



Indiana
Department
of
Health

Hospital Survey Protocols and Processes

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OUR MISSION:

**To promote, protect, and improve
the health and safety of all Hoosiers.**

OUR VISION:

**Every Hoosier reaches optimal health
regardless of where they live, learn,
work, or play.**



Agenda

Department Overview

- Who we are
- What we do
- Who we survey
- By the numbers

Survey Process

Complaint Intake and Survey Process

EMTALA

Trend information

Serious Reportable Events

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State Survey Agency Overview

- Approximately 220 survey staff
- An additional 50 support staff
- IDOH surveys hospitals, ambulatory surgery centers, birthing centers, nursing homes, residential care facilities, home health agencies, personal services agencies, ICF/IID facilities, hospice facilities, ESRD facilities, Rural Health Clinics, DCS residential care facilities, and more.
- IDOH also licenses the majority of these agency types and handle licensure actions
- We meet other legal obligations, such as the creation and maintenance of the Temporary Health Care Services Agency Registry.

State Survey Agency Overview

- IDOH conducts approximately 8,000+ surveys per year
- IDOH receives approximately 8,000 complaints a year
- IDOH receives an additional 20,000 facility reported incidents a year, reporting allegations of abuse, neglect, or misappropriation of the elderly
- All of these must be triaged by our Complaints Team and then are reviewed by a program supervisor

The Survey Process

Regulatory & Policy Reference

Regulatory and Policy Reference

- The Medicare Conditions of Participation for hospitals are found at 42 CFR Part 482.
- Survey authority and compliance regulations can be found at 42 CFR Part 488 Subpart A.
- Should an individual or entity (hospital) refuse to allow immediate access upon reasonable request to either a State Agency or CMS surveyor, the Office of the Inspector General (OIG) may exclude the hospital from participation in all Federal healthcare programs in accordance with 42 CFR § 1001.1301.
- The regulatory authority for the photocopying of records and information during the survey is found at 42 CFR 489.53(a)(13).

Regulatory and Policy Reference

- The CMS State Operations Manual (SOM) provides CMS policy regarding survey and certification activities.
- Although the survey generally occurs during daytime working hours (Monday through Friday), surveyors may conduct the survey at other times. This may include weekends and times outside of normal daytime (Monday through Friday) working hours.
- All hospital surveys (except for preoccupancy surveys) are unannounced. You will not receive advance notice of a survey.

State Operations Manual

Appendix A - Survey Protocol, Regulations, and Interpretive Guidelines for Hospitals

Task 1 - Off-Site Survey Preparation

Task 2 - Entrance Activities

Task 3 - Information Gathering/Investigation

Task 4 - Preliminary Decision Making and Analysis of Findings

Task 5 - Exit Conference

Task 6 – Post-Survey Activities

Psychiatric Hospital Survey Module

Psychiatric Unit Survey Module

Rehabilitation Hospital Survey Module

Inpatient Rehabilitation Unit Survey Module

Hospital Swing-Bed Survey Module

Task 1 - Off-Site Survey Preparation

1. General Objective
2. Off-Site Survey Preparation
3. Team Meeting

Task 2 - Entrance Activities

1. Arrival
2. Entrance Conference
3. Hospital Tours
4. Initial On-Site Team Meeting
5. Sample Size Selection

Task 3 - Information Gathering & Investigation

1. Survey Locations
2. During the Survey
3. Patient Review
4. Observations
5. Interviews
6. Document Review
7. Photocopies
8. Completion of Hospital/CAH Medicare Database Worksheet

Task 4 - Preliminary Decision Making and Analysis of Findings

1. General Objectives
2. Preparation
3. Discussion Meeting
4. Determining the Severity of Deficiencies
5. Gathering Additional Information

Task 5 - Exit Conference

1. General Objective
2. Prior to the Exit Conference
3. Discontinuation of an Exit Conference
4. Recording the Exit Conference
5. General Principles
6. Exit Conference Sequence
 - Introductory Remarks
 - Ground Rules
 - Presentation of Findings
 - Closure

