2026 Regulatory Update

Health Law Webinar

December 10, 2025

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The Big Picture

- Regulatory change is slower than promised.
- “Fraud” discussion is likely to intensify.
- It feels like it could be rocky period for hospitals.
  - More uninsured patients.
  - Higher pressure not to make patients pay.
- We’ve sought a lot of injunctive relief in the past year.
- The loping of Loper Bright?
- More non-intervened cases?

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Telehealth Generally

- Several telehealth flexibilities enacted during the COVID-19 PHE are scheduled to expire after January 30, 2026, including:
  - Originating (i.e., Patient) Site Flexibilities – urban or rural, including at home.
  - Distant (i.e., Provider) Site Flexibilities – Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs); provider's home.
  - Provider Type Flexibilities – e.g., Physical Therapists, Occupational Therapists, Speech Language Pathologists and Audiologists.
  - Audio-Only Services for Non-Behavioral Health Services.
  - Mental Health Flexibilities – Moratorium on requirement for in-person visit within six months of patient starting mental health telehealth services.

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Telehealth Generally (Cont.)

- Bipartisan Legislative Efforts to Extend Flexibilities.
  - Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act of 2025 (S. 1261 / H.R. 4206).
    - Would permanently extend COVID-era telehealth flexibilities.
  - Telehealth Modernization Act (S. 2709 / H.R. 5081).
    - Would extend COVID-era telehealth flexibilities through September 30, 2027.
- Most likely resolution of January 30, 2026 telehealth cliff: another short-term extension by Congress.
- 2026 Physician Fee Schedule includes preservation and expansion of telehealth flexibilities that do not require congressional action.

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Changes to Medicare Telehealth Services List

- Simplified three-step review process for requested additions to list:
  - Step 1 – Determine whether the service is separately payable under the PFS.
  - Step 2 – Determine whether the service is subject to the provisions of section 1834(m) of the Social Security Act.
  - Step 3 – Determine whether the service is capable of being furnished using an interactive, two-way audio-video telecommunications system.
- Eliminated distinction between provisional and permanent services.

Additions to Medicare Telehealth Services List

- Multiple-Family Group Psychotherapy.
  - CPT code 90849.
- Group Behavioral Counseling for Obesity.
  - CPT code G0473.
- Infections Disease Add-On.
  - CPT code G0545.
- Auditory Osseointegrated Sound Processor Services.
  - CPT codes 92622 and 92623.

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Permanent Removal of Certain Telehealth Frequency Limitations

- Subsequent Inpatient Visits.
  - CPT codes 99231, 99232 and 99233.
- Subsequent Nursing Facility Visits.
  - CPT codes 99307, 99308, 99309 and 99310.
- Critical Care Consultation Services.
  - HCPCS codes G0508 and G0509.

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Telehealth from Practitioner's Home

- During the PHE, CMS allowed telehealth practitioners to provide telehealth services from their homes while billing from their enrolled practice locations instead of their home addresses.
- Was extended through December 31, 2025 in the CY 2025 PFS.
- Rather than extending again in the CY 2026 PFS, CMS stated that it did not need to extend this flexibility via rulemaking (i.e., in the PFS) because the policy is now addressed in subregulatory guidance (see next slide).

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Telehealth from Practitioner's Home (Cont.)

- In Q15 and A15 in a Telehealth FAQ for CY 2026 that was last updated on November 14, 2025, CMS clarified:
  - "Practitioners who furnish telehealth services from their homes but have a physical practice location are not required to report their home address on their Medicare enrollment application. Practitioners can enroll and bill from their physical practice location as if they furnished the telehealth service in person."
  - "…telehealth practitioners whose only physical practice location is their home address will need to enroll their home address as a practice location.
- The FAQ includes guidance on how virtual-only practitioners may suppress their street address details in the Medicare database.

