. Telehealth FAQ frames it as: continuing virtual presence for teaching physicians in all settings only for Medicare telehealth services, using audio/video real-time communications for the key portion of the telehealth service.
       - https://www.cms.gov/files/document/telehealth-faq-updated-11-26-2025.pdf

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Question 7 – FAQ as of 11/24/25

- **Q7:** What are the current guidelines for virtual presence for teaching physicians who furnish telehealth services involving residents?
- **A7:** In the CY 2026 PFS final rule, we established that beginning January 1, 2026, we are continuing to allow teaching physicians to have a virtual presence in all teaching settings, but only for services furnished as a Medicare telehealth service. This will continue to permit teaching physicians to have a virtual presence during the key portion of the Medicare telehealth service for which payment is sought, through audio/video real-time communications technology, for all residency training locations.

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Telehealth – Audio Only

- The CY 2026 Telehealth FAQ reiterates that two-way, real-time audio-only may be used for certain behavioral health services in the patient's home under defined conditions (e.g., clinician is capable of audio-video; beneficiary cannot or does not consent to audio-video).
- **Note:**
  - Audio-only may be permitted for certain telehealth services, but audio-only does not satisfy "virtual direct supervision" under the CY 2026 PFS supervision policy.

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RHC - FQHC

- RHC/FQHC services requiring direct supervision: finalized the same virtual (audio/video) direct supervision approach.
- For **non-behavioral health visits** via telecom tech in RHCs/FQHCs,
  - Finalized continued billing/reporting via G2025, including audio-only through **12/31/2026**.

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Policies for Chronic Illness and Behavioral Health

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Behavioral Health Policy Changes

- Digital Mental Health Treatment (DMHT) - HCPCS G0552–G0554
  - There was a transcription issue in the proposed rule – just clarified in final rule otherwise no changes
  - DMHT still requires order, must be FDA 510(k)-cleared or De Novo authorized and be documented as integrated into a plan of care.
  - CMS signals an “iterative” path from behavioral health digital therapeutics toward chronic conditions such as ADHD.

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New Integrated Behavioral Health

- New Codes:
  - **G0568 – Initial** psychiatric collaborative care management (first calendar month) with required elements including: outreach/engagement; ***initial assessment with validated rating scales***; individualized treatment plan; psychiatric consultant review; registry entry and tracking; weekly caseload consultation; brief evidence-based interventions (behavioral activation, motivational interviewing, etc.).
  - **G0569 – Subsequent** psychiatric collaborative care management (subsequent month) including registry-based tracking; weekly caseload consultation; ongoing collaboration/coordination; treatment change recommendations (including meds) based on psychiatric consultant; brief interventions; validated rating scales monitoring; relapse prevention planning/discharge preparation.

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New Integrated Behavioral Health

- New Codes:
  - **G0570** – Care management services for behavioral health conditions (monthly) including assessment/follow-up monitoring with validated rating scales; behavioral health care planning; facilitating/coordinating psychotherapy/pharmacotherapy/counseling/psychiatric consultation; continuity with a designated care-team member
    - Direct crosswalk to existing CoCM/BHI services for work RVUs and PE inputs:
    - G0568 ↔ CPT 99492 (work RVU 1.88)
    - G0569 ↔ CPT 99493 (work RVU 2.05)
    - G0570 ↔ CPT 99484 (work RVU 0.93)
    - CMS finalized the valuation approach as proposed, emphasizing comparability to existing CoCM/BHI.

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Chronic Illness: Community and Behavioral Health

- Certain behavioral health visits to count as the **initiating visit** for Community Health Integration (CHI).
  - Psychiatric diagnostic evaluation: CPT 90791
  - Health Behavior Assessment/Intervention (HBAI): 96156, 96158, 96159, 96164, 96165, 96167, 96168
- Social Determinant Of Health (SDOH) Risk Assessment has changed:
  - **G0136:**“Administration of a standardized, evidence-based assessment of physical activity and nutrition, 5–15 minutes, not more often than every 6 months

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Chronic Illness: Medicare Diabetes Prevention Program

- CMS reiterated that MDPP remains structured as a group-based preventive service where financial sustainability *depends heavily on participation volume and group capacity.*
- CMS did not adopt an RVU-based reimbursement approach or bill-as-add-on alongside APCM; CMS maintained MDPP's FFS + performance-based methodology focused on outcomes (e.g., weight loss milestones).
- CMS noted MDPP suppliers already have flexibility to provide Beneficiary Engagement Incentives (BEIs); CMS did not revise payment methodology to separately account for medically tailored meals (viewed as a BEI).