Task 6 – Post-Survey Activities

General Objective

General Procedures

Plan of Correction

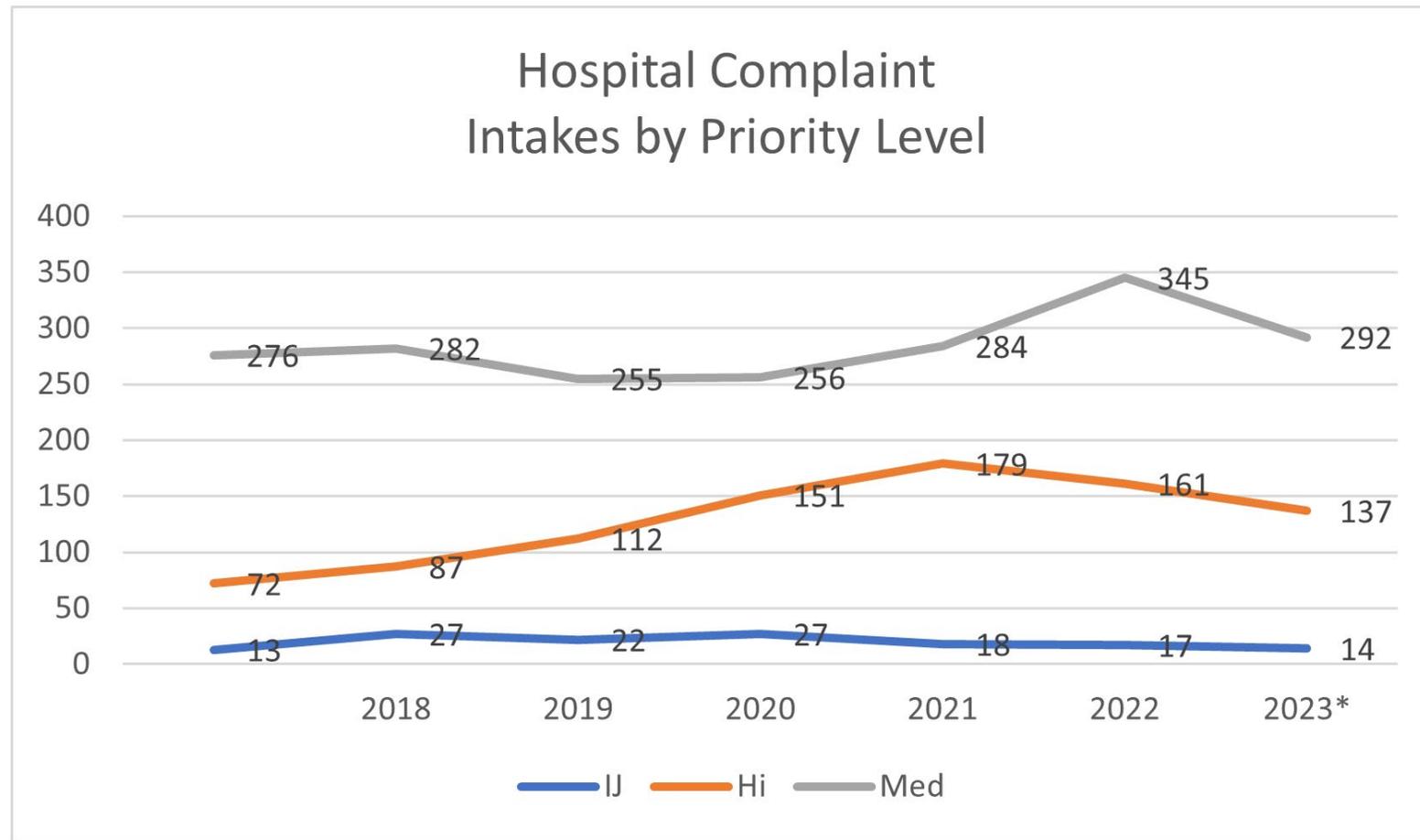
- 42 CFR 488.28(a) and §489.53(a)(1)

