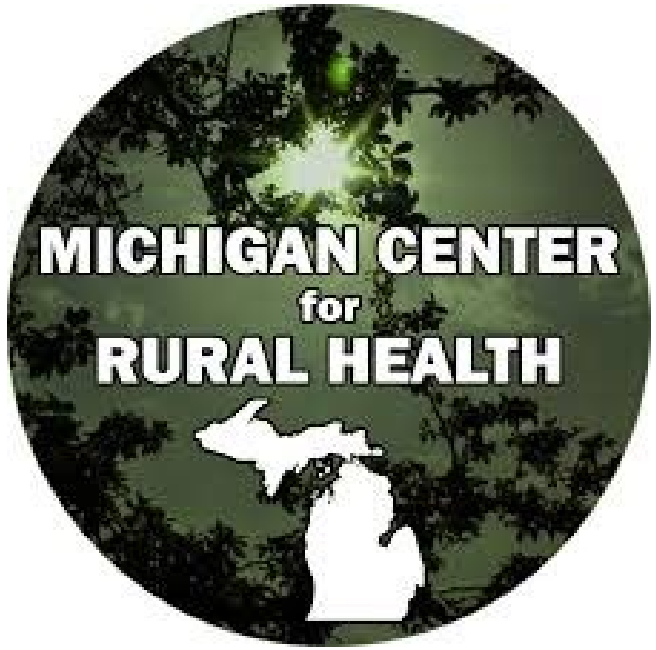
Michigan Rural Health Conference

Health Law Updates

April 24, 2025



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ADVISORY SERVICES

Agenda

Michigan Updates

- Earned Sick Time Act
- Recent Michigan House Bills

Federal Updates

- Telehealth – Medicare Waivers and DEA Rules
- Executive Order 14273
- CMS Request for Information
- 2025 Non-Monetary Compensation (Stark Law)

Michigan Updates

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Earned Sick Time Act (ESTA)

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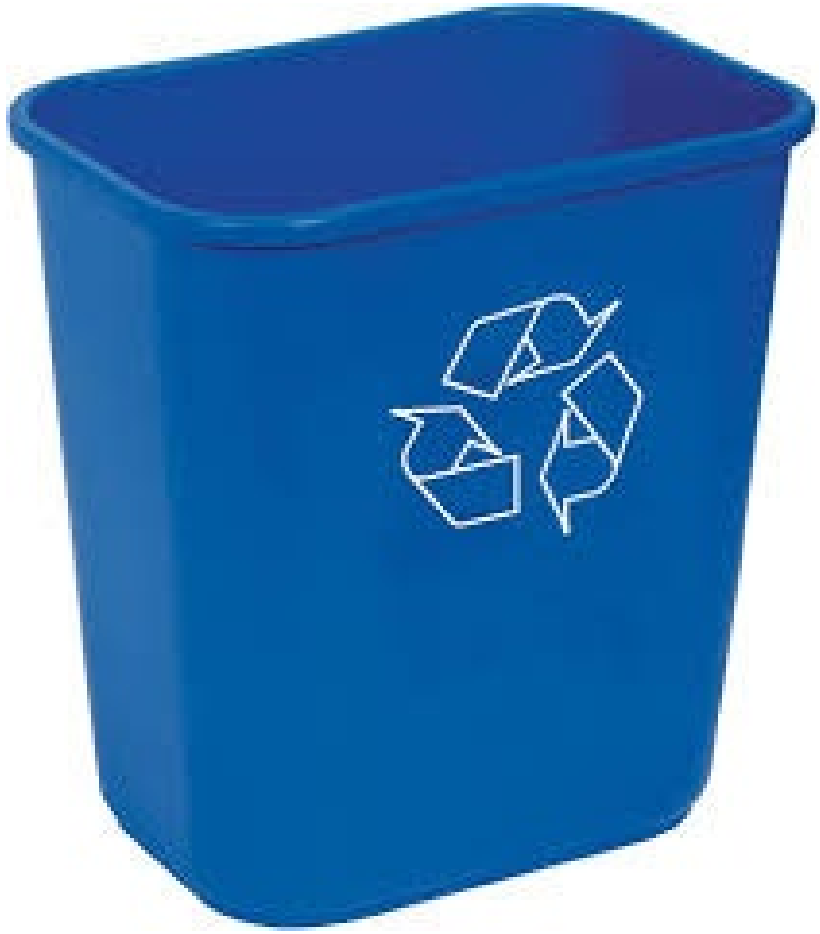
ESTA Background