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“Direct Supervision” via Virtual Presence

- Pre-PHE, direct supervision generally required the supervising physician or practitioner to be physically present.
- During the PHE, direct supervision was expanded to include “virtual presence through audio/video real-time communications technology (excluding audio-only)”.
  - Requires supervisor’s ability to be “immediately available” via such technology, not continuous real-time presence/monitoring via such technology.
- Was previously extended through December 31, 2025 for all services requiring direct supervision and permanently for a certain subset of services.

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“Direct Supervision” via Virtual Presence (Cont.)

- CMS has now amended the definition of “direct supervision” at 42 CFR 410.26(a)(2) to permanently include “virtual presence through audio/video real-time communications technology (excluding audio-only)”.
- Applies to all services requiring direct supervision except for services that have a global surgery indicator of 010 or 090:
  - 010 – Minor surgery with a 10-day global period.
  - 090 – Major surgery with a 90-day global period.
  - Rationale for exclusion: the need for rapid on-site decision-making in the event of an adverse clinical situation.

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Virtual Presence Permitted for Teaching Physicians, with Limitations

- Pre-PHE, teaching physicians were generally required to be physically present during services provided by residents.
- During the PHE, teaching physicians were permitted to be virtually present.
- After the PHE, CMS announced an intent to reinstate requirement of physical presence, but this was previously delayed through CY 2025.
- CMS has now reversed course and permanently extended this policy.
- Applies to residents in all teaching settings, but only with respect to services furnished virtually (e.g., a three-way telehealth visit, with the patient, resident, and teaching physician in separate locations).

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Telehealth in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

- Extended payment for telehealth services furnished by practitioners located in these facilities through January 30, 2026.
  - Continued use of HCPCS code G2025 for non-behavioral health services.
- Extended delay of the in-person visit requirement for mental health services furnished via telehealth by RHCs and FQHCs to beneficiaries in their homes through January 30, 2026.
- Permanent adoption of definition of “direct supervision” that allows such supervision through real-time audio and visual interactive telecommunications (excluding audio-only).

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Prescribing Controlled Substances Via Telehealth to Patients That Have Not Been Evaluated in Person

- Background:
  - Ryan Haight Act of 2008 generally requires an in-person medical evaluation of a patient before prescribing a controlled substance.
  - Suspended during PHE.
  - DEA and HHS jointly proposed new rules in March 2023, making permanent certain of the PHE flexibilities and rolling back others.
  - Proposed rules generated over 38,0000 public comments and multiple DEA listening sessions.
  - PHE flexibilities were previously extended through December 31, 2025.
- On November 10, 2025, the DEA signaled a further extension is imminent.

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Hospital at Home

- On December 1, 2025, the House of Representatives unanimously passed the Hospital Inpatient Services Modernization Act (H.R. 4313).
  - Would extend the Acute Hospital Care at Home program through September 30, 2030 (had previously been extended through January 30, 2026).
  - Referred to the Senate Committee on Finance on December 2, 2025.
  - Given bipartisan support and broad stakeholder backing, the bill is widely expected to pass the Senate and be signed into law, though a lapse on January 30, 2026 remains possible.

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Home Health Prospective Payment System Final Rule and CMS Year-End Grab Bag (90 FR 55342)

- CY 2026 Payment and Policy Updates for Home Health Agencies.
- Changes to Medicare Enrollment Provisions:
  - Significant expansion of retroactive revocation authority (and associated overpayment exposure).
  - Additional bases for revocation or deactivation.
- Changes to Durable Medical Equipment, Prosthetic Devices, Prosthetics, Orthotics, & Supplies (DMEPOS) Accreditation Provisions:
  - More frequent DMEPOS supplier surveys and reaccreditations.
  - Stricter requirements for becoming and remaining a DMEPOS accrediting organization.

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Efficiency Adjustment

- Historically CMS has relied on survey data from the American Medical Association and the Specialty Society Relative Value Scale Update Committee ("RUC") to estimate practitioner time, work intensity, and practice expense for purposes of establishing work RVUs for codes used for payment.
- CMS discussed the challenges of using survey data to establish work RVU details and indicated that these challenges undermine the accuracy of recommendations.
- CMS argues that there are efficiencies gained in work RVUs for non-time-based codes. Non-time-based codes should become more efficient over time as they become more common, professionals gain more experience, technology is improved, and other operational improvements are implemented.

