

Sepsis-3 in Practice: Designing a Pre-Bill Validation Program That Improves Quality and Compliance

Presented by:
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Trust Methodist.

Objectives

1. Describe the purpose and regulatory framework of DRG validation.
2. Differentiate DRG validation from coding validation.
3. Explain the clinical, regulatory, and operational factors driving the transition from Sepsis-2 to Sepsis-3.
4. Describe the design, implementation, and workflow of a pre-bill sepsis validation process.
5. Evaluate the measurable compliance and quality outcomes of a structured DRG validation program.
6. Identify best practices for implementing a successful sepsis validation and downgrade prevention program.

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DRG Validation Purpose & Regulatory Framework

False Claims Act

- False Claims Act of 1863 imposes civil liability on any person (or organizations) who **knowingly** submits, or causes the submission of, a false or fraudulent claim to the Federal government.
- "Knowingly" is actual knowledge, deliberate ignorance, or reckless disregard.
- Includes **submitting a claim with a higher weighted DRG than supported by the medical record** (upcoding).
  - Upcoding (overcoding) – assigning a billing code that is more complex or costly than the actual service provided; considered fraudulent and can lead to severe consequences, including fines, audits, imprisonment, and damage to professional reputation.
  - Downcoding (undercoding) – assigning a lower-level code than the service or procedure warrants; can lead to lost revenue, and administrative strain.

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CMS Regulations

- "The purpose of DRG validation is to ensure that diagnostic and procedural information…coded and reported by the hospital on its claims matches the attending physician's description **and the information contained in the medical record**."

  - CMS Medicare Program Integrity Manual

  - Was the claim coded and sequenced correctly based on the applicable coding rules and provider documentation?

- "Clinical validation involves a clinical review of the case to see whether or not the patient **truly possesses the conditions** that were documented in the medical record."

  – RAC Statement of Work

  - Does the clinical evidence support the condition that the provider documented?

- Overall regulatory purpose: Medicare payment integrity

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Coding Guidelines

Code assignment and Clinical Criteria

The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis. If there is conflicting medical record documentation, query the provider.

- Official Coding Guidelines (OCG), Section I.A.19

- "…diagnosing a patient's condition is solely responsibility of the provider"
- "The guideline noted addressed coding, not clinical validation"
- "Clinical validation is beyond the scope of DRG (coding) validation… This type of review can only be performed by a clinician…"
- "A facility or a payer may require that a physician use a particular clinical definition or a set of criteria when establishing a diagnosis…"

-ICD-10-CM/PCS Coding Clinic, Fourth Quarter, ICD-10, 2016

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Noncompliance Outcomes

Consequences of submitting clinically invalid diagnoses:

- improper DRG payment
- excessive denials and rework
- unnecessary appeals
- risk of regulatory audits and penalties

Over-coding leads to downgrades in CC's/MCC's (e.g., AKI and encephalopathy).

Medicare trust fund is paying audit contractors

"When diagnoses are obviously invalid, the CDI team – coding, clinical documentation specialists, physician advisor – is certainly qualified to make a decision to omit a code. After all, there are no consequences for removing a clinically invalid diagnosis code but more serious problems if you don't."

- Dr. Pinson, a leading coding and documentation expert

In 2023, Pinson & Tang received the AHIMA Influencer Award for their commitment and contributions to the HI profession with their ground-breaking CDI Pocket Guide®

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DOJ: Benchmark Case

Department of Justice

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RHODE ISLAND-BASED HOSPITAL TO PAY $400,000 TO SETTLE HEALTH-CARE FRAUD ALLEGATIONS

WASHINGTON, D.C. — Roger Williams Medical Center, a hospital based in Providence, Rhode Island, has agreed to pay $400,000 to resolve allegations of Medicare fraud, the Justice Department announced today.

The settlement relates to allegations that the medical center violated the False Claims Act by "upcoding" a pneumonia diagnosis code. Upcoding is the practice of assigning false diagnosis codes – i.e., a diagnosis code that is not supported by the physician's documentation in the medical record – on claims submitted to Medicare in order to increase reimbursements.

Under Medicare, hospitals are reimbursed through the DRG (Diagnostic Related Groups) coding system in which hospitals assign diagnosis codes for each patient discharge and those codes determine the DRG to which a patient discharge is assigned. The government's reimbursement is then based on the assigned DRG. In this case, Roger Williams was able to increase its reimbursements when it assigned a false, higher reimbursing pneumonia diagnosis code, rather than the correct, lower reimbursing diagnosis code.

"This settlement demonstrates our ongoing commitment to vigorously pursue allegations of fraud and abuse in the Medicare system," said Assistant Attorney General Robert D. McCallum of the Civil Division. "The Medicare system operates on the good faith and honesty of its providers, and we cannot tolerate misuse of the reimbursement system for financial gain."

Roger Williams also has entered into a corporate compliance agreement with the Department of Health and Human Services. The integrity provisions are designed to ensure continuing compliance by the hospital with Medicare and other federal health programs. The provisions compel Roger Williams to retain an independent review organization to perform regular billing and coding reviews including random claims reviews; to provide coding and compliance training to employees; and to retain a compliance officer and compliance committee with responsibility for developing and implementing policies designed to ensure compliance with federal health care program requirements and the integrity provisions. Stipulated penalties are provided for in the event of a breach of the integrity provisions.

This case was part of a qui tam or whistleblower lawsuit originally filed in 1996 by relator Health Outcomes Technologies. Under the False Claims Act, private individuals or firms can file suit on behalf of the government and share in any recovery. As a result of the settlement, the Doylestown, Pennsylvania-based company will receive a $57,540.

The case was handled by the Justice Department's Civil Division, in collaboration with the Office of Inspector General for the Department of Health and Human Services.

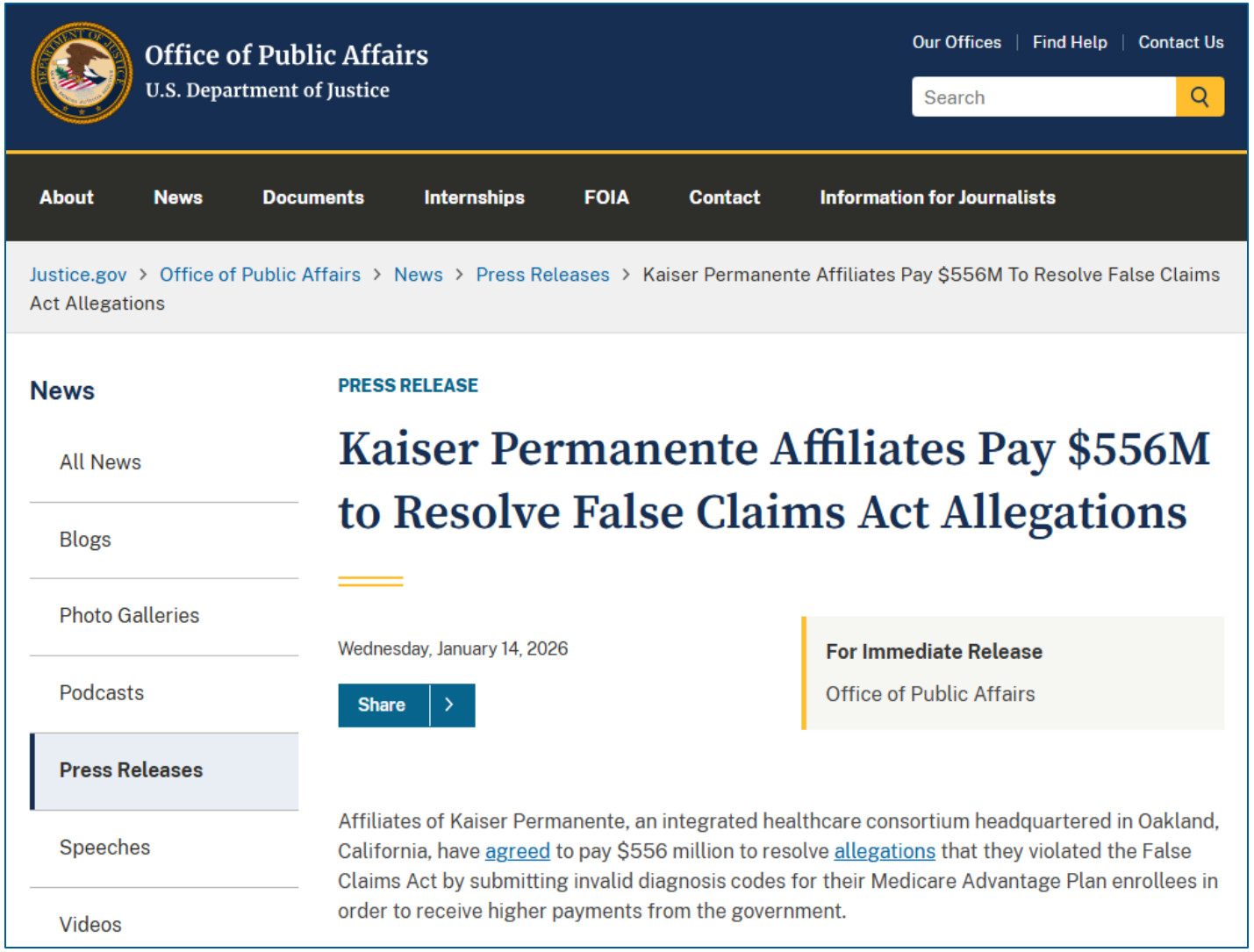
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02-599