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Rationale for Change to Skin Substitute

- Industry ownership and changes in the industry have led to a significant increase in expense for the Medicare program in the facility and non-facility
- “Part B spending for these products rose from approximately $250 million in 2019 to over $10 billion in 2024, a nearly **40-fold increase**, while the number of patients receiving these products only doubled”
- In 2023 rule a number of concerns were expressed and the need to unify the approach across settings was noted.

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Highlights of 2026 Rules – MPFS / OPPS

- Reclassified most skin substitute products (when applied in covered procedures) to be paid as incident-to supplies, rather than using ASP-like biological payment logic.
- Policy applies across settings, including hospital outpatient departments (HOPD under OPPS) and physician offices (PFS non-facility), to promote cross-setting consistency.
- CMS aligned product grouping to FDA regulatory pathways (e.g., 361 HCT/P, PMA, 510(k)).
- CY 2026 uses a single national "transition" payment rate per cm^2 (CMS intends to propose differentiated category rates in future rulemaking).
- Published in Federal Register - describes the final rate as **$127.14/$cm^2$**.

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2023 Objectives Across the Spectrum

- *(1) ensuring a consistent payment approach for skin substitute products across the physician office and hospital outpatient department settings;*
- *(2) ensuring that appropriate HCPCS codes describe skin substitute products;*
- *(3) employing a uniform benefit category across products within the physician office setting, regardless of whether the product is synthetic or comprised of human- or animal-based material, so we can incorporate payment methodologies that are more consistent; and*
- *(4) promoting clarity for interested parties on CMS skin substitutes policies and procedures.*

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Historic Processes

- *Prior to 2026, Medicare is paying for most skin substitutes as biologicals using the methodology under section 1847A of the Act, each skin substitute product receives a unique billing code (typically, a Level II HCPCS code) and payment limit*.
- In contrast, OPPS bundled the low-cost skin substitutes into the procedure while reviewing and assigning high-cost into a payment method.
- This represents a diversity in the approach that CMS is trying to avoid

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Proposal and Final Determination

- **Proposed:**
  - Starting January 1, 2026, to separately pay for the provision of certain groups of skin substitute products as incident-to supplies when, for those products that are coverable under Medicare's rules, they are used during a covered application procedure paid under the **PFS in the non-facility setting or under the OPPS**
  - CMS stated: "..primary policy objectives is to ensure a consistent payment approach for skin substitute products across the physician office and hospital outpatient department settings; and so, we ultimately determined that the suite of products referred to as skin substitutes **should be treated in a uniform manner across different outpatient care settings**, to the extent permitted by applicable law."

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Proposal and Final Determination

- CMS stated: "*Depending on the outcomes of this final policy, we may consider packaging skin substitute products with the related application procedures in both the hospital outpatient setting and non-facility setting in future rulemaking.*"
- Stated that the new policy is likely to reduce the current profiteering practices under the pharmaceutical designation. This resulted in an overuse of expensive skin substitutes as a matter of course.
- We clarify that skin substitute products that are not regulated as drugs or biological products under section 351 of the PHS Act and that are paid as incident to supplies are **not subject to the Medicare discarded drug policy**. At this time, skin substitutes are excluded from Part B inflation rebates as described at § 427.101(b)(5) and as finalized in the CY 2025 PFS final rule (89 FR 98235).

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Proposal and Final Determination

- **Commenters concerns**: *"They described a system where manufacturers can launch new, clinically undifferentiated products at inflated prices and offer deep discounts to providers, who then profit from the spread between their acquisition cost and the high Medicare reimbursement rate."*
- *"We believe this policy will dramatically reduce these problematic behaviors in both the physician office and hospital outpatient settings. We also believe this policy has the potential to prevent these harmful practices from occurring in different settings of care, including hospice and home health."*
- *Finalized a policy to consider products that are not in sheet form to be skin substitutes for the purpose of providing separate payment as incident-to supplies under this policy.*

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Summary – Skin Substitutes

- Used the OPPS rates in a singular determination for payment rates
- Effective Jan 1, 2026: Separately pay for covered skin substitute products as incident-to supplies in non-facility and hospital outpatient settings.
- Create three payment groups for covered sheet skin substitutes based on FDA regulatory pathway: PMA, 510(k), and 361 HCT/P (assigned by approval/clearance/self-determination).
- CY 2026 estimated rate: ~$127.28 per cm^2 (before geographic adjustments) for PMA, 510(k), and 361 HCT/P categories. Updated after publication to **$127.14/cm^2$**
- Maintain current HCPCS codes for skin substitutes, and apply the single rate to each code.

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Payment Groups - PMA, 510(k), and 361 HCT/P

1. **PMA — Premarket Approval (Class III devices)**
   - This is the highest level of FDA scrutiny.
   - Used for high-risk, complex biologic or tissue-engineered skin substitutes.
   - Requires clinical trial data demonstrating safety & effectiveness.
2. **510(k) — Premarket Notification (Class II devices)**
   - Used when the product is **substantially equivalent** to an existing legally marketed device.
   - These are typically **lower-risk, device-type skin substitutes**, often made from ECM, collagen, or synthetic matrices.