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Efficiency Adjustment

- CMS proposed the efficiency adjustment “to take into account changes in medical practice and better reflect the resources involved in furnishing services paid under the PFS.”
- Assumes that the intraservice portion of physician time and the work intensity will decrease as the practitioner develops expertise performing the specific service.
- Newly established codes, E/M, and certain telehealth service codes are exempt from the 2026 efficiency adjustment.
- Time-based services are excluded from the efficiency adjustment.
- The final CMS efficiency adjustment rate is -2.5%, a negative adjustment for CY 2026.

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Chronic Illness and Behavioral Health

- According to CMS, six in ten Americans have at least one chronic disease, and four in ten have two or more chronic diseases.
- Behavioral health conditions are among the most common chronic health conditions in the country.
- CMS goal is to improve understanding and reduce chronic disease rates with considerations made for nutrition, physical activity, healthy lifestyles, reliance on medication and treatments, technology habits, environmental impacts, and food and drug quality and safety.
- CMS notes that having a usual source of primary care can be positively associated with better receipt of recommended prevention services and effective management of chronic disease.

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Chronic Illness and Behavioral Health

- Integrating behavioral health with usual primary care.
- Optional add-on codes for Advanced Primary Care Management to facilitate providing complementary behavioral health integration services.
- Removes the time-based requirements of existing behavioral health integration and collaborative care model codes to reduce documentation requirements for billing.
- CMS anticipates that reducing the burden on practitioners to deliver behavioral health integration will make it more likely that such services will be furnished by primary care providers.
- Digital mental health treatment payment policies expanded to include payment for devices used in the treatment of ADHD.

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IPPS - Highlights

- IPPS Payment Rates.
  - Increase in operating payment rates for general acute care hospitals that successfully participate in the Hospital Inpatient Quality Reporting (IQR) program and are meaningful electronic health record users under the Medicare Promoting Interoperability Program of 2.6%.
  - FY 2026 is projected to have a hospital market basket increase of 3.3%, and that metric was reduced by a 0.7 percentage point productivity adjustment.
- Transition for Discontinuing the Low Wage Index Hospital Policy.
  - D.C. Circuit Court held in 2024 that the policy must be vacated.
  - CMS adopting a “budget-neutral narrow transitional exception” for calculating FY 2026 IPPS for low wage index hospitals which will be significantly impacted by discontinuation of the low wage index hospital policy.
  - Exception expected to operate similar to the 2025 interim transitional policy.

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IPPS - Highlights

- CMS finalized modification of four current measures for the Hospital IQR program and the removal of four measures beginning with the CY 2024 reporting period/FY 2026 payment determination.
    - Added Medicare Advantage patients to the current cohort of patients and shortened performance periods from 3 to 2 years for:
        - Hospital-Level, Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty.
        - Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Ischemic Stroke Hospitalization with Claims-Based Risk Adjustment for Stroke Severity.
    - Lowered submission thresholds to allow for up to two missing laboratory results and up to two missing vital signs, reduced core clinical data elements submission requirement to 70% or more of discharges, and reduced the submission requirement of linking variables to 70% or more of discharges.
        - Hybrid Hospital-Wide Readmission.
        - Hybrid Hospital-Wide Mortality.

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OPPS/ASCs - Highlights

- OPPS/ASC Payment Rates.
  - Update to the payment rates for hospitals meeting applicable quality reporting requirements and ASCs meeting relevant quality reporting requirements by 2.6%.
- Elimination of the Inpatient Only (IPO) List.
  - CMS is phasing out the IPO list over a 3-year period, beginning with the removal of 285 procedures for CY 2026.
- ASC Covered Procedures List (CPL).
  - Criteria changes to eliminate five of the general exclusion criteria and move them to a new section as nonbinding physician considerations for patient safety.
  - Also adding 271 codes to the CPL that are being removed from the IPO list.

