

MDH Updates for MNASCA

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Agenda

- CMS Mission and Priorities Document for 2026
- Survey Activities
- Process for New Ambulatory Surgical Centers
- Reporting Adverse Events



CMS Mission and Priorities

DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop C2-21-16



Center for Clinical Standards and Quality

Admin Info: 25-11-All

DATE: September 12, 2025

Baltimore, Maryland 21244-1850

TO: State Survey Agency Directors

FROM: Directors, Quality, Safety & Oversight Group (QSOG) and Survey & Operations

Group (SOG)

SUBJECT: Fiscal Year Mission & Priorities Document (MPD) - Transition to Web-Based

Updates

Memorandum Summary

The Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG) remain dedicated to ensuring the health and safety of all Americans. The Fiscal Year (FY) 2026 MPD reflects this dedication, along with our ongoing commitment to strengthen oversight, enhance enforcement, increase transparency, and improve quality of care.

The MPD structure includes three sections: (1) a spotlight on new policy or reinforcement of existing policy since the issuance of the previous FY MPD; (2) standing general information; and (3) a listing of the priority tier structure for survey & certification activities for all certified provider and supplier types.

This administrative memo represents the final communication of the MPD updates through this format. Beginning in FY 26, the MPD tier table and all accompanying documents will be updated and published directly on the CMS QSOG MPD website prior to the beginning of each fiscal year, or as necessary.

Background:

The MPD is an annual document that directs the work of QSOG, SOG, and State Survey Agencies (SAs) based on regulatory changes, adjustments in budget allocations, new initiatives, and new requirements based on statute. The MPD covers survey, certification, enforcement, and the Medicare funding allocation process for states. In addition, it provides background information for each of the certified provider and supplier types, accreditation and deeming surveys. Survey activities must be scheduled and conducted per the priority tier structure provided in the MPD. The four priority tiers reflect statutory mandates and program emphasis, with tier 1 being the highest priority and tier 4 being the lower priority.

2026 Mission and Priorities document

Fiscal Year (FY) 2026

Mission & Priorities

document (MPD) –

Action | CMS

Priority Tier Structure for Survey & Certification Activities for ASCs

TIER 1	TIER 2	TIER 3
Complaint Investigations prioritized as IJ for acute and continuing care (ACC) providers/suppliers (deemed and non-deemed). Full Surveys Pursuant to Complaints: Full surveys may be required by the CMS Location after each complaint investigation that finds condition level non-compliance for deemed providers/suppliers.	Targeted Surveys (25%): The state performs surveys totaling 25% of all non-deemed ASCs in the state (or at least 1, whichever is greater) focusing on ASCs not surveyed in more than 4 years or based on state judgment for those ASCs more at risk of quality problems. Some of the targeted surveys may qualify to count toward the tier 3 priority. Complaint investigations prioritized as Non-IJ high Initial certification Provider/Supplier with a CMS determined access to care issue (the provider is responsible for providing	6-Year Interval: Additional surveys are done to ensure that no more than six years elapse between surveys for any 1 non-deemed ASC. Initial certification: All others not listed under Tier 1 or 2 Note: Currently, we are doing Tier 1 and Tier 2 work. Initial Certifications that fall under Tier 3 may be done by an Accrediting Organization in lieu of the State Agency at this time.
10/09/2025	the information).	5



Survey Activities

Routine Survey Activity 2025

MDH had no ASC stand-alone complaint investigations in FY25.

Survey Activities 2025 cont.

MDH performed 14 recertification and licensure surveys FY25.

- 6 surveys had no deficiencies/licensing orders cited or issued.
- 7 surveys had citations related to:
 - Discharging patients with a responsible adult.
 - QAPI: LSC docs.
 - Posting of Rights/Information contained on posting (ex: Medicare Ombudsman).
 - Emergency preparedness: Shelter in place, Use of volunteers, Role Under the Secretary.
 - Patient rights: providing upon admission.

