2022 Michigan Center for Rural Health

Health Law Updates

HALL RENDER
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Agenda

- Article 1, Section 28, Right To Reproductive Freedom
- MSSP Updates and Changes
- Update: New Rural Emergency Hospital
- Increased Enforcement and Oversight to Combat Telemedicine Fraud

Right To Reproductive Freedom

Right To Reproductive Freedom

- *"Every individual has a fundamental right to reproductive freedom, which entails the right to make and effectuate decisions about all matters relating to pregnancy, including but not limited to prenatal care, childbirth, postpartum care, contraception, sterilization, abortion care, miscarriage management, and infertility care"*

  - Use of the term "individual" means that the proclaimed right to reproductive freedom would apply to any person, regardless of age

Right To Reproductive Freedom

- Michigan law currently requires minors to obtain parental consent before obtaining abortions, except where a judge decides that such consent is not required
- The text expressly addresses contraception, sterilization and infertility care, which could (would?) include vasectomies, hysterectomies, medications and gender affirmation surgeries

Right To Reproductive Freedom

- *"Unless justified by a compelling state interest achieved by the least restrictive means"*
  - This standard is met *"only if it is for the limited purpose of protecting the health of an individual seeking care, consistent with accepted clinical standards… and does not infringe on that individual's autonomous decision-making."*
  - Unlike other sections of the proposal, this prohibition does not expressly prohibit "the state" from certain actions. Whether this prohibition on burdening the proclaimed right would apply to non-state actors (for example, health systems that are unwilling to participate in abortions or sterilizations) is unclear
  - However, no state law could burden an individual's "right to make and effectuate decisions about all matters relating to pregnancy" unless that law met that threshold

Right To Reproductive Freedom

- *“Unless justified by a compelling state interest achieved by the least restrictive means”*
  - The restrictive definition of “compelling state interest” means that the health of the individual seeking care is the only interest that lawmakers could seek to protect in making laws that may burden the proclaimed right

Right To Reproductive Freedom

- Allow the regulation of *"the provision of abortion care after fetal viability"* which is determined by *"the professional judgment of an attending health care professional and based on the particular facts of the case,"* and further requires the fetus to be able to survive *"outside the uterus without the application of extraordinary medical measures."*
  - This means that pre-viability laws would not be permitted
  - This would also presumably prevent anyone other than the pregnant individual's doctor from determining fetal viability with respect to any particular pregnancy
  - What would constitute *"extraordinary medical measures?"*

Right To Reproductive Freedom

- Not allow abortion bans if *"in the professional judgment of an attending health care professional, [the abortion] is medically indicated to protect the life or physical or mental health of the pregnant individual"*
    - This appears to mean that in the event of any ban on abortions, a pregnant individual's doctor could prevent the abortion ban from applying due to concerns about the pregnant individual's life or physical or mental health

Right To Reproductive Freedom

- Prohibits the state from penalizing, prosecuting or taking "adverse action against someone for aiding or assisting a pregnant individual in exercising their right to reproductive freedom with their voluntary consent."
  - This appears to mean that nobody – whether or not they are a health care provider – could be prosecuted for helping a pregnant individual with the proclaimed right of reproductive freedom (e.g., prenatal care, childbirth, postpartum care, contraception, sterilization, abortion care, miscarriage management and infertility care) with the individual's consent
    - Assisting a minor to obtain an abortion
    - Impact on malpractice claims?
- Invalidates Michigan's 1930s law criminalizing abortions

MSSP Updates and Changes

MSSP Updates and Changes

- CMS made changes to the MSSP to address three concerns:
  - growth in the number of beneficiaries assigned to ACOs has plateaued,
  - higher spending populations are increasingly underrepresented in the program since the change to regionally adjusted benchmarks, and
  - access to ACOs appears inequitable as shown by data indicating that Black (or African American), Hispanic, Asian/Pacific Islander, and American Indian/Alaska Native beneficiaries are less likely to be assigned to a Shared Savings Program ACO

MSSP Updates and Changes

- One change is to provide advance shared savings payments in the form of advance investment payments (AIPs) to certain new, low revenue ACOs that can be used to support their participation in the Shared Savings Program; provide greater flexibility in the progression to performance-based risk
    - The ACO is not a renewing ACO or re-entering ACO (50 percent of its ACO participants were included on the ACO participant list of the same ACO in any of the 5 most recent performance years)
    - The ACO has applied to participate in the Shared Savings Program under any level of the BASIC track glide path and is eligible to participate in the Shared Savings Program,
    - The ACO is inexperienced with performance-based risk Medicare ACO initiatives
    - The ACO is a low revenue ACO (an ACO whose total Medicare Parts A and B FFS revenue of its ACO participants is less than 35 percent of the total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries)