"…the medical center violated the False Claims Act by "upcoding" a pneumonia diagnosis code."

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DOJ: 2026 Press Release



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Kaiser Permanente Affiliates Pay $556M to Resolve False Claims Act Allegations

Wednesday, January 14, 2026

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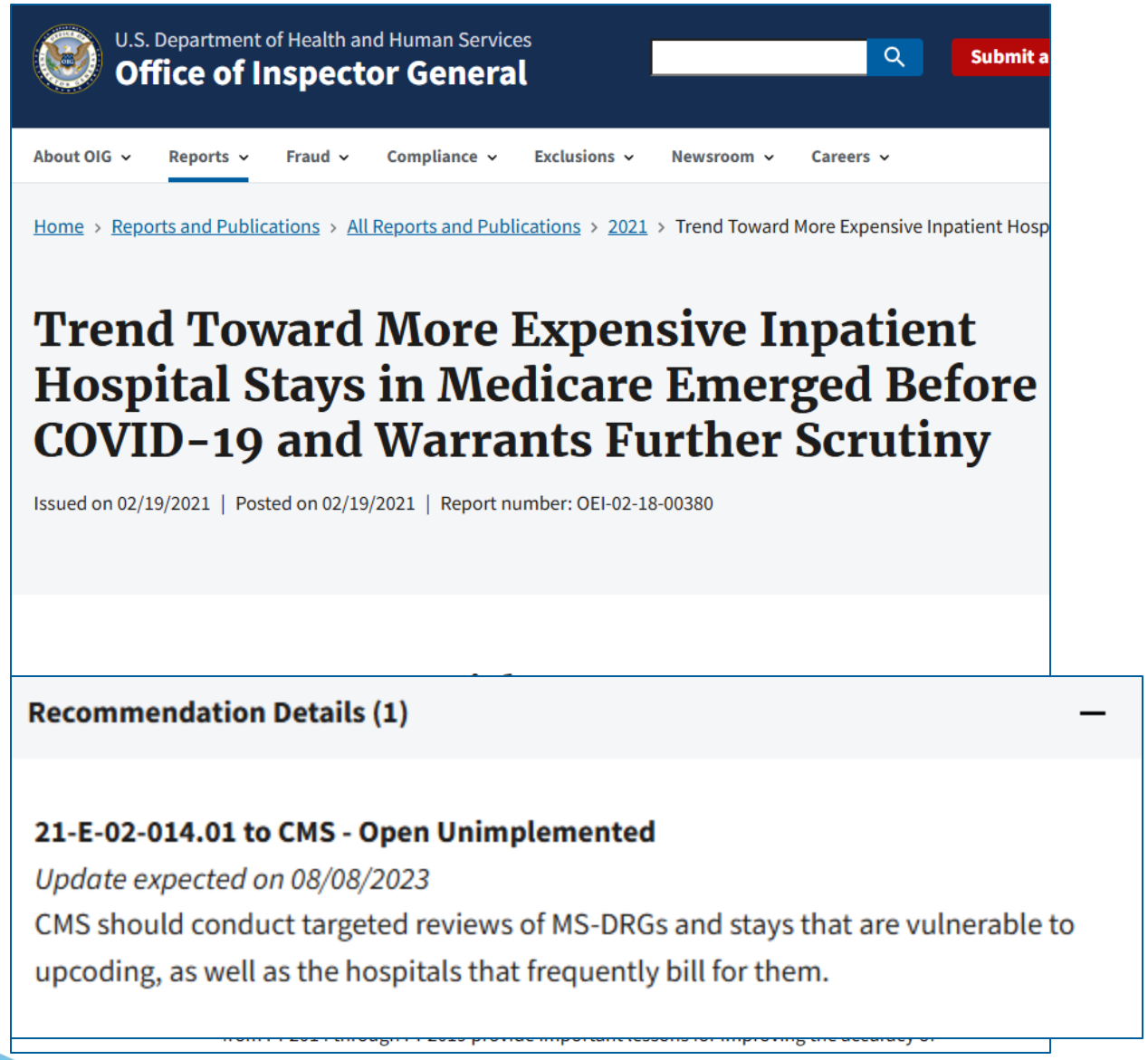
Affiliates of Kaiser Permanente, an integrated healthcare consortium headquartered in Oakland, California, have agreed to pay $556 million to resolve allegations that they violated the False Claims Act by submitting invalid diagnosis codes for their Medicare Advantage Plan enrollees in order to receive higher payments from the government.

"…violated the False Claims Act by submitting **invalid diagnosis** codes for their Medicare Advantage Plan enrollees in order to receive higher payments from the government."

"…United States holds healthcare providers and plans accountable when they knowingly submit or cause to be submitted false information to CMS to obtain inflated Medicare payments."

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OIG Payment Scrutiny



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Trend Toward More Expensive Inpatient Hospital Stays in Medicare Emerged Before COVID-19 and Warrants Further Scrutiny

Issued on 02/19/2021 | Posted on 02/19/2021 | Report number: OEI-02-18-00380

Recommendation Details (1)

21-E-02-014.01 to CMS - Open Unimplemented

Update expected on 08/08/2023

CMS should conduct targeted reviews of MS-DRGs and stays that are vulnerable to upcoding, as well as the hospitals that frequently bill for them.

HOW WE DID THIS STUDY

"We analyzed paid Medicare Part A claims… We identified trends in hospital billing and Medicare payments for stays at the highest severity level."

WHAT WE FOUND

"Hospitals are increasingly billing for inpatient stays at the highest severity level… nearly a third of these stays lasted a particularly short amount of time and over half of the stays billed at the highest severity level had only one diagnosis qualifying them for payment at that level."

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DRG Downgrade Example

	APR DRG		MS DRG		Principal Dx	Secondary Dx	Secondary Dx
MCR	SOI	ROM	R. Wt.	Estimated $			
DRG 871	1	2	1.9425	$18,263	Sepsis	Pneumonia	Encephalopathy
DRG 194	2	2	0.8059	$9,749	Pneumonia	Encephalopathy	HTN
DRG 195	1	1	0.6285	$8,420	Pneumonia	HTN	DM 2

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Transition from Sepsis-2 to Sepsis-3: Clinical Factors

Why Update the Definitions?