Survey Activity New ASC

The MDH completed 5 State Licensure Walkthroughs for NEW construction.

There are 3 PENDING new ASC facilities being built and/or waiting for clearances.



Reporting Adverse Events

Adverse Event Reporting 1/9

How many are aware of:

- 1) What Adverse Event Reporting is/what is required to be reported?
- 2) Where to report?
- 3) How long do you have to report?



Adverse Event Reporting 2/9

 Licensed Ambulatory Surgical Centers are required to report Adverse Health Events to the Patient Safety Registry at: <u>Minnesota Hospital Association</u> (https://my.mnhospitals.org).

■ MN. Stat. 144.7065 Facility Requirements to Report, Analyze, and Correct

 Each facility shall report the occurrence of any of the adverse health care events as soon as is reasonably and practically possible, but no later than 15 working days after discovery of the event.

Adverse Event Reporting 3/9

Surgical Events

- Surgery or other invasive procedure performed on a wrong body part that is not consistent with the
 documented informed consent for that patient. Reportable events under this clause do not include
 situations requiring prompt action that occur in the course of surgery or situations whose urgency precludes
 obtaining informed consent;
- Surgery or other invasive procedure performed on the wrong patient;
- The wrong surgical or other invasive procedure performed on a patient that is not consistent with the
 documented informed consent for that patient. Reportable events under this clause do not include
 situations requiring prompt action that occur in the course of surgery or situations whose urgency precludes
 obtaining informed consent;
- Retention of a foreign object in a patient after surgery or other invasive procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained; and
- Death during or immediately after surgery or other invasive procedure of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

Adverse Event Reporting 4/9

Product or Device Events

- Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the facility when the contamination is the result of generally detectable contaminants in drugs, devices, or biologics regardless of the source of the contamination or the product;
- Patient death or serious injury associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Device includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators; and
- Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

Adverse Event Reporting 5/9

Patient Protection Events

- A patient of any age, who does not have decision-making capacity, discharged to the wrong person;
- Patient death or serious injury associated with patient disappearance, excluding events involving adults who have decision-making capacity; and
- Patient suicide, attempted suicide resulting in serious injury, or self-harm resulting in serious injury or death while being cared for in a facility due to patient actions after admission to the facility, excluding deaths resulting from self-inflicted injuries that were the reason for admission to the facility.

Adverse Event Reporting 6/9

Care Management Events

- Patient death or serious injury associated with a medication error, including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose;
- Patient death or serious injury associated with unsafe administration of blood or blood products.
- Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within 42 days post- delivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy;
- Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy;
- Stage 3, 4 or unstageable ulcers acquired after admission to a facility, excluding progression from stage 2 to stage 3 if stage 2 was recognized upon admission;
- Artificial insemination with the wrong donor sperm or wrong egg;
- Patient death or serious injury associated with a fall while being cared for in a facility;
- The irretrievable loss of an irreplaceable biological specimen; and
- Patient death or serious injury resulting from the failure to follow up or communicate laboratory, pathology, or radiology test results.

Adverse Event Reporting 7/9

Environmental Events

- Patient death or serious injury associated with an electric shock while being cared for in a facility, excluding events involving planned treatments such as electric countershock;
- Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances;
- Patient death or serious injury associated with a burn incurred from any source while being cared for in a facility.
- Patient death or serious injury associated with the use of or lack of restraints or bedrails while being cared for in a facility.

Adverse Event Reporting 8/9

Potential Criminal Events

- Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider;
- Abduction of a patient of any age;
- Sexual assault on a patient within or on the grounds of a facility; and
- Death or serious injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.

Adverse Event Reporting 9/9

Radiologic Events

 Death or serious injury of a patient associated with the introduction of a metallic object into the MRI area.

Resources

MDH Fact Sheet - Adverse Health Events
Reporting Law: Minnesota's 29
Reportable Events (pdf)
(https://www.health.state.mn.us/facilities
/patientsafety/adverseevents/docs/adver
se29events.pdf)





Thank You!

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