MSSP Updates and Changes

- One change is to provide advance shared savings payments in the form of advance investment payments (AIPs) to certain new, low revenue ACOs that can be used to support their participation in the Shared Savings Program; provide greater flexibility in the progression to performance-based risk
    - The ACO must submit, as part of its application to participate in the Shared Savings Program, a supplemental application information in the form and manner and by a deadline specified by CMS
    - ACO would be required to submit a spend plan as part of its application for AIPs
        - identify how the ACO will spend the AIPs to build care coordination capabilities (including coordination with community-based organizations) and address specific health disparities
        - identify the categories of goods and services that will be purchased, the dollar amounts to be spent on the various categories, and such other information as may be specified by CMS
        - spend plan must include a statement that the ACO has established a separate designated account spend plan must include a statement that the ACO has established a separate designated account

MSSP Updates and Changes

- One change is to provide advance shared savings payments in the form of advance investment payments (AIPs) to certain new, low revenue ACOs that can be used to support their participation in the Shared Savings Program; provide greater flexibility in the progression to performance-based risk
    - CMS may review the spend plan at any time and require the ACO to make changes to its spend plan
    - ACO must publicly report its spend plan as a part of its public reporting requirements
    - Upfront payment of $250,000
    - Quarterly payments based on attribution certain risk factors (i.e.: dual eligible)
    - Capped at 10,000 beneficiaries

MSSP Updates and Changes

- Another change is to establish a health equity adjustment to an ACO's Merit-based Incentive Payment System (MIPS) quality performance category score used to determine shared savings and losses to recognize high quality performance by ACOs serving a higher proportion of underserved populations
- Also, CMS is a sliding scale reflecting an ACO's quality performance for use in determining shared savings for ACOs, and revise the approach for determining shared losses for ENHANCED track ACO
- Also, CMS is modifying the benchmarking methodology to strengthen financial incentives for long term participation by reducing the impact of ACOs' performance and market penetration on their benchmarks, and to support the business case for ACOs serving high risk and high dually eligible populations to participate

MSSP Updates and Changes

- Also, CMS is expanding opportunities for certain low revenue ACOs participating in the BASIC track to share in savings, and
- CMS is also permitting ACOs up to 7 years of upside only participation (instead of the current 2 years)

RURAL EMERGENCY HOSPITALS

New Rural Emergency Hospital Designation

- New REH designation created by Consolidated Appropriations Act, 2021
- Goal is to maintain access to emergency care services in rural areas
- Eligible hospitals
  - CAHs or Rural PPS Hospitals with 50 or fewer beds
  - In existence as of 12/27/20 (not available for closed or new hospitals)

New Rural Emergency Hospital Designation (cont'd)

- Services
  - No inpatient services
  - Average patient length of stay under 24 hours
  - Emergency (CAH equivalent standards) and observation services
  - Other medical and health services on outpatient basis as specified by HHS
- Must meet other requirements: state law, staffing, transfer agreement with Level I or II trauma center

New Rural Emergency Hospital Designation (cont'd)

- Application: In order to transition to become an REH, an existing hospital must "an action plan for initiating rural emergency hospital services"
- One of the most important REH enrollment provisions being finalized in the final rule is that the facility may submit a Form CMS-855A, change of information application (rather than an initial enrollment application), in order to convert from a CAH to an REH

New Rural Emergency Hospital Designation (cont'd)

- Requirements: An REH must:
  - Have a transfer agreement in place with a Level I or II trauma center; and
  - Maintain a staffed emergency department, including staffing 24 hours a day, seven days a week by a physician, nurse practitioner, clinical nurse specialist, or physician assistant; and
  - Meet CAH-equivalent Conditions of Participation (CoPs) for emergency services; and
  - Meet applicable state licensing requirements; and

New Rural Emergency Hospital Designation (cont'd)

- Requirements (cont'd)
  - Meet quality reporting standards established by the HHS Secretary
    - The standards for REHs closely align with the current CAH CoPs in most cases, while accounting for the uniqueness of REHs and statutory requirements
    - REH policies also closely align to the current hospital and ambulatory surgical center standards, such as the polices for outpatient service requirements and the life safety code (LSC), respectively
  - Meet requirements applicable to skilled nursing facilities in the case where the REH includes a distinct part unit; and