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OPPS/ASCs - Highlights

- Increased focus on price transparency.
  - Requirements for hospitals to make public actual dollar amounts in their machine-readable file (MRF).
  - Replacement of the estimated amount with the median amount, and addition of the 10th and 90th percentile allowed amounts.
  - Lookback period must be at least 12 months and no more than 15 months prior to posting the MRF for the median amount, 10th and 90th percentile allowed amounts, and count of allowed amounts.
  - Modification to the MRF Affirmation Statement
  - Including Organizational/Type 2 NPIs in the MRF

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CMS and MAHA

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CMS and MAHA

- 1. Repurposing of the SDOH Risk Assessment Code
- 2. Advanced Primary Care Behavioral Health Integration
- 3. Adjustments to the Star Ratings System
- 4. Expanding Access to the Medicare Diabetes Prevention Program

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Repurposing of the SDOH Risk Assessment Code

- HCPCS code G0136 (2024).
  - Allows clinicians to bill Medicare for performing a validated assessment of Social Determinants of Health (SDOH) of the patient that may interfere with the clinician's diagnosis or treatment of the patient.
    - **Old code description**: Administration of a standardized, evidence-based social determinants of health risk assessment tool, 5 to 15 minutes, not more often than every 6 months.
- Going forward (code # will remain same and stay on telehealth list).
  - CMS changing code description to align with the Administration's efforts to address root causes of chronic illness such as physical activity and nutrition.
  - **New code description**: 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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Adjustments to the Star Ratings System

- Background.
- What is changing?
  - Removing of the Health Equity Index.
  - Removal of 12 measures from the Star Ratings.
  - Addition of one new measure.

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Adjustments to the Star Ratings System Cont.

- Removal of the Health Equity Index.
  - Proposed rule would not implement the Excellent Health Outcomes for All (EHO4All) reward, otherwise known as the Health Equity Index, which was finalized under Biden Administration and set to take effect in 2027.
    - Purpose was to reward plans that perform well for enrollees with social risk factors.
    - Specifically dual eligibles (Medicare + Medicaid); low-income beneficiaries and those with disabilities.
- Going forward.
  - Continue using the existing reward factor (rewards high performance across all measures) instead of equity specific bonus.

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Adjustments to the Star Ratings System Cont.

TABLE 1: MEASURES PROPOSED TO BE REMOVED FROM THE STAR RATINGS

Part C or D	Measure Name	Star Ratings Year Proposed for Removal
C	Plan Makes Timely Decisions about Appeals	2029 Star Ratings
C	Reviewing Appeals Decisions	2029 Star Ratings
C	Special Needs Plan (SNP) Care Management	2029 Star Ratings
C	Call Center – Foreign Language Interpreter and TTY Availability	2028 Star Ratings
D	Call Center – Foreign Language Interpreter and TTY Availability	2028 Star Ratings
C and D	Complaints about the Health/Drug Plan	2029 Star Ratings
D	Medicare Plan Finder Price Accuracy	2029 Star Ratings
C	Diabetes Care – Eye Exam	2029 Star Ratings
C	Statin Therapy for Patients with Cardiovascular Disease	2028 Star Ratings
C and D	Members Choosing to Leave the Plan	2029 Star Ratings
C	Customer Service	2029 Star Ratings
C	Rating of Health Care Quality	2029 Star Ratings

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Adjustments to the Star Ratings System Cont.

TABLE 2: SUMMARY OF NEW INDIVIDUAL STAR RATING MEASURES FOR PERFORMANCE PERIODS BEGINNING ON OR AFTER JANUARY 1, 2027

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	CMIT ID	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
Part C Measures								
Depression Screening and Follow-Up	The average percentage of eligible MA plan members who were screened for clinical depression using a standardized instrument and, if screened positive, received follow-up care within 30 days.	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS	The calendar year 2 years prior to the Star Ratings year	Not available	Clustering	MA-PD and MA-only

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Expanding Access to the Medicare Diabetes Prevention Program

- What is the MDPP?
  - Preventive health initiative designed to help Medicare beneficiaries with prediabetes avoid developing type 2 diabetes.
  - Based on the CDC's National Diabetes Prevention Program.
  - Evidence-based lifestyle change program covered under Medicare Part B.
  - Focuses on behavioral interventions proven to reduce diabetes risk.
  - Year-long Program; beneficiaries receive group sessions where they are provided coaching centered around achieving weight loss through physical fitness and healthy eating habits.