The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3) published in 2016:

- **Prior definition revision in 2001 with limited updates – unchanged since 1991 (25 years)**
- **Advances in pathobiology, management, and epidemiology of sepsis**
- **Limitations of previous definitions:** included an **excessive focus on inflammation**, the **misleading model** that sepsis follows a continuum through severe sepsis to shock, and **inadequate specificity and sensitivity** of the systemic inflammatory response syndrome(SIRS)criteria. Multiple definitions and terminologies for sepsis, septic shock, and organ dysfunction, leading to **discrepancies in reported incidence and observed mortality**.

- PROCESS A task force(n = 19)with expertise in sepsis pathobiology, clinical trials, and epidemiology was convened by the Society of Critical Care Medicine and the European Society of Intensive Care Medicine. Definitions and clinical criteria were generated through meetings, Delphi processes, analysis of electronic health record databases, and voting, followed by circulation to international professional societies, requesting peer review and endorsement (by 31 societies).

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The Third International Consensus Definitions

RECOMMENDATIONS:

- **Sepsis** should be defined as life-threatening organ dysfunction caused by a dysregulated host response to infection.

  For clinical operationalization, organ dysfunction can be represented by an increase in the Sequential [Sepsis-related] Organ Failure Assessment (SOFA) score of 2 points or more, which is associated with an in-hospital mortality greater than 10%.

- **Septic shock** should be defined as a subset of sepsis in which particularly profound circulatory, cellular, and metabolic abnormalities are associated with a greater risk of mortality than with sepsis alone.

  Clinical definition: vasopressor requirement to maintain a mean arterial pressure of 65 mm Hg or greater and serum lactate level greater than 2 mmol/L(>18 mg/dL) in the absence of hypovolemia. This combination is associated with hospital mortality rates greater than 40%.

- **Conclusions and Relevance:**

  These updated definitions and clinical criteria should replace previous definitions, offer greater consistency for epidemiologic studies and clinical trials, and facilitate earlier recognition and more timely management of patients with sepsis or at risk of developing sepsis

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SOFA Chart

Table 1. Sequential [Sepsis-Related] Organ Failure Assessment Score[a]

System	Score 0	1	2	3	4
Respiration					
Pao_2/Fio_2, mm Hg (kPa)	≥400 (53.3)	<400 (53.3)	<300 (40)	<200 (26.7) with respiratory support	<100 (13.3) with respiratory support
Coagulation					
Platelets, $\times 10^3/\mu L$	≥150	<150	<100	<50	<20
Liver					
Bilirubin, mg/dL (μmol/L)	<1.2 (20)	1.2-1.9 (20-32)	2.0-5.9 (33-101)	6.0-11.9 (102-204)	>12.0 (204)
Cardiovascular	MAP ≥70 mm Hg	MAP <70 mm Hg	Dopamine <5 or dobutamine (any dose)[b]	Dopamine 5.1-15 or epinephrine ≤0.1 or norepinephrine ≤0.1[b]	Dopamine >15 or epinephrine >0.1 or norepinephrine >0.1[b]
Central nervous system					
Glasgow Coma Scale score[c]	15	13-14	10-12	6-9	<6
Renal					
Creatinine, mg/dL (μmol/L)	<1.2 (110)	1.2-1.9 (110-170)	2.0-3.4 (171-299)	3.5-4.9 (300-440)	>5.0 (440)
Urine output, mL/d				<500	<200

Abbreviations: Fio_2, fraction of inspired oxygen; MAP, mean arterial pressure; Pao_2, partial pressure of oxygen.

[a] Adapted from Vincent et al.[27]

[b] Catecholamine doses are given as μg/kg/min for at least 1 hour.

[c] Glasgow Coma Scale scores range from 3-15; higher score indicates better neurological function.

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Recommended Sepsis Reporting

Table 2. Terminology and *International Classification of Diseases* Coding

Current Guidelines and Terminology	Sepsis	Septic Shock
1991 and 2001 consensus terminology[9,10]	Severe sepsis Sepsis-induced hypoperfusion	Septic shock[13]
2015 Definition	Sepsis is life-threatening organ dysfunction caused by a dysregulated host response to infection	Septic shock is a subset of sepsis in which underlying circulatory and cellular/metabolic abnormalities are profound enough to substantially increase mortality
2015 Clinical criteria	Suspected or documented infection and an acute increase of ≥2 SOFA points (a proxy for organ dysfunction)	Sepsis[a] and vasopressor therapy needed to elevate MAP ≥65 mm Hg and lactate >2 mmol/L (18 mg/dL) despite adequate fluid resuscitation[13]
Recommended primary *ICD* codes[a]		
ICD-9	995.92	785.52
ICD-10[a]	R65.20	R65.21
Framework for implementation for coding and research	Identify suspected infection by using concomitant orders for blood cultures and antibiotics (oral or parenteral) in a specified period[b] Within specified period around suspected infection[c]: 1. Identify sepsis by using a clinical criterion for life-threatening organ dysfunction 2. Assess for shock criteria, using administration of vasopressors, MAP <65 mm Hg, and lactate >2 mmol/L (18 mg/dL)[d]	

When Sepsis-3 criteria is met, the ICD-10-CM code for "severe sepsis" should be used in reporting.

Documentation examples:

- "Hypotension (MAP < 70) and creatinine 1.2 **due to** severe sepsis"

- "T. bilirubin of 1.2 and thrombocytopenia **secondary to** severe sepsis"

- "Severe sepsis due to Pseudomonas pneumonia **with associated** hypoxic respiratory failure"

- "Acute kidney injury **due to** severe sepsis from pyelonephritis"

The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3)
https://jamanetwork.com/journals/jama/fullarticle/2492881

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Transition from Sepsis-2 to Sepsis-3: Operational & Regulatory Drivers

DRG Downgrade National Trends

1. Rapid increase in downgrade volume
   - DRG downgrades are up ~57% since 2022
     - Hospitals spent $19.7 billion appealing denied claims in 2022
     - Closely tied to overall denial rates (~11–12% of claims)

     - Becker's Hospital Review, 10/2025

   - AI-driven payer scrutiny (major shift)
     - Payers now use automated adjudication + predictive analytics
     - Claims are flagged instantly for:
       - Outlier DRG patterns
       - Utilization rates of diagnoses that increase DRG weight
       - LOS vs diagnosis mismatches

2. Rise of clinical validation denials
   - Clinical validation - the #1 denial category in CDI programs (~87%)

     - ACDIS

   - Payers are second-guessing physician diagnoses

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DRG Downgrade National Trends, cont.