New Rural Emergency Hospital Designation (cont'd)

- Payment and 340B
  - OPPS: 105% of APC rate
  - Monthly facility payment (based on average CAH benefit in 2019 over PPS)
  - Increased each year by hospital market basket percent
  - SNF: PPS rates but no cost-based swing bed reimbursement
  - MPFS: no Method II
  - No 340B eligibility

New Rural Emergency Hospital Designation (cont'd)

- By statute, REHs can provide emergency, observation, telehealth and RHC services. Other outpatient services may be provided as designated by CMS.
- REHs are limited to a 24-hour average length of stay.
  - the time calculation begins with the registration, check-in, or triage of the patient and ends with the discharge of the patient from the REH (which occurs when the physician or other appropriate clinician has signed the discharge order or at the time the outpatient service is completed and documented in the medical record)

REH Advantages	REH Disadvantages
Receive monthly REH facility payment.	While there will be some expense reduction from closing inpatient services, not all expenses that support inpatient operations will be eliminated.
Can maintain SNF units.	If converting from CAH, swing bed services no longer paid based on reasonable costs.
5% increase in OPPS/APC payments.	Cash would lose cost-based reimbursement for outpatient services. Rural Sole Community Hospitals would lose 7.1% OPPS add-on.
	Cannot reclassify for wage index (MGCRB)
	Cannot bill Method II for professional services.
	Appears that REHs will not qualify for 340B Program (drug discounts and contact pharmacy revenue).

Increased Enforcement and Oversight to Combat Telemedicine Fraud

Increased Enforcement and Oversight to Combat Telemedicine Fraud

- On September 2, 2022, the Office of the Inspector General ("OIG") published a study assessing potential Medicare program integrity risks related to the proliferation of telehealth services
  - OIG identified 1,714 providers with billing practices deemed "high risk"
  - These providers billed approximately 500,000 beneficiaries and received $127.7 million in Medicare fee-for-service payments

Increased Enforcement and Oversight to Combat Telemedicine Fraud

- OIG is recommending that CMS:
  - strengthen monitoring and targeted oversight of telehealth services
  - provide additional education to providers on appropriate billing for telehealth services
  - improve the transparency of "incident to" services when clinical staff primarily delivered the telehealth service
  - identify telehealth companies that bill Medicare
  - follow up on the providers identified in the report

Increased Enforcement and Oversight to Combat Telemedicine Fraud

- Among the allegations contained in court documents, the government alleged that telemedicine companies arranged for medical professionals to order expensive genetic tests and durable medical equipment regardless of patient need and sometimes without any patient interaction or with only a brief telephonic conversation
- The OIG has identified seven "suspect characteristics:"
  - The purported patients for whom the Practitioner orders or prescribes items or services were identified or recruited by the Telemedicine Company, telemarketing company, sales agent, recruiter, call center, health fair, and/or through internet, television, or social media advertising for free or low out-of-pocket cost items or services

Increased Enforcement and Oversight to Combat Telemedicine Fraud

- The OIG has identified seven "suspect characteristics:"
  - The Practitioner does not have sufficient contact with or information from the purported patient to meaningfully assess the medical necessity of the items or services ordered or prescribed
  - The Telemedicine Company compensates the Practitioner based on the volume of items or services ordered or prescribed, which may be characterized to the Practitioner as compensation based on the number of purported medical records that the Practitioner reviewed
  - The Telemedicine Company only furnishes items and services to Federal health care program beneficiaries and does not accept insurance from any other payor
  - The Telemedicine Company claims to only furnish items and services to individuals who are not Federal health care program beneficiaries but may in fact bill Federal health care programs

Increased Enforcement and Oversight to Combat Telemedicine Fraud

- The OIG has identified seven “suspect characteristics:”
  - The Telemedicine Company only furnishes one product or a single class of products (e.g., durable medical equipment, genetic testing, diabetic supplies, or various prescription creams), potentially restricting a Practitioner's treating options to a predetermined course of treatment
  - The Telemedicine Company does not expect Practitioners (or another Practitioner) to follow up with purported patients nor does it provide Practitioners with the information required to follow up with purported patients (e.g., the Telemedicine Company does not require Practitioners to discuss genetic testing results with each purported patient)

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