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Expanding Access to the MDPP Cont.

- What is changing?
  - CMS is extending flexibilities allowed during COVID-19 PHE to allow MDPP suppliers to deliver some or all MDPP sessions via distance learning.
  - MDPP suppliers are not required to maintain in-person delivery capability through December 31, 2029.
  - Addition of coverage for on-demand (asynchronous), online delivery of MDPP to increase access and program participation among suppliers and beneficiaries.
  - Weight documentation flexibilities.

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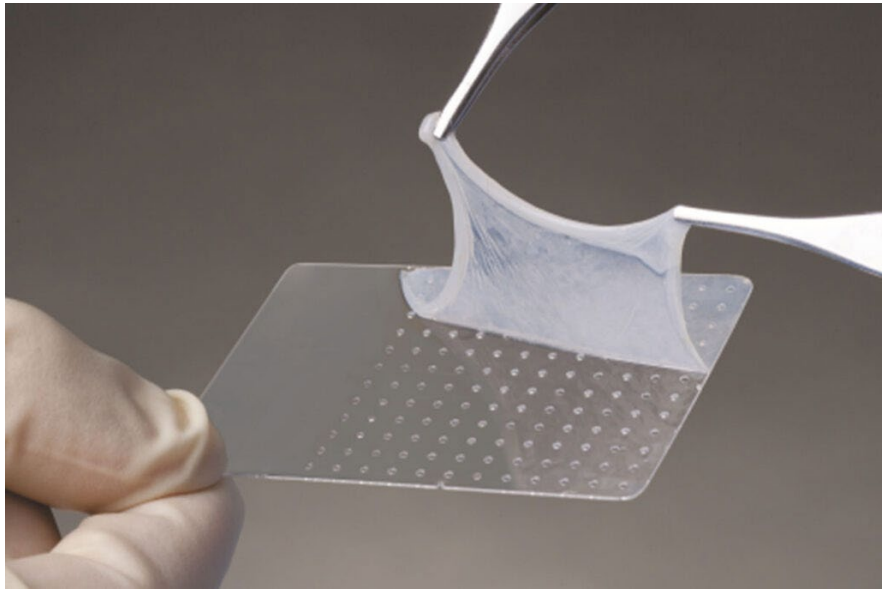
Payment of Skin Substitutes

- A skin substitute?
- Background.
  - Medicare Part B spending on skin substitutes rose from $252 million in 2019 to over $10 billion in 2024.



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Payment of Skin Substitutes Cont.

- Current Payment Structure.
  - Under the existing model all skin substitutes are paid under Medicare Part B as biologics, using the average sales price (**ASP**) + 6% methodology, with each product separately coded and priced.
    - **ASP**: calculated by Part B drug manufacturers as a volume-weighted average of their sales prices of Part B-covered biological products to all customers in the U.S.
    - CMS then uses this information to set payment limits, typically at ASP + 6%.
- New Payment Structure.
  - Medicare will reimburse for skin substitutes based upon a substitute's specific regulatory classification.

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Payment of Skin Substitutes Cont.

- Going forward.
  - **Biological products** licensed under Section 351 of the Public Health Service (PHS) Act will continue to be reimbursed under traditional ASP methodology.
  - **All other skin substitute products** will be reimbursed as “incident to” supplies under the physician fee schedule and subject to a flat payment rate of $127.28/cm^2.
    - Includes: devices subject to premarket approval (PMA); devices subject to 510(k) clearance; human cells, tissues, and cellular and tissue-based products regulated by Section 361 of PHS Act.
    - CMS will continue to offer separate reimbursement for the application service and the product. The amount above covers the product's payment.