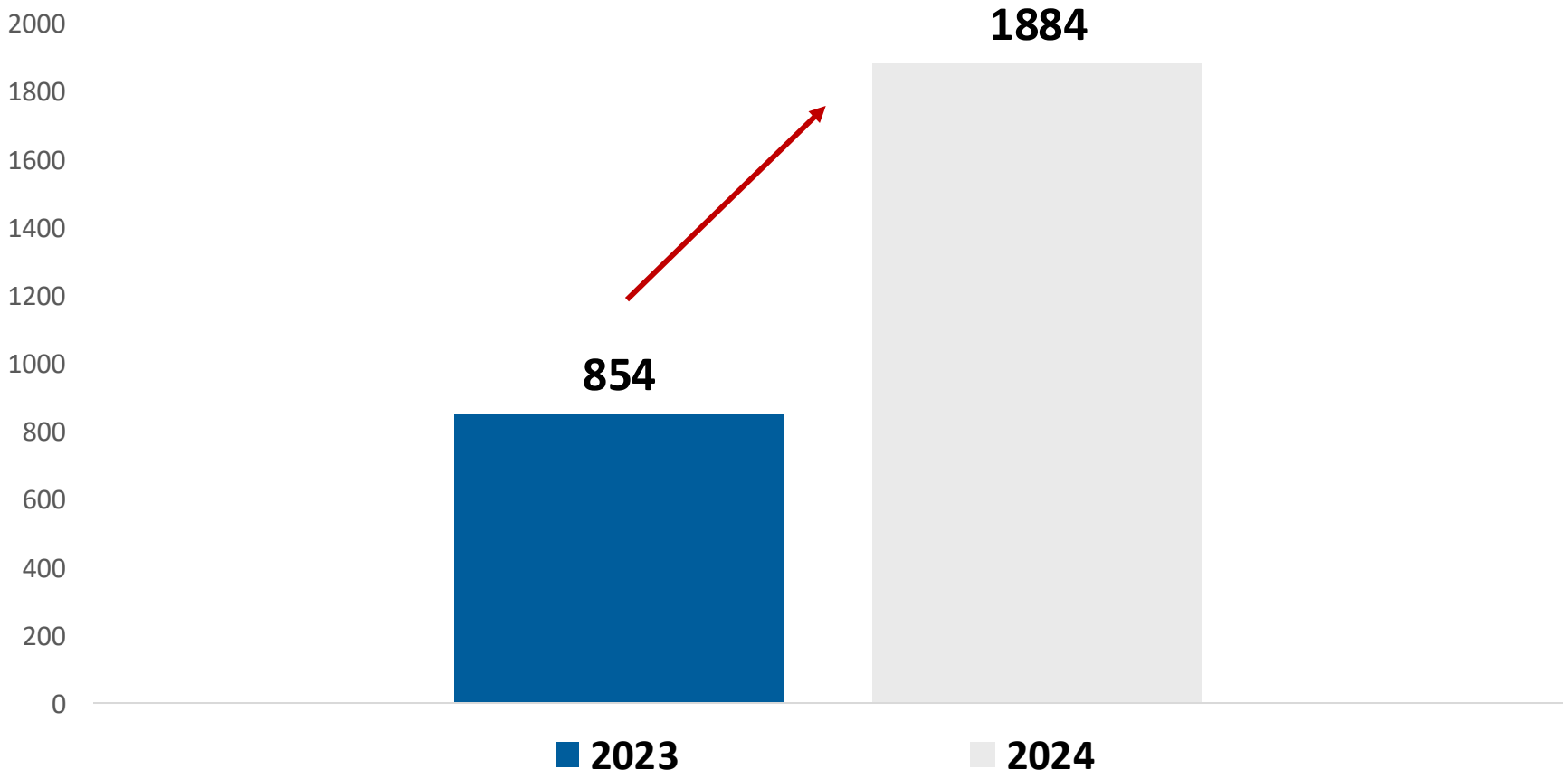
3. Organizational movement from reactive to proactive defense

- Using pre-bill clinical validation
- Aligning documentation practices with industry standards
- Addressing documentation gaps at the front end
- Breaking organizational silos to form a strong unified front



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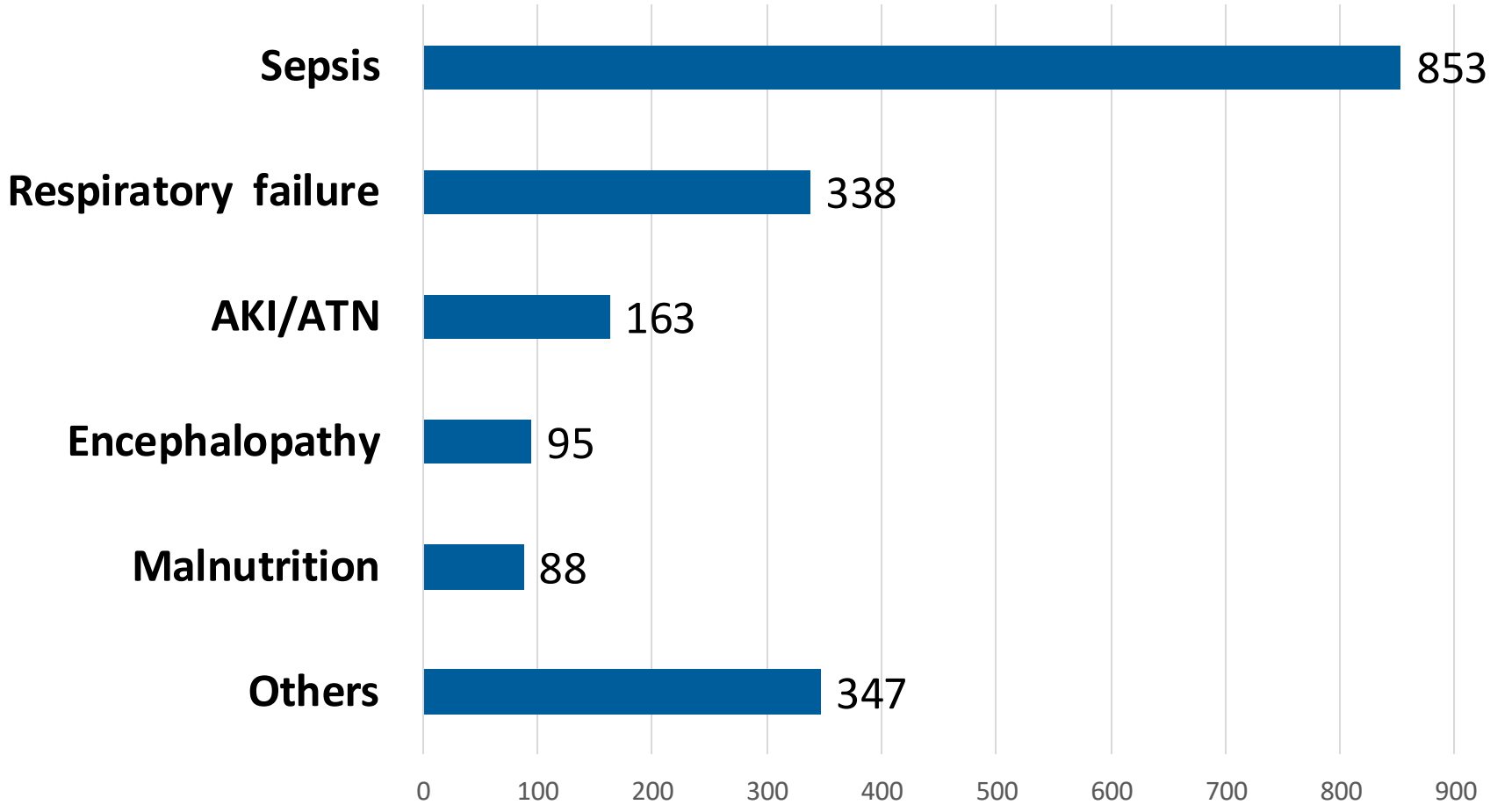
MHS Clinical DRG Downgrades