Michigan's Earned Sick Time Act (ESTA) was set to take effect on February 21, 2025.

However, late on February 20, 2025, the Michigan Legislature passed House Bill 4002 to amend the ESTA.

Governor Whitmer signed the amendment into law on February 21, 2025, and it went into immediate effect.

Summaries Prior to February 21, 2025…



Amendments to ESTA

Employees who are exempted from the amended ESTA are:

- (i) individuals employed by the federal government;
- (ii) individuals who work under a policy that allows the individual to schedule their own working hours and prohibits the employer from taking adverse employment action if the individual does not schedule a minimum number of hours;
- (iii) unpaid trainees or interns; and
- (iv) individuals employed under Michigan's Youth Employment Standards Training Act.

Small businesses are defined as those who employ 10 or fewer individuals on their payroll for 20 or more calendar workweeks either in the current or immediately preceding calendar year.

- There is a delayed implementation date of October 1, 2025, for small businesses to comply with the requirements of the amended ESTA.

Amendments to ESTA

All eligible employees must accrue one hour of paid sick leave for every 30 hours worked.

Employers can cap employees' use of paid sick leave to 72 hours (or 40 hours for small businesses) annually.

Alternatively, employers may frontload 72 hours of paid sick leave (or 40 hours for small businesses). If paid sick leave is frontloaded, employers will not be required to track and calculate their employees' accrual of paid sick leave.

An employer's paid leave policy may be used to comply with the requirements of the amended ESTA as long as it provides at least the same amount of time as provided under the amended ESTA and may be used for the same purposes under the amended ESTA.

Amendments to ESTA

Paid sick leave must be paid at a pay rate equal to the greater of either an employee's hourly wage or base wage.

An employer is not required to include overtime pay, holiday pay, bonuses, commissions, supplemental pay, piece rate pay, tips or gratuities in the calculation of an employee's hourly wage or base wage.

Amendments to ESTA

An employer may require employees to provide up to 7 days of advance notice for foreseeable uses of earned sick time.

For unforeseeable absences, employees must provide notice: (i) “as soon as practicable;” or (ii) in accordance with the employer’s policy on using sick time, if (a) the employer notifies the employee of their policy after February 21, 2025, and (b) the policy allows employees to provide notice after the employee is aware of the need to use sick leave.

Reasonable documentation may be required for absences of more than 3 consecutive days. The employee must provide this documentation within 15 days after the employer’s request.

Amendments to ESTA

As of March 23, 2025, employers must have notified their employees of their policy, which must include:

(i) the amount of paid leave available;

(ii) how the benefit year is calculated;

(iii) the terms under which paid sick leave may be used; and

(iv) a prohibition against retaliation for an employee's request or use of paid sick leave.

Employees no longer have the right to file a private lawsuit against an employer for violations of the ESTA.

Instead, employees who believe that a violation has occurred may file a complaint with the Department of Labor and Economic Opportunity.