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The One Big Beautiful Bill Act & Medicaid

- Background.
- Specific Changes.
  - Work requirement: 80hrs/per month to maintain eligibility.
  - State provider taxes.
  - More frequent eligibility checks.
  - Copayments (New).

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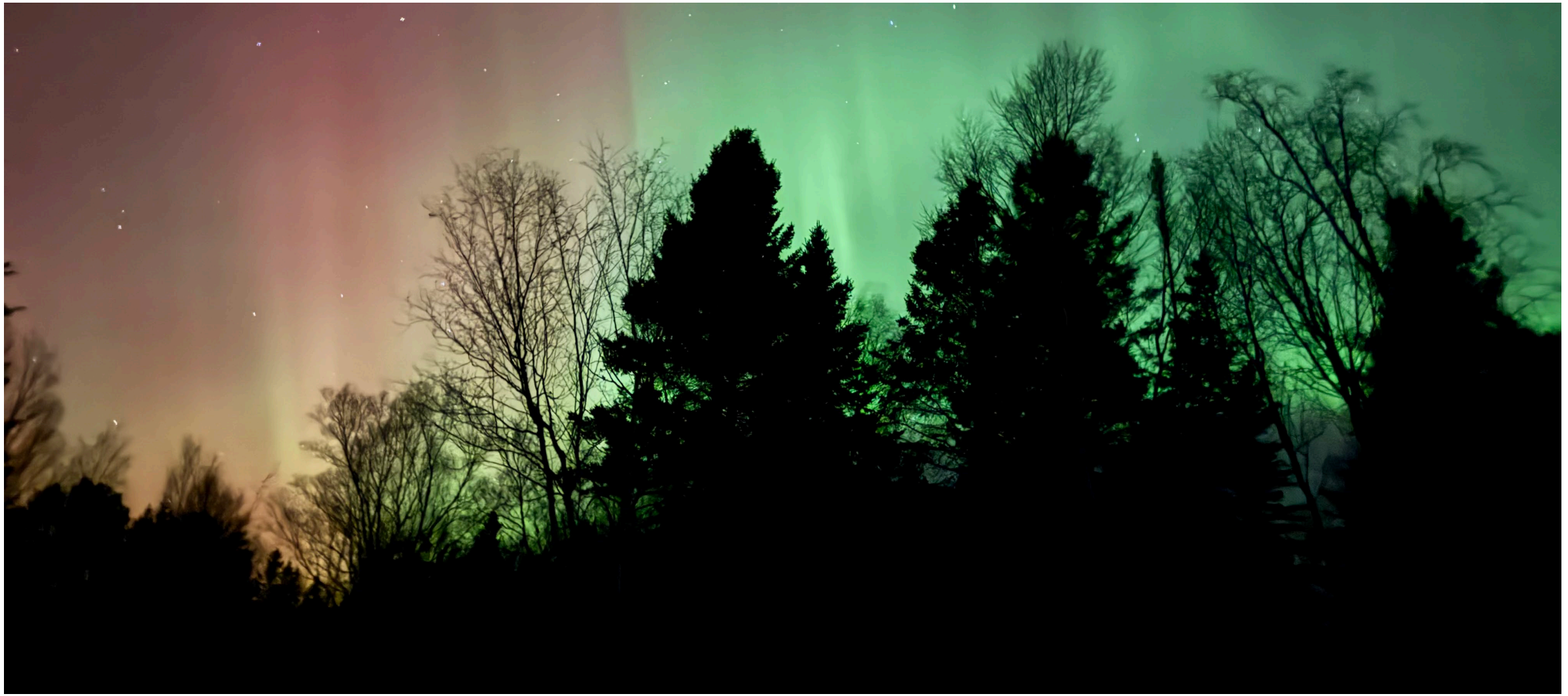

Fredrikson

Presenters

Amy Anderson
Attorney
612.492.7327
amyanderson@fredlaw.com

David Glaser
Attorney
612.492.7143
dglaser@fredlaw.com

Sean Nagle
Attorney
612.492.7386
snagle@fredlaw.com

Ethan Wold
Attorney
612.492.7375
ecwold@fredlaw.com

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