MDH Updates for MNASCA

Nicole Osterloh | Federal Operations Supervisor & Lead ASC Supervisor

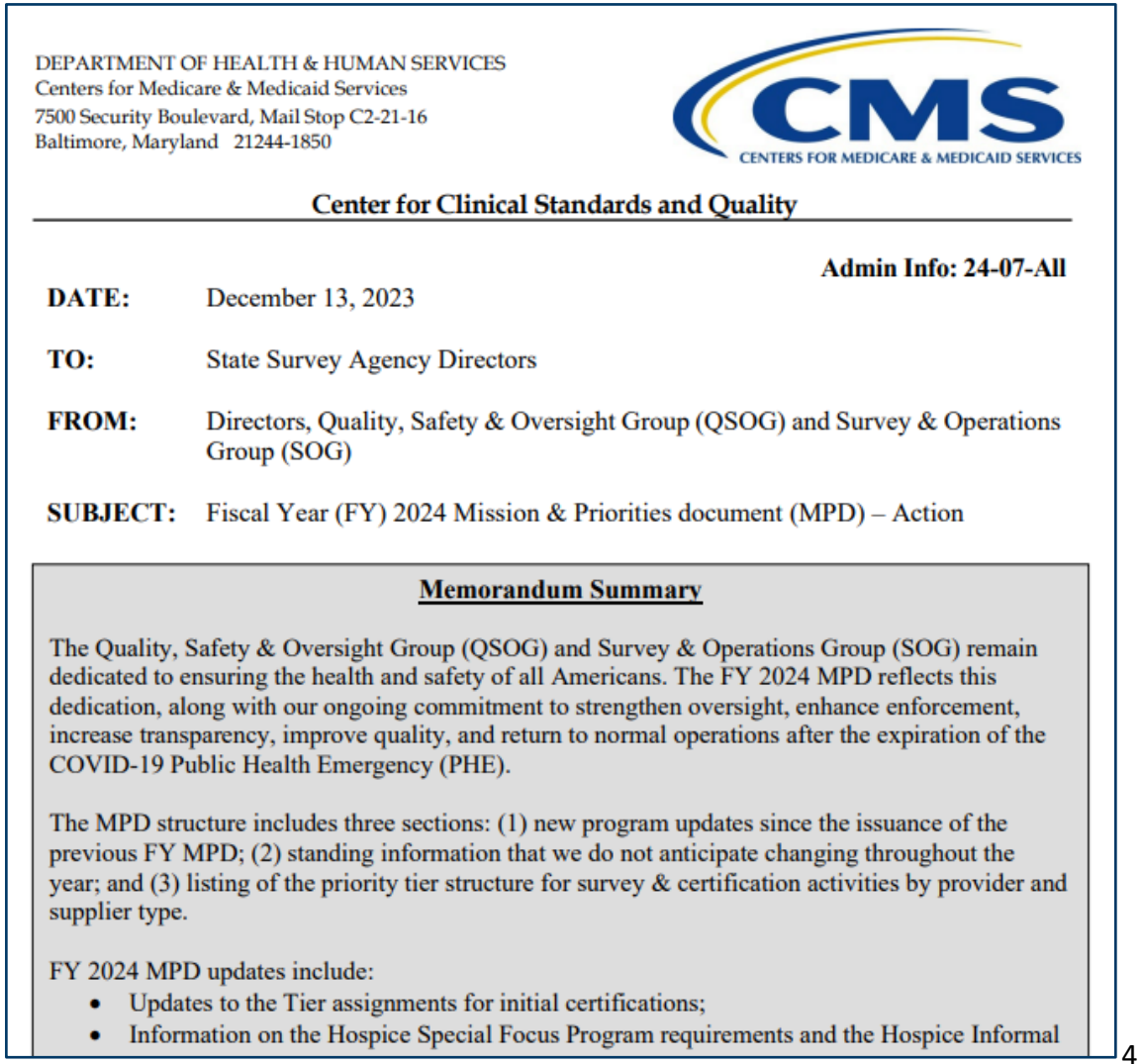
Agenda

- CMS Mission and Priorities Document for 2024
- Survey Activities
- Process for New Ambulatory Surgical Centers
- Reporting Adverse Events

CMS Mission and Priorities

2024 Mission and Priorities document

[Fiscal Year 2024 Mission & Priorities document - Action (pdf) (https://www.cms.gov/files/document/admin-info-24-07-all.pdf)]



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality

Admin Info: 24-07-All

DATE: December 13, 2023

TO: State Survey Agency Directors

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

SUBJECT: Fiscal Year (FY) 2024 Mission & Priorities document (MPD) – Action

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 FY 2024 MPD reflects this dedication, along with our ongoing commitment to strengthen oversight, enhance enforcement, increase transparency, improve quality, and return to normal operations after the expiration of the COVID-19 Public Health Emergency (PHE).

The MPD structure includes three sections: (1) new program updates since the issuance of the previous FY MPD; (2) standing information that we do not anticipate changing throughout the year; and (3) listing of the priority tier structure for survey & certification activities by provider and supplier type.

FY 2024 MPD updates include:

- Updates to the Tier assignments for initial certifications;
- Information on the Hospice Special Focus Program requirements and the Hospice Informal

Priority Tier Structure for Survey & Certification Activities for ASCs

TIER 1	TIER 2	TIER 3
Complaint Investigations prioritized as IJ – deemed ASC's: only with CMS Location authorization; survey to be initiated within two days of CMS Location authorization. **Initial certification:** Provider/Supplier with a CMS determined **access to care issue** (the provider is responsible for providing the information)	**Targeted Surveys (25%):** The state performs surveys totaling 25% of all non-deemed ASCs in the state (or at least 1) focusing on ASCs not surveyed in more than 4 years or based on state judgment for those ASCs more at risk of quality problems. **Complaint investigations prioritized as non-IJ high:** to be initiated within 45 days (for deemed ASCs, within 45 days of CMS Location authorization).	**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.

Priority Tier Structure for Survey & Certification Activities for ASCs cont.

TIER 1	TIER 2	TIER 3
	Initial certification - Provider/Supplier's application to Medicare exceeds 150 days with a deeming option: If more than 150 days has passed since the MAC has recommended approval of the application and a deeming option exists, then the initial certification would be a Tier 2 priority.	

2024 Mission and Priorities document cont.

NOTE: NON-DEEMED ASC are the same as above for Tier 1 work
(IJ complaints and initial certification for facilities identified with care issues).

They do not require prior authorization by the CMS RO.

Survey Activities

Survey Activity 2024

MDH has investigated 3 Immediate Jeopardy Complaints with ASC within the last year.

No deficiencies were cited.

Survey Activities 2024 cont.

MDH performed 6 recertification/licensure surveys FY24.

- 4 surveys had no deficiencies/licensing orders cited or issued.
- 2 surveys had citations related to:
  - Discharging patients with a responsible adult
  - Emergency preparedness:
    - 0004 Review of the EP plan (review and potentially revise every 2 years)
    - 0024 Use of Volunteers
    - 0037 Training on EP plan (initially upon hire and every 2 years thereafter)

Survey Activity x 1 year

The MDH completed 6 State Licensure Walkthroughs for NEW construction.

There are 6 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:

https://patientsafetyregistry.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.

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/adverse29events.pdf)]

Thank You!

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