House Bills 4131 & 4579

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HBs 4131 & 4579

- Both Bills modify MCL 500.3476
- Sec. 3476. (1) An insurer that delivers, issues for delivery, or renews in this state a health insurance policy shall not require face-to-face contact between a health care professional and a patient for services appropriately provided through telemedicine, as determined by the insurer. An insurer described in this subsection shall not require a health care professional to provide services for a patient through telemedicine unless the services are contractually required per the terms of a contract between the insurer and an affiliated provider or a third-party vendor for telemedicine first or telemedicine-only products, and clinically appropriate as determined by the health care professional. Telemedicine services must be provided by a health care professional who is licensed, registered, or otherwise authorized to engage in the health care professional's health care profession in the state where the patient is located. Telemedicine services are subject to all terms and conditions of the health insurance policy agreed on between the policy holder and the insurer, including, but not limited to, required copayments, coinsurances, deductibles, and approved amounts. If a service is provided through telemedicine under this section, the insurer shall provide at least the same coverage for that service as if the service involved face-to-face contact between the health care professional and the patient.

House Bill 4580

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HB 4580

(9) The medical assistance program and Healthy Michigan program shall not do any of the following:

(a) Impose quantity or dollar amount maximums or limitations for services delivered using telemedicine that are more restrictive than those imposed on comparable in-person services.

(b) Reimburse distant providers for telemedicine services at a lower rate than comparable services rendered in person, except when reimbursing a provider who exclusively provides telemedicine services.

(c) Impose specific requirements or limitations on the technologies used to deliver telemedicine services, unless necessary to ensure the safety of a recipient, and the technology is compliant with requirements of the health insurance portability and accountability act of 1996, Public Law 104-191.

(d) Impose additional certification, location, or training requirements on health care professionals who are distant providers as a condition of reimbursing the distant provider for telemedicine services.

(e) Require a recipient to use telemedicine services in lieu of in-person consultation or contact.

Federal Updates

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Telehealth – Medicare Waivers and DEA Rules

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Background

On March 15, the President signed the **Full-Year Continuing Appropriations and Extensions Act, 2025** (Continuing Resolution) to fund the federal government through September 30.

The Continuing Resolution extends several key virtual care payment policies just weeks before the pandemic-era telehealth flexibilities were set to expire.

Background

On March 20, the Drug Enforcement Administration (DEA) and the U.S. Department of Health and Human Services (HHS) **announced** a delay in implementation of the **final rule** establishing special requirements for prescribing buprenorphine to treat Opioid Use Disorder (OUD) via telemedicine until December 31, 2025.

Continuing Resolution

- Under the Continuing Resolution, the following will continue to apply through September 30, 2025:
  - Medicare beneficiaries will be able to continue accessing telehealth services in any geographic area in the United States, rather than only in rural areas.
  - Medicare beneficiaries will be able to continue accessing virtual care from their homes for telehealth visits that Medicare pays for, rather than being required to travel to a health care facility.
  - Certain Medicare telehealth visits can continue to be delivered using audio-only technology (such as a telephone) if the patient is unable to use both audio and video, such as a smartphone or computer.

Acute Hospital Care at Home

The Acute Hospital Care at Home (“AHCAH”) program was also extended through September 30, 2025.

The AHCAH program was authorized by CMS to cover more than 60 conditions, including asthma, chronic obstructive pulmonary disease, pneumonia and other conditions that can be safely managed in the patient’s home during the PHE.

Buprenorphine Telemedicine Prescribing Final Rule - Delayed

Original effective date of the Final Rule was February 18, 2025.

The rule finalized a policy that would permit DEA-registered practitioners to use audio-only telemedicine interactions to prescribe up to a 6-month supply of buprenorphine to treat OUD, without having conducted an in-person medical evaluation.

However, consistent with the White House's **Regulatory Freeze Memorandum**, the Agencies subsequently delayed the Buprenorphine Prescribing Rule's effective date to March 21, 2025.

Buprenorphine Telemedicine Prescribing Final Rule - Delayed

Since the Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications permits practitioners to prescribe via telemedicine through December 31, 2025, the DEA and CMS have postponed the Rule's effective date again to align with the expiration of those flexibilities.

This means that DEA-registered practitioners will continue to be permitted to issue prescriptions for controlled medications (including prescriptions for buprenorphine) to patients for whom they have not conducted an in-person medical evaluation, provided:

The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of their professional practice;

The telemedicine communication is conducted using an audio-visual (or audio-only, in the case of buprenorphine prescriptions for OUD), real-time, two-way interactive communications system; and

The practitioner is acting in accordance with applicable federal and state law.