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Payment Groups - PMA, 510(k), and 361 HCT/P

3. **361 HCT/P — Human Cells, Tissues, and Cellular/Tissue-Based Products**
    - Regulated under **Section 361 of the Public Health Service Act** (NOT as drugs/devices).
    - To qualify as a **361 HCT/P**, a product must:
    - be minimally manipulated
    - be intended for homologous use
    - not rely on metabolism of living cells
    - not be combined with another article (with some exceptions)

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Summary – Skin Substitutes

- Treat non-sheet form products as skin substitutes for separate incident-to payment; price via MACs.
- Convert all skin substitute product codes to add-on codes with ZZZ indicator

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Regulatory Changes for Submission

- Submitter will be **manufacturer not the provider**
- “Manufacturers of drugs payable under Medicare Part B are required, as part of the submission of average sales price (ASP) data, to submit reasonable assumptions including fair market value (FMV) documentation for current, new, and renewed contracts.”
- “These requirements apply to all contracts that include fees, price concessions, or other remuneration that may affect ASP calculations.”

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Fair Market Value Requirements

- Fair Market Value (FMV) documentation standard
  - “CMS will accept well-detailed summaries of FMV methodologies that clearly describe the data sources, assumptions, and rationale supporting the determination.”
  - “FMV determinations must support that any fees excluded from ASP calculations qualify as bona fide service fees.”
  - “All FMV determinations for current contracts are **due by April 30, 2026**, with the submission of ASP data for the first quarter of sales in 2026.

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Enforcement Changes

- CMS enforcement and integrity rationale
  - “These policies are intended to strengthen the integrity of ASP reporting and ensure that only bona fide service fees are excluded from ASP calculations.”
  - “CMS is concerned that insufficient documentation and pass-through of fees may result in inaccurate ASP reporting and inflated Medicare payment amounts.”

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Quality Payment Program (QPP) & MIPS

- **High Level trend:**
  - Not a lot of changes to quality with stable QPP in 2026
  - Longer-term shift toward MIPS Value Pathways (MVPs) and cross-program alignment
  - 6 New Value Pathways (MVPs)
    - Diagnostic Radiology
    - Interventional Radiology
    - Neuropsychology
    - Pathology
    - Podiatry
    - Vascular Surgery

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Quality Payment Program (QPP) & MIPS

- Existing MVPs have only receive maintenance to align with current quality improvement.

- **MIPS Changes:**
  - Finalized threshold of 75 points through 2030 (Performance year 2028)
  - Any new measures will have a 2-year reporting only period
  - 5 new MIPS
    - Q512 — *Prevalent Standardized Kidney Transplant Waitlist Ratio (PSWR)*
    - Q513 — *Patient Reported Falls and Plan of Care*
    - Q514 — *Diagnostic Delay of Venous Thromboembolism in Primary Care*
    - Q515 — *Screening for Abnormal Glucose Metabolism in Patients at Risk of Developing Diabetes*
    - Q516 — *Hepatitis C Virus (HCV): Sustained Virological Response (SVR)*

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Quality Payment Program (QPP) & MIPS

- **MIPS Changes:**
  - 10 measures were removed
- **Improvement Activities:**
  - 3 new improvement activities added :
    - Improving Detection of Cognitive Impairment in Primary Care (IA_PM_27)
    - Integrating Oral Health Care in Primary Care (IA_PM_28)
    - Patient Safety in Use of Artificial Intelligence (AI) (IA_PSPA_34)
  - 8 improvement activities removed (including some finalized previously with delayed implementation)

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Quality Payment Program (QPP) & MIPS

- **Improvement Activities:**
  - Two changed *subcategories*:
    - Advancing Health and Wellness - Added
    - Achieving Health Equity - Removed

- **MIPS Interoperability:**
  - Modification to the Security Risk Analysis measure;
  - Modification to the High Priority Practices Safety Assurance Factors for Electronic Health Record (EHR) Resilience (SAFER) Guide measure; and
  - Adoption of one new optional bonus measure, the Public Health Reporting Using Trusted Exchange Framework and Common Agreement (TEFCATM) measure.

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Quality Payment Program (QPP) & MIPS

- **Performance Threshold:** The threshold to avoid a penalty remains at **75 points** through the 2028 performance period.
- **New MIPS Value Pathways (MVPs):** Six new MVPs were added for 2026, including **Diagnostic Radiology, Pathology, and Podiatry**, as CMS continues its push to sunset traditional MIPS.

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Questions?

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