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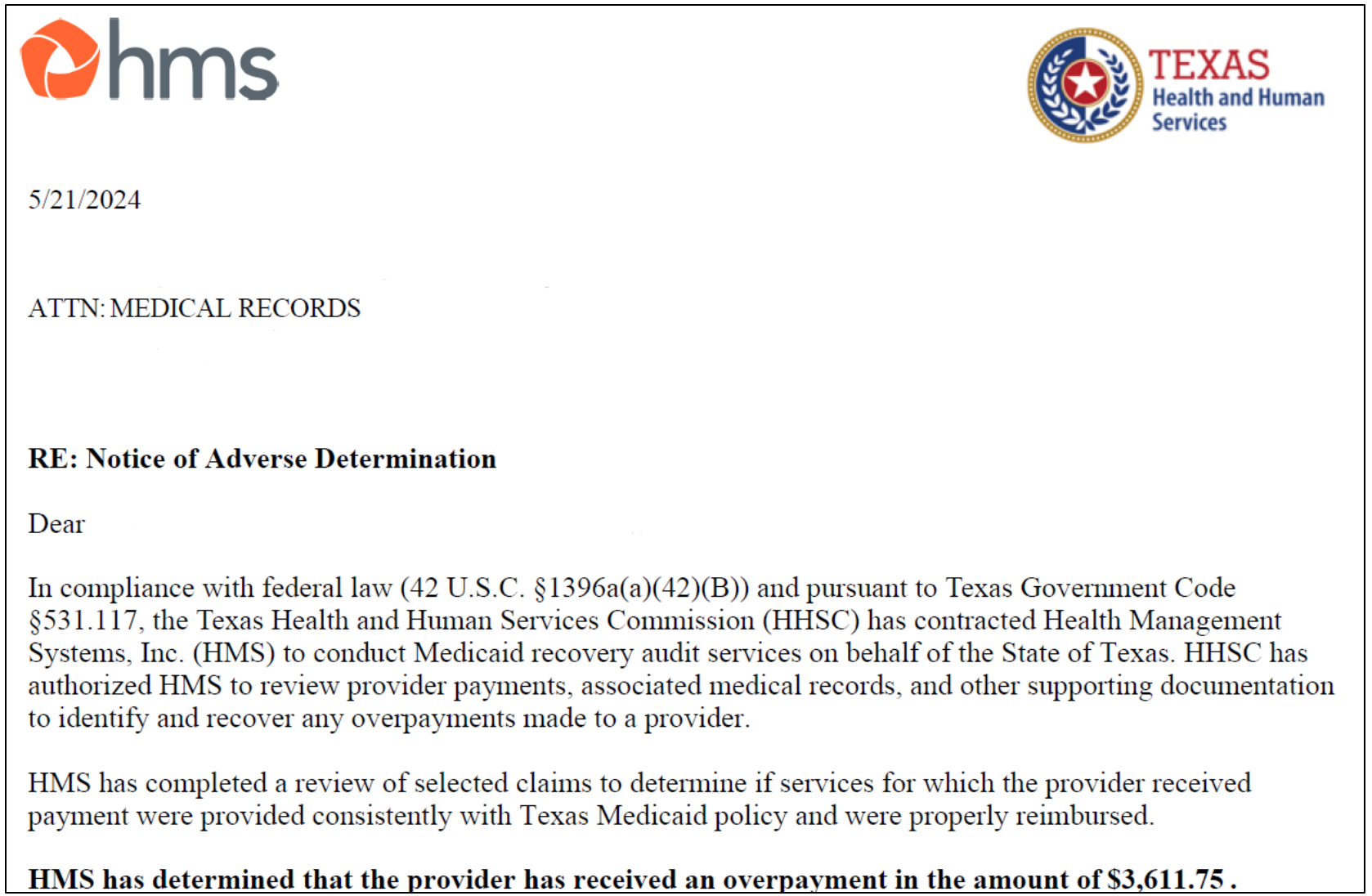
Top 5 Denied Diagnoses - 2024

1. Sepsis
2. Respiratory Failure
3. AKI/ATN
4. Encephalopathy
5. Malnutrition



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Texas HHS: RAC Denial



hms

TEXAS Health and Human Services

5/21/2024

ATTN: MEDICAL RECORDS

RE: Notice of Adverse Determination

Dear

In compliance with federal law (42 U.S.C. §1396a(a)(42)(B)) and pursuant to Texas Government Code §531.117, the Texas Health and Human Services Commission (HHSC) has contracted Health Management Systems, Inc. (HMS) to conduct Medicaid recovery audit services on behalf of the State of Texas. HHSC has authorized HMS to review provider payments, associated medical records, and other supporting documentation to identify and recover any overpayments made to a provider.

HMS has completed a review of selected claims to determine if services for which the provider received payment were provided consistently with Texas Medicaid policy and were properly reimbursed.

HMS has determined that the provider has received an overpayment in the amount of $3,611.75 .

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Texas HHS: RAC Denial, cont.

Narrative:

The hospital reported a principal ICD-10-CM diagnosis code assignment of A41.89 OTHER SPECIFIED SEPSIS. A Clinical Validation review was completed on this billed diagnosis per specific criteria supported by the reference(s) below.

Based upon the review of the medical record, this code was not validated and has been removed and replaced with ICD-10-CM diagnosis code U07.1 COVID-19 as principal. ICD-10-CM diagnosis code A41.89 OTHER SPECIFIED SEPSIS is not clinically valid as it did not meet criteria for the following reasons:

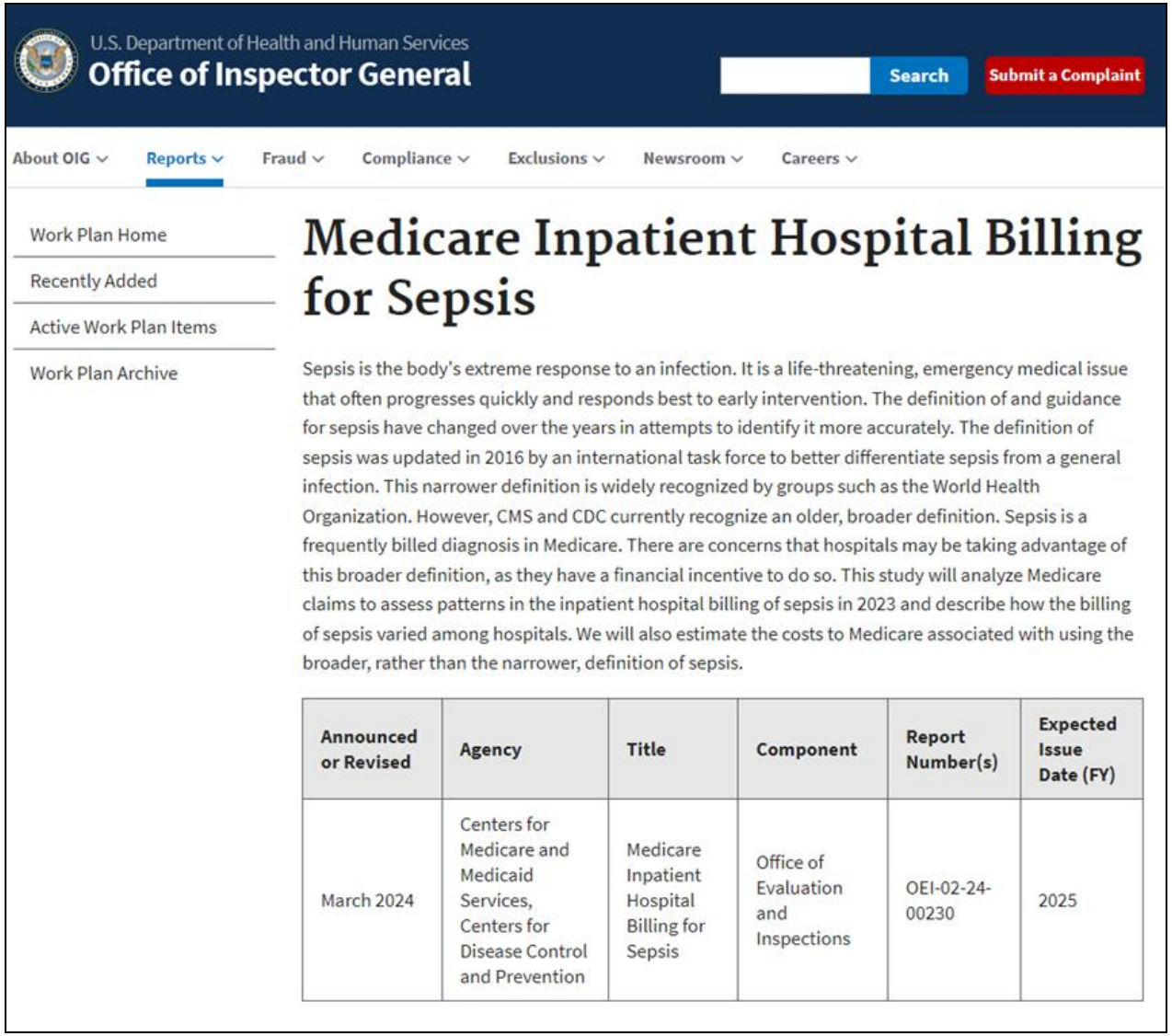
- *While sepsis is written, this condition is not clinically supported in the medical records provided*
- *Patient's oxygen saturations were in the 90s with no documentation linking hypoxia to infection/sepsis*
- *A combination of laboratory values, respiratory and perfusion assessments did not indicate an acute SOFA score change of greater than*