Practical Takeaways

The extension of the Medicare telehealth flexibilities and the delay of the Buprenorphine Prescribing Rule maintain the status quo.

Given the short-term nature of the extensions until the end of FY 2025, Congress will need to work in the 119th Congress to explore further extensions and/or more permanent legislation addressing telehealth.

It is critical that virtual care stakeholders continue to monitor legislative and regulatory efforts to address Medicare coverage and reimbursement for telehealth services, as well as the DEA's rules to address controlled substance prescriptions through telemedicine.

Executive Order 14273 (Lowering Drug Prices by Once Again Putting Americans First)

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Background

On April 15, 2025, President Trump signed an Executive Order titled "Lowering Drug Prices by Once Again Putting Americans First"

- Improving upon the Inflation Reduction Act
- Reducing the Prices of High-Cost Drugs for Seniors
- Appropriately Accounting for Acquisition Costs of Drugs in Medicare
- Promoting Innovation, Value, and Enhanced Oversight in Medicaid Drug Payment
- Access to Affordable Life-Saving Medications
- Reevaluating the Role of Middlemen
- Accelerating Competition for High-Cost Prescription Drugs
- Increasing Prescription Drug Importation to Lower Prices
- Reducing Costly Care for Seniors
- Improving Transparency into Pharmacy Benefit Manager Fee Disclosure
- Combating Anti-Competitive Behavior by Prescription Drug Manufacturers

Appropriately Accounting for Acquisition Costs of Drugs in Medicare (Section 5)

Within 180 days of the date of the Order (October 12, 2025):

- The Secretary of HHS must publish a plan to conduct a survey to determine the hospital acquisition cost for covered outpatient drugs at hospital outpatient departments.
- Following the conclusion of this survey, the Secretary shall consider and propose any appropriate adjustments that would align Medicare payment with the cost of acquisition, consistent with the budget neutrality requirements.

Sound Familiar?

Starting in 2018, HHS reduced the reimbursement rate for the 340B covered drugs from Average Sales Price (ASP) plus 6% to ASP minus 22.5% for 340B eligible hospitals.

Following HHS's decision, the American Hospital Association challenged the payment reduction, arguing that the Medicare statute did not authorize the payment reduction.

In 2022, the case ultimately went to the US Supreme Court, where the Court found CMS's payment policy in 2018 and 2019 unlawful.

Sound Familiar?

Following the decision, CMS made lump-sum payments to 340B hospitals related to the 2018 – 2022 and reverted to paying the default rate – ASP plus 6% – for the remainder of CY 2022 and reprocessed claims at that higher rate.

The basis for the Court's decision stemmed from a strict interpretation of the statutes created by Congress to set reimbursement rates for outpatient drugs. CMS had long used the second option based on the drugs' average price. The Court emphasized this option does not allow for any variation in this methodology.

The first option requires CMS to survey hospitals' average acquisition costs prior to making rate changes. Because no survey was conducted, CMS failed to follow the statute, and the payment cuts contradict the statute.

Access to Affordable Life-Saving Medications (Section 7)

- Within 90 days of the date of the Order (July 14, 2025), the Secretary must take action to ensure future grants available to “Health Centers” under section 330(e) of the Public Health Service Act are conditioned:
    - Upon Health Centers making insulin and injectable epinephrine available at or below pricing under the 340B Program (plus a minimal administration fee) to individuals with low incomes who:
        - have a high cost-sharing requirement for either insulin or injectable epinephrine;
        - have a high unmet deductible; or
        - have no healthcare insurance.

Sound Familiar?

In July 2020, President Trump issued an executive order which included similar 340B requirements

July 2020

Sep. 2021

In September 2021, the Biden administration rescinded the 340B rule before it took effect.