Patient Safety Work Product

Example of a Complaint

- Death in the hospital
- Policy Requires Root cause analysis
- Root cause analysis shows substantial problems
- We need to know if the policy was followed
- What were the recommended steps
- Were the steps converted to action

Complaints by Year and Priority



Complaint Intake and Survey Process

State Operations Manual

Chapter 5 - Complaint Procedures

5000 - Management of Complaints and Incidents

Purpose and Overview of the Complaint/Incident Process

5010 - General Intake Process

Information to Collect From Complainant

Information to Provide to Complainant

Notification to the RO

5075 - Priority Definitions

Immediate Jeopardy

- “A situation in which the provider’s noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.”

Non-Immediate Jeopardy - High Priority

- “[I]f the alleged noncompliance with the applicable Conditions of Participation, Coverage or Certification, or EMTALA requirements, if found to be true and uncorrected, would not represent an IJ, but would result in a determination of substantial noncompliance, i.e., at least one condition-level deficiency.”

Non-Immediate Jeopardy - Medium Priority

- “[I]f the alleged noncompliance with one or more standards within a Condition of Participation, Condition for Coverage or Condition for Certification is limited in manner and degree and/or caused, or may cause, harm that is of limited consequence and does not impair the individual’s mental, physical and/or psychosocial status or function.”

Non-Immediate Jeopardy – Low Priority

- “[I]f the alleged noncompliance with one or more standards within a Condition of Participation, Coverage or Certification may have caused physical, mental and/or psychosocial discomfort that does not constitute injury or damage. ”

5075.9 - Maximum Time Frames Related to the Federal Onsite Investigation of Complaints/Incidents

Provider Type	Intake Prioritization			
	Immediate Jeopardy (IJ)	Non-IJ High	Non-IJ Medium	Non-IJ Low
Nursing home complaints	SA must initiate an onsite survey within 3 business days of receipt of the initial report.	SA must initiate an onsite survey within an annual average of 15 business days of receipt of the initial report, not to exceed 18 business days.	SA must initiate an onsite survey within 45 calendar days of receipt of the initial report.	SA must track/trend for potential focus areas during the next onsite survey, or initiate a new complaint survey.
Nursing home incidents	With inadequate resident protection, SA must initiate an onsite survey within 3 business days of receipt of the initial report. With potentially adequate resident protection, SA must initiate an onsite survey within 7 business days of receipt of the initial report. See Section 5310.2A.	SA must initiate an onsite survey within an annual average of 15 business days of receipt of the initial report, not to exceed 18 business days.	With an inadequate facility response, SA must initiate an onsite survey within 45 calendar days of receipt of the initial report.	With a potentially adequate facility response, SA must track/trend for potential focus areas during the next onsite survey, or initiate a new complaint survey.
Non-deemed non-long term care providers/suppliers	SA must initiate an onsite survey within 2 business days of receipt.	SA must initiate an onsite survey within 45 calendar days of prioritization	SA must investigate no later than when the next onsite survey occurs	SA must track/trend for potential focus areas during the next onsite survey.
Deemed providers/suppliers	SA must initiate an onsite survey within 2 business days of receipt of RO authorization	SA must initiate an onsite survey within 45 calendar days of receipt of RO authorization.	Complainant is referred to the applicable accrediting organization(s)	Complainant is referred to the applicable accrediting organization(s)
EMTALA	SA must initiate an onsite survey within 2 business days of receipt of RO authorization.	SA must initiate an onsite survey within 45 calendar days of receipt of RO authorization	N/A	N/A
Death associated with restraint/seclusion-Hospitals	SA must initiate an onsite survey within 2 business days of receipt of RO authorization.	N/A	N/A	N/A
Fires resulting in serious injury or death	SA must initiate an onsite survey within 2 business days of receipt.	N/A	N/A	N/A