SOFA: sequential organ failure assessment

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OIG Sepsis Scrutiny



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Medicare Inpatient Hospital Billing for Sepsis

Sepsis is the body's extreme response to an infection. It is a life-threatening, emergency medical issue that often progresses quickly and responds best to early intervention. The definition of and guidance for sepsis have changed over the years in attempts to identify it more accurately. The definition of sepsis was updated in 2016 by an international task force to better differentiate sepsis from a general infection. This narrower definition is widely recognized by groups such as the World Health Organization. However, CMS and CDC currently recognize an older, broader definition. Sepsis is a frequently billed diagnosis in Medicare. There are concerns that hospitals may be taking advantage of this broader definition, as they have a financial incentive to do so. This study will analyze Medicare claims to assess patterns in the inpatient hospital billing of sepsis in 2023 and describe how the billing of sepsis varied among hospitals. We will also estimate the costs to Medicare associated with using the broader, rather than the narrower, definition of sepsis.

Announced or Revised	Agency	Title	Component	Report Number(s)	Expected Issue Date (FY)
March 2024	Centers for Medicare and Medicaid Services, Centers for Disease Control and Prevention	Medicare Inpatient Hospital Billing for Sepsis	Office of Evaluation and Inspections	OEI-02-24-00230	2025

TIMELINE

March 15, 2024	**Announced**
Today	**Office of Evaluation and Inspections In-Progress**
Est FY2026	Estimated Fiscal Year for Project Completion

Work Plan Type:
Office of Evaluation and Inspections

HHS Agencies:
Centers for Medicare and Medicaid Services
Centers for Disease Control and Prevention

Issue Areas:
Financial Stewardship | Hospitals

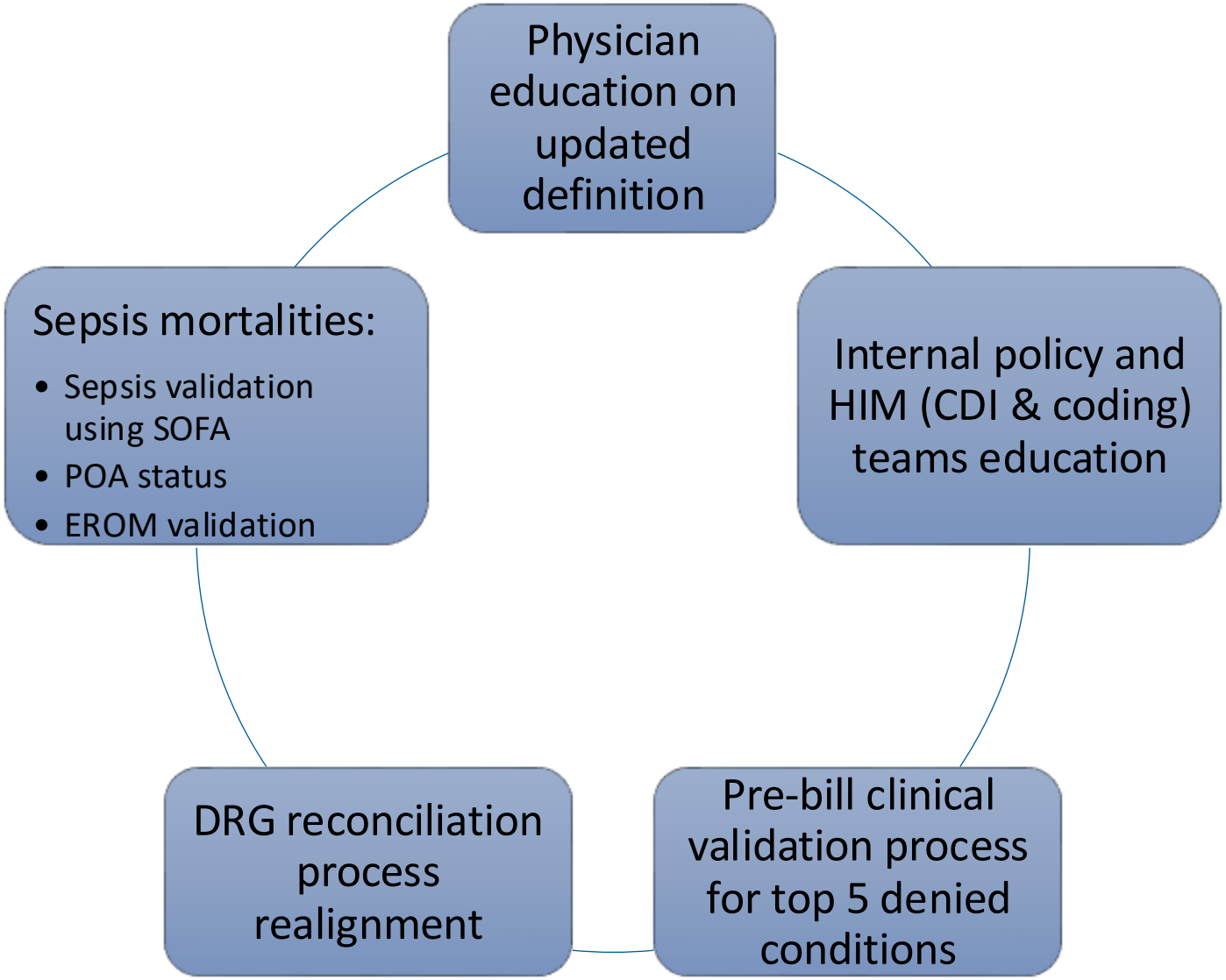
Target Groups:
Elderly

Financial Groups:
Medicare A

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MHS Process for Pre-bill Clinical Validation

MHS DRG Validation Strategies



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Provider Education

- In-person and virtual CDI education sessions
- Present real-world case studies
- Provider shadowing with virtual meetings to provide feedback
- Clinical indicators required to support diagnoses
  - focus on top 5 denied diagnoses
    - Sepsis-3 definition change
    - KDIGO
    - GLIM
- CDI tip sheet
- Sepsis tip sheet



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Department Guidelines for Clinical Validation

Clinical validation of the top 5 denied diagnoses:

1. Sepsis (has to meet Sep-3 criteria)
2. Respiratory Failure (all types)
3. AKI/ATN/AKI on CKD
4. Encephalopathy (all types)
5. Malnutrition (all degrees)



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Clinical Validation (CV) Workflow

Step 1
- Coder identifies the top 5 denied diagnoses.

Step 2
- Pre-bill clinical validation request sent to CDI work queue by coders.

Step 3
- CDI team lead assigns CV request to CDSs.

Step 4
- CDS reviews the charts within 24 - 48 hours of assignment.