Reducing Costly Care for Seniors (Section 11)

- Within 180 days of the date of the Order (October 12, 2025), the Secretary shall:
  - Evaluate and (if appropriate) propose regulations to:
    - Ensure that payment within the Medicare program is not encouraging a shift in drug administration volume away from “less costly” physician office settings to “more expensive” hospital outpatient departments.

Executive Order 14192 - CMS Request for Information

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Background

On January 31, 2025, President Trump issued Executive Order (EO) 14192 "Unleashing Prosperity Through Deregulation," which stated the Administration policy to “significantly reduce the private expenditures required to comply with Federal regulations to secure America’s economic prosperity and national security and the highest possible quality of life for each citizen.”

EO 14192 requires agencies publicly promulgating new regulations or proposing regulations for notice and comment, to identify at least 10 existing regulations to be repealed.

This builds on EO 13771, which set forth that agencies must eliminate two regulations for each one new regulation issued.

Background

On April 11, 2025, CMS issued a Request for Information (RFI) to solicit public feedback on potential changes to Medicare regulations.

The stated purpose of the RFI is for CMS to seek “public input on approaches and opportunities to streamline regulations and reduce administrative burdens on providers, suppliers, beneficiaries, Medicare Advantage and Part D plans, and other stakeholders participating in the Medicare program.”

Purpose

CMS identified that healthcare providers serving Medicare beneficiaries face numerous regulatory requirements that…

> "while intended to protect the health and safety of the beneficiaries, often result in duplicative efforts and unnecessary administrative burdens. These requirements can divert resources from patient care, contribute to inefficiencies, and can create financial strain on providers."

- CMS then included the following as examples of standards which "are intended to improve quality and protect the health and safety of beneficiaries, but which also create redundancy with existing state requirements or have no measurable impact on improving the quality of patient care":
  - Conditions of Participation (CoPs)
  - Conditions of Coverage (CFC)

Background

CMS also stated that reporting and documentation requirements for quality, value-based purchasing programs, and payment policies can necessitate significant additional administrative resources from providers and duplicate private insurance requirements.

CMS is seeking specific information from healthcare providers, researchers, stakeholders, health and drug plans, and other members of the public to inform the development and implementation of strategies to support the goals of the Executive Order.

RFI – Survey

Streamline Regulatory Requirements

- Are there existing regulatory requirements (including those issued through regulations but also rules, memoranda, administrative orders, guidance documents, or policy statements), that could be waived, modified, or streamlined to reduce administrative burdens without compromising patient safety or the integrity of the Medicare program?
- Which specific Medicare administrative processes or quality and data reporting requirements create the most significant burdens for providers?
- Are there specific Medicare administrative processes, quality, or data reporting requirements, that could be automated or simplified to reduce the administrative burden on facilities and providers?

RFI – Survey

Opportunities to Reduce Administrative Burden of Reporting and Documentation

- What changes can be made to simplify Medicare reporting and documentation requirements without affecting program integrity?
- Are there opportunities to reduce the frequency or complexity of reporting for Medicare providers?
- Are there documentation or reporting requirements within the Medicare program that are overly complex or redundant? If so, which ones? Please provide the specific Office of Management and Budget (OMB) Control Number or CMS form number.

RFI – Survey

Identification of Duplicative Requirements

- Which specific Medicare requirements or processes do you consider duplicative, either within the program itself, or with other healthcare programs (including Medicaid, private insurance, and state or local requirements)?
- How can cross-agency collaboration be enhanced to reduce duplicative efforts in auditing, reporting, or compliance monitoring?
- How can Medicare better align its requirements with best practices and industry standards without imposing additional regulatory requirements, particularly in areas such as telemedicine, transparency, digital health, and integrated care systems?

Additional Recommendations

2025 Non-Monetary Compensation to Physicians

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Background

The federal Stark Law provides that if an entity has a financial relationship with a physician, the physician may not refer to the entity for the provision of "designated health services" (e.g., inpatient and outpatient hospital services, imaging, laboratory, radiation therapy, physical and occupational therapy, etc.), and the entity may not bill for such services **unless an exception is met**.