Complaint Survey Process

5078 – Pre-Survey Activities

5079 – Entrance Conference - Non-Long Term Care
Providers/Suppliers

5080 - Investigation Findings and Reports

5080.1 - Report to the Complainant

5080.2 - Survey Exit Conference and Report to the
Provider/Supplier

5100 - Investigation of Complaints for Deemed Providers/Suppliers

Basis for Investigation

Initial Response to Complainant

Post-Survey Procedures

Substantial Compliance

Condition-Level, IJ

Condition-Level, Non-IJ

Full Survey after Complaint Survey with Condition-level Deficiencies,
When Authorized by the RO

EMTALA

5400 - Investigations Involving Alleged Emergency Medical Treatment and Labor Act (EMTALA) Violations

5410 – EMTALA and Born-Alive Infants Protection Act of 2002

5420 - Basis for Investigation

5430 - RO Direction of Investigation

5440 - Conducting an Investigation

Selecting the Team

Scheduling the Investigation

Guidelines for Surveyors Conducting Investigations

Conducting the Investigation

Exit Conference

Forwarding Report of Investigation to the RO

5460 - RO Review of Investigation

Hospital Is In Compliance - Past Violation, No Termination

Hospital Is In Compliance - No Past Violation

Hospital Is Not in Compliance - Immediate Jeopardy to Patient Health and Safety

Hospital Is Not in Compliance - Situation Does Not Pose an Immediate Jeopardy to Patient Health and Safety

5465 - Procedures for the 5-day QIO Review of Alleged Violations of 42 CFR 489.24

5470 - Termination Procedures for EMTALA Violations

Procedures for Termination when the EMTALA Violation is an Immediate Jeopardy to Patient Health and Safety

Procedures for Termination When the EMTALA Violation is Not Immediate Jeopardy to Patient Health and Safety

Procedures for QIO Review of Confirmed EMTALA Violation

Procedures for Coordinating 60 day QIO Review

EMTALA Case Referral to OIG

Releasing QIO Assessment

Trend Information

5 Most Common Tags (Federal)

FY 2021			FY 2022			FY 2023		
Tag	Desc.	#	Tag	Desc.	#	Tag	Desc.	#
395	RN Supervision of Nursing Care	17	395	RN Supervision of Nursing Care	24	395	RN Supervision of Nursing Care	23
398	Supervision of Contract Staff	10	392	Staffing and Delivery of Care	11	392	Staffing and Delivery of Care	9
392	Staffing and Delivery of Care	9	144	Patient Rights: Care in Safe Setting	8	144	Patient Rights: Care in Safe Setting	8
700	Physical Environment	5	2400	Compliance with 489.24	7	115	Patient Rights	5
714	Fire Control Plans	5	398	Supervision of Contract Staff	6	145	Patient Rights: Free from abuse/harassment	4

SREs

- In the last legislative session, SREs reported to the Department were aligned with the National Quality Forum list of SREs instead of those in the Indiana Administrative Code
- There have been some common questions we can address

SREs – 7C, Sexual Abuse/Assault

Definition: 7C. *Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting*

Common Questions:

Q: What constitutes “sexual abuse/assault”

A: An act that would constitute a crime under Indiana Code §§ 35-42-4

Q: What if a person who committed the act doesn’t have the capacity to understand what they are doing? I.e., patient with severe dementia

A: For an act to be a crime, a person generally has to understand what they are doing – “be aware of a high probability that he is doing so.” If a person lacks capacity, a report generally does not need to be filed.

SREs – 7C, Sexual Abuse/Assault

Definition: 7C. *Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting*

Q: What if a person doesn't want to report the crime?

A: If hospital staff knows that a sexual assault has occurred, they should report it regardless if the victim of the act doesn't want to report it to law enforcement.

If hospital staff have no evidence that a sexual assault has occurred other than a person's allegation, and that person:

1. Makes a report to law enforcement → Report an SRE*
2. Doesn't make a report to law enforcement → Don't report an SRE

* An entity may defer to the decision of the local prosecuting attorney if there is an allegation alone. If there is additional evidence the entity is aware of that corroborates the report (i.e., video, additional witnesses, etc.) the SRE should be filed immediately.

SREs – 7C, Sexual Abuse/Assault

Definition: 7C. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting

Further Examples...

Questions?

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