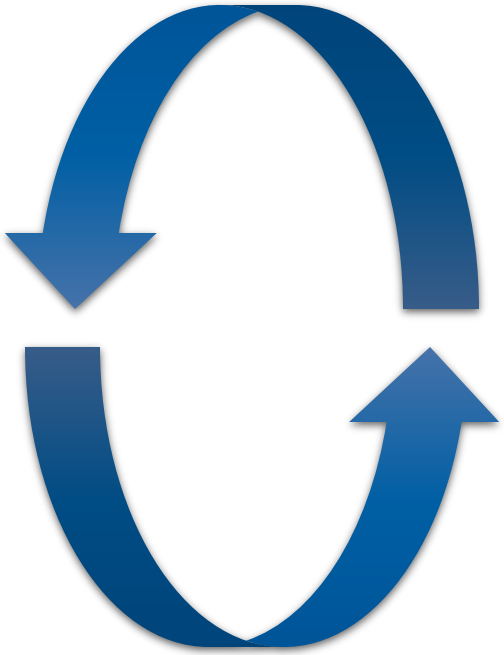
Step 5
- CDS sends it back to coding with CV determination/query outcome.

Step 6
- Coding is adjusted accordingly.

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DRG Reconciliation Process

- Shift from post-bill to pre-bill DRG reconciliation
- Account reviewed by CDI are sent back to CDI for reconciliation after final coding - closing the loop
- Separate WQ created
- Final check prior to claim drop
- Goals:
  - Identify discrepancies and resolve mismatches pre-bill.
  - Confirm diagnoses billed are supported by clinical evidence in the medical record.
  - Ensure accuracy and compliance.
  - Reduce denials from incorrect DRG assignment.



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Breaking Silos

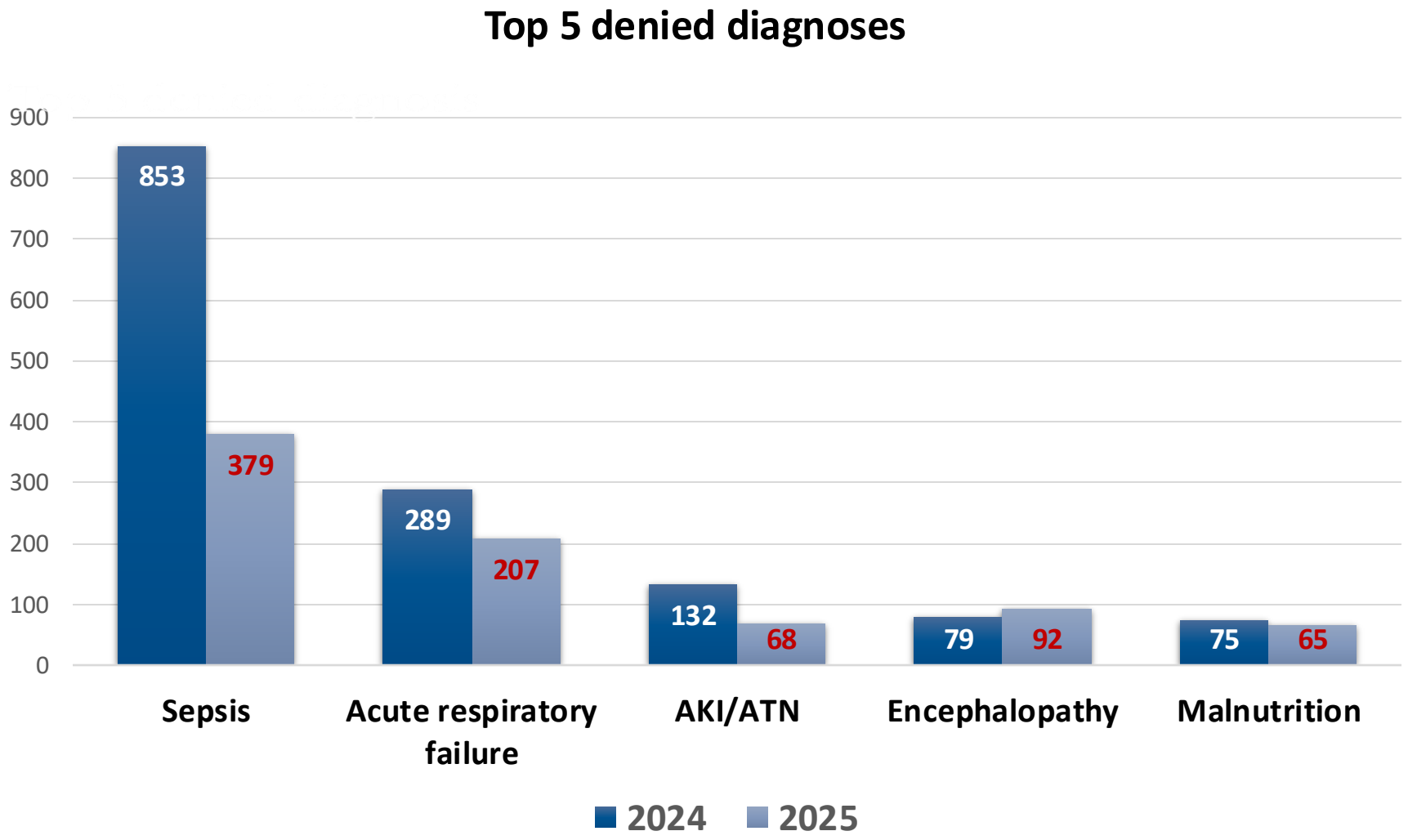
- Collaboration between CDI, Coding, and Quality: sepsis mortality reviews
- DRG Validation Continuous Improvement
  - Updating departmental guidelines
  - Workflow gaps/issues
  - Denials/appeals trend changes
  - Close appeal follow-up
  - Escalations to payer representatives
  - Arbitration



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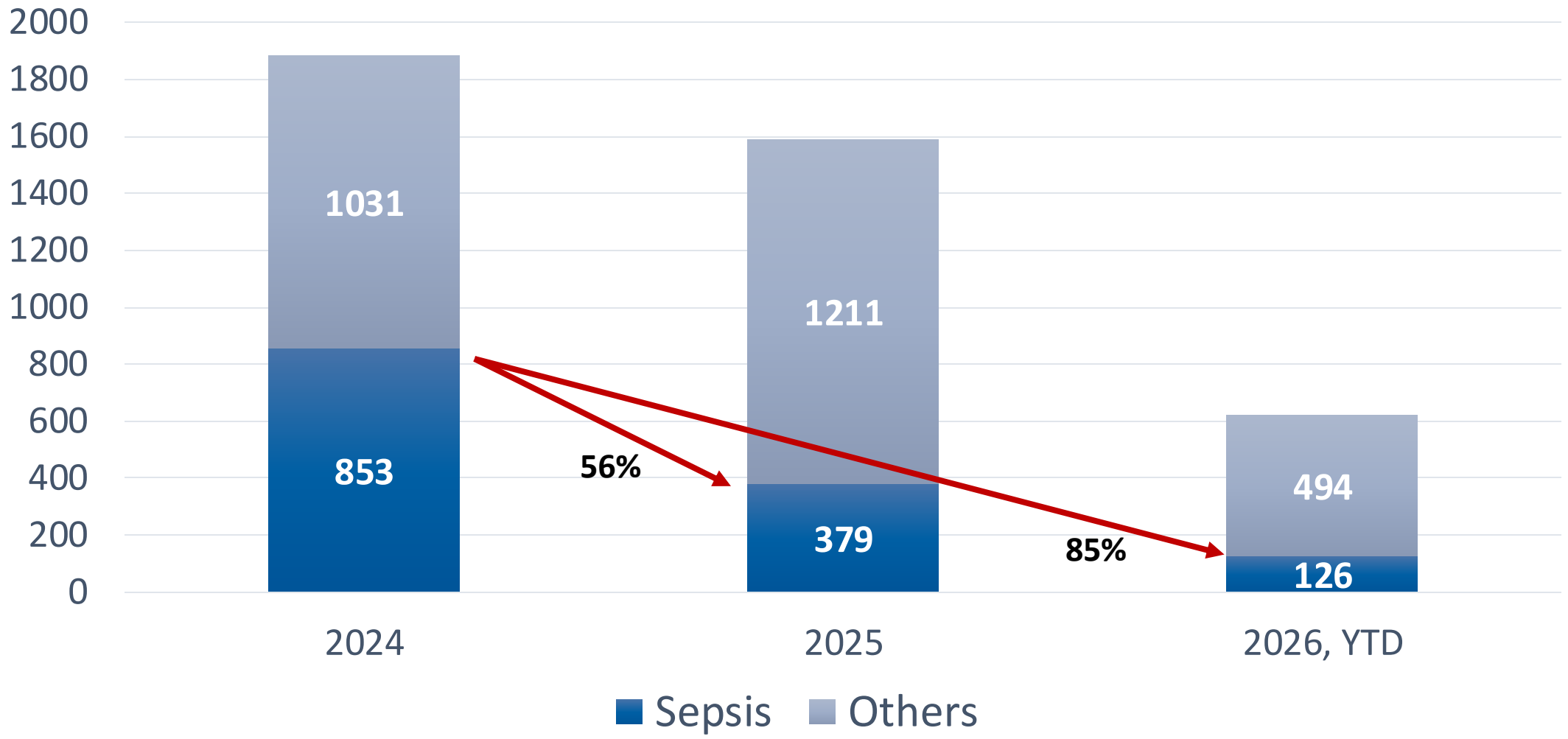
MHS DRG Validation Process Outcomes