A "financial relationship" under the Stark Law is construed broadly to mean all remuneration from an entity to a physician, including in-kind compensation.

Background

Pursuant to the Stark Law regulations at **42 C.F.R. § 411.357**, there are exceptions for non-monetary compensation.

Generally, the non-monetary compensation exception may be used to protect items or services provided to a physician such as entertainment, meals, certain CME and other non-cash equivalent benefits.

Additionally, the medical staff incidental benefit exception can be used to cover meals, parking and other incidentals provided by a hospital to a member of the medical staff while “on campus.”

Background

In calendar year 2025 entities may provide non-monetary compensation to physicians up to an aggregate amount of $519.

The dollar limit for “medical staff incidental benefits” provided by a hospital to a member of its medical staff is less than $45 per occurrence.

Other requirements of the Stark Law exceptions for non-monetary compensation and medical staff incidental benefits also need to be met.

Non-Monetary Compensation

Compensation from an entity in the form of items or services (not including cash or cash equivalents such as gift cards) that does not exceed an aggregate of $519 per year, if all of the following conditions are satisfied:

The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.

The compensation may not be solicited by the physician or the physician's practice (including employees and staff members).

Non-Monetary Compensation

Where an entity has inadvertently provided non-monetary compensation to a physician in excess of the $519 limit, such compensation will be deemed within the $519 limit if the value of the excess non-monetary compensation is no more than 50% of the $519 limit and the physician returns to the entity the excess non-monetary compensation (or an amount equal to the value of the excess non-monetary compensation).

The return must be made by the *earlier of* the end of the calendar year in which the excess non-monetary compensation was received or within 180 consecutive calendar days following the date the excess non-monetary compensation was received by the physician.

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This “return” option may be used by an entity only once every three years with respect to the same referring physician.

Medical Staff Incidental Benefits

Compensation in the form of items or services (not including cash or cash equivalents) from a hospital to a member of the medical staff when the item or service is used on the hospital's campus, if all of the following conditions are met:

1. The compensation is offered to all members of the medical staff practicing in the same specialty (but not necessarily accepted by every member to whom it is offered) without regard to the volume or value of referrals or other business generated between the parties.
2. Except with respect to the identification of medical staff on a hospital website or in hospital advertising, the compensation is provided only during periods when the medical staff members are making rounds or are engaged in other services or activities that benefit the hospital or its patients.
3. The compensation is provided by the hospital and used by the medical staff members only on the hospital's campus.
4. Compensation, including, but not limited to, internet access, pagers or two-way radios, used away from campus only to access hospital records or information or to access patients or personnel who are on the hospital campus, as well as the identification of the medical staff on a hospital website or in hospital advertising, meets this "on campus" requirement.

Medical Staff Incidental Benefits

The compensation is reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services to the hospital.

The compensation is of low value (that is, less than $45) with respect to each occurrence of the benefit (e.g., each meal given to a physician while he or she is serving patients who are hospitalized must be of low value).

The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

Other facilities and health care clinics (including, but not limited to, federally qualified health centers) that have bona fide medical staff may provide compensation under this exception on the same terms and conditions applied to hospitals.

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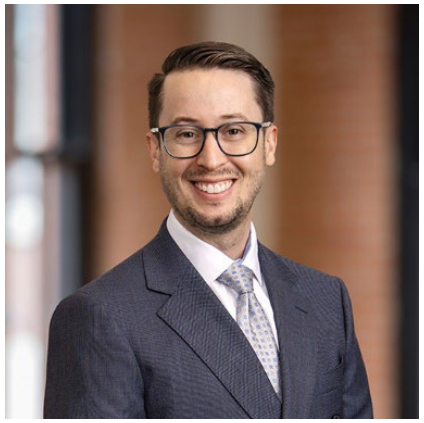
Presenter



Andrew Heberling

Attorney

aheberling@hallrender.com

(248) 457-7807

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Questions?

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