Decreased Denials



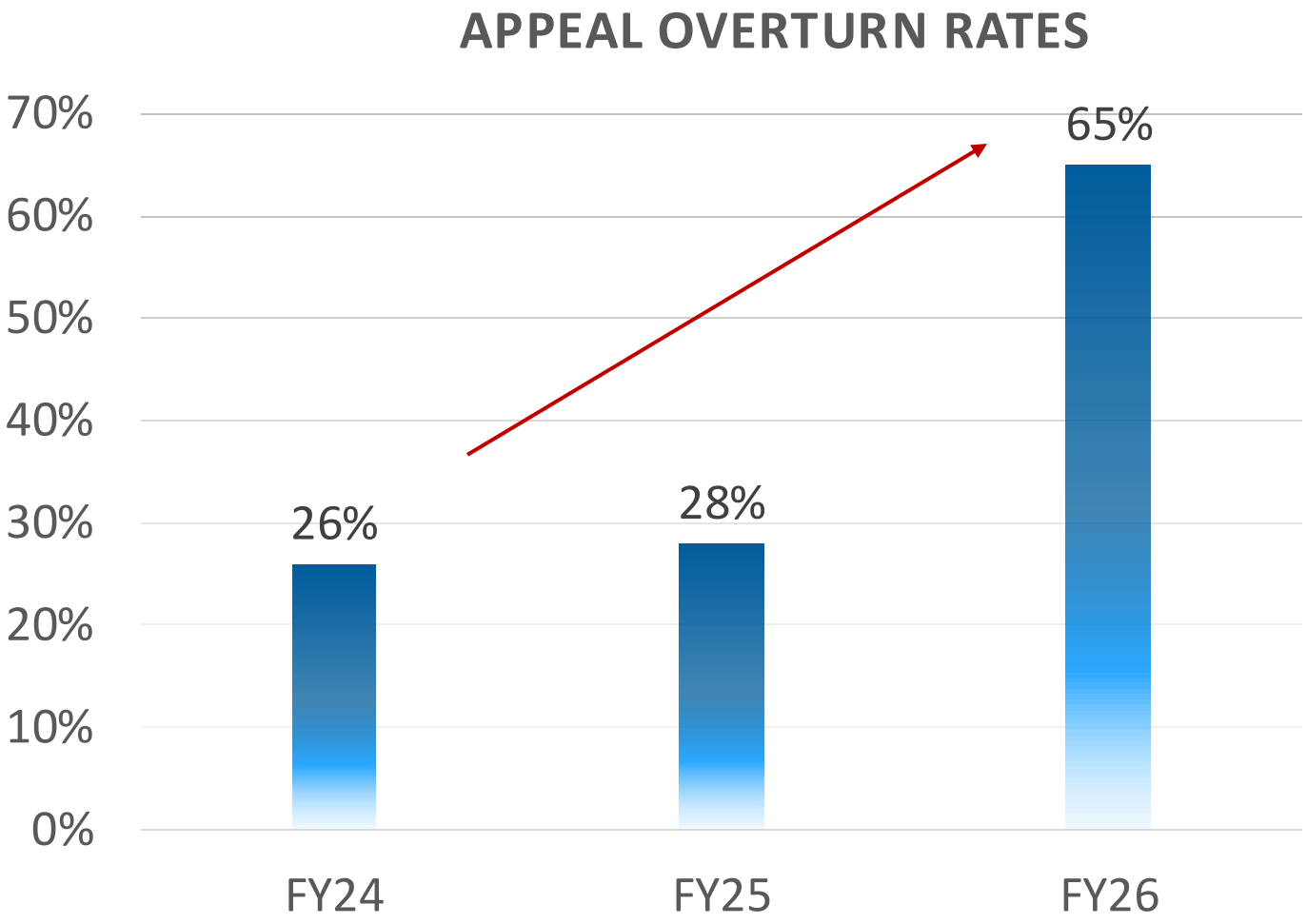
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Clinical Validation DRG Downgrades Trends



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Increased Appeal Overturn Rates





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Metrics show outcomes are on the rise, with hundreds of lives saved



Martin L. Koonsman,
MD, FACS, CPE
Chief Medical Officer

Patient safety and quality metrics show significant progress in the past year, and over the past five years. I would like to highlight how much outcomes have improved across the health system:

- **Overall mortality** – We finished the year at 0.68 observed-to-expected ratio, representing 666 lives saved. That is a 7% improvement over the past year and a 26% improvement since fiscal year 2020.
- **Sepsis mortality** – Methodist finished the year at 0.74 O/E ratio, representing 221 lives saved and better than top quartile performance in the nation, which was 0.79 O/E. This represents a 10% improvement over the past year year, and a 47% improvement since fiscal year 2020.
- **Falls with injury** – The system's performance was better than top quartile in the nation, improving 16% over the past year and 51% since fiscal year 2020.

With regard to hospital-acquired infections, we still have work to do but we have made significant improvements:

- **Hospital acquired C. diff.** – Outcomes improved 7% from the previous year and 46% from fiscal year 2020.
- **Catheter-associated urinary tract infection (CAUTI)** – 35% improvement over prior year and 26% improvement since fiscal year 2020. This is the only hospital-acquired infection performing at better than top quartile performance.
- **Catheter-associated bloodstream infection** – No improvement over the past year, but outcomes have improved 52% since fiscal year 2020.

I would like to thank our medical staff for the work that they do to drive this improvement, as well as their commitment to compassionate, quality healthcare.

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Summary of Outcomes

- Compliance:
  Proactive internal control to ensure readiness for external scrutiny
  - RAC audits
  - OIG scrutiny
  - Payor audits

- Financial:
  - Improved payment retention with decreasing downgrades
    - Sepsis denials down 85%
    - AKI denials by 48.5%
  - Appeal overturn rate increase from 28% (FY 24-25) to 65% (FY 25-26)

- Quality:
  More accurate data for severe sepsis mortalities O:E

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Sepsis Validation & DRG Downgrade Prevention: Key Components

Sepsis Validation & Downgrade Prevention Steps

1. Assess organizational risk exposure
2. Focus on top 5 high-impact diagnoses (sepsis #1)
3. Secure executive and operational alignment
4. Standardize compliant query practices
5. Drive targeted physician education and engagement
6. Establish clear policies, governance, and workflows
7. Build a robust, data-driven appeals strategy
8. Implement performance monitoring and continuous improvement

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Questions and Comments



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