The Medicare Survey and Sanctions Process
Missouri Alliance for Home Care

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PROGRAM FOCUS
- Medicare Home Health Survey Process
- Immediate Jeopardy Citations
- New Intermediate Sanctions
- Rights of Appeal

The Metrics
- Since July 1, 2014, CMS has:
  - Imposed sanctions on 15 HHAs
  - 22 sanctions overall across the 15 HHAs
  - 8 Civil Monetary Penalties
  - 8 Payment Suspensions
  - 2 Directed Plan of Corrections
  - 4 Directed In-Service Training
  - ____ Immediate jeopardy HHA termination actions
The Law

- Section 1891 of the Social Security Act
- Amended by the OBRA 1987
- Each HHA “shall be subject to a standard survey not later than 36 months after the date of the previous standard survey”
- Allows flexibility within 36 month interval
- Standard surveys may be conducted also
  - Within 2 months of change of ownership
  - Within 2 months of complaints

The Law

- Standard survey
  - Case-mix stratified sample of individuals
  - Visits in patient homes
  - Standardized assessment
  - Quality of care indicators
  - Tested and validated protocol
  - By qualified individuals
    - Not the HHA’s staff member or consultant within 2 years
    - No personal or financial interest in HHA

The Law

- Extended survey
  - When standard survey finds substandard care
  - Or at discretion of Secretary or state survey agency
  - Immediately after standard survey (not later than 2 weeks)
  - Reviews policies and procedures
The Law

- Immediate jeopardy
  - Health and safety of patients
  - Immediate action to remove jeopardy and correct deficiencies through intermediate sanctions and remedies
  - Or terminate the certification/participation of the HHA
  - May impose sanctions in addition

The Law

- Not an immediate jeopardy
  - “no longer in compliance with” Conditions of Participation
  - “Secretary may (for a period not to exceed 6 months) impose intermediate sanctions” ...“in lieu of terminating the certification of the agency”
  - If noncompliance continues after intermediate sanctions, “the Secretary shall terminate the certification of the agency”

The Law

- “If the Secretary determines that a home health agency...is in compliance...but, as of a previous period, did not meet such requirements, the Secretary may provide for a civil money penalty....for the days which it finds that the agency was not in compliance with such requirements.”
The Law

- The Secretary may continue payments...with respect to a home health agency not in compliance...over a period of not longer than 6 months, if
  - it is more appropriate to take alternative action to assure compliance...than to terminate the certification
  - the agency has submitted a plan and timetable for corrective action...and the Secretary approves the plan
  - the agency agrees to repay to the Federal Government payments received...if the corrective action is not taken in accordance with the approved plan

The Law

- Intermediate sanctions
  - “not later than April 1, 1989”
  - “civil money penalties in an amount not to exceed $10,000 for each day of noncompliance”
  - “suspension of all or part of the payments to which a home health agency would otherwise be entitled”
  - “the appointment of temporary management”
  - “not terminated”... until HHA “has management capability to ensure continued compliance”

The Law

- Intermediate sanctions
  - “in addition to sanctions otherwise available under State or Federal law”
  - Payment suspension terminates when HHA “is in substantial compliance”
Regulatory Developments

- April 1, 1989 deadline for implementation under the law
- Medicare issue a proposed rule on August 2, 1991
- OIG issued report on Medicare’s failure to promulgate intermediate sanction consistent with OBRA 1987 law on March 2, 2012

The New Survey and Sanctions Rule

- Codifies HHA survey process
- Establishes intermediate sanctions
  - Civil money penalties and payment suspensions effective 7-1-14
  - Other sanction effective 7-1-13
- Establishes Informal Dispute Resolution process
  - Effective 7-1-14

CMS Expectations of Survey Process

- CMS expects the survey process will:
  - Keep providers in substantial compliance with CoPs
  - Correct deficiencies and ensure corrections are long-lasting
  - Have providers address all deficiencies promptly
  - Patients will receive the care needed to attain and maintain their highest practicable functional capacity
Definitions

- 42 CFR 488.705
  - Survey types
    - Standard, abbreviated standard, extended, partial extended, and complaint
  - Deficiencies
    - Condition-level deficiency, deficiency, noncompliance, standard-level deficiency, substandard care, and substantial compliance

Survey Process: 488.710-735

- Follows statutory standards
- Standard survey
- Partial Extended survey
- Extended survey
- Unannounced survey
- Frequency and content
- Surveyor qualifications

Definitions: 488.805

- Immediate jeopardy
- Directed plan of correction
- New admission
- Per instance
- Plan of correction
- Repeat deficiency
- Temporary management
Immediate Jeopardy Defined

- 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 patient(s).” 42 CFR 488.805
  - Threat is real and important
  - Harm is likely to occur in very near future
  - High probability that serious harm could occur at any time or already has occurred and could occur again

Immediate Jeopardy

- Determining IJ—State Operations Manual
  - Only ONE individual needs to be at risk
  - Abuse or neglect
  - Psychological harm included
  - The HHA created the situation or allowed a harmful situation to continue
  - HHA had the opportunity to institute corrective measures

Immediate Jeopardy

- Triggers
  - Failure to protect from abuse
  - Failure to prevent neglect
  - Failure to protect from psychological harm
  - Failure to protect from undue adverse medication consequences and/or failure to provide medications as prescribed
  - Failure to provide adequate nutrition and hydration to support and maintain health
  - Failure to protect from widespread nosocomial infections; e.g., failure to practice standard precautions, failure to maintain sterile techniques during invasive procedures and/or failure to identify and treat nosocomial infections
  - Failure to correctly identify individuals
  - Failure to safely administer blood products and safety monitor organ transplantation
  - Failure to provide safety from fire, smoke and environment hazards and/or failure to educate staff in handling emergency situations
### Immediate Jeopardy

**Decision Making:**
- Has actual harm occurred?
- Is there a likelihood of potential serious harm?
- Does the potential serious harm meet the definition of Immediate Jeopardy, e.g., serious injury, harm, impairment, or death?
- Is the potential serious harm likely to occur in the very near future, if immediate action is not taken?
- Did the facility have knowledge of the situation?
- If so, when did they first become aware? After the doctor’s order was written? Did they thoroughly investigate the circumstances?
- Did they implement corrective measures?
- Does this meet the definition of Immediate Jeopardy?
- Which is the most appropriate tag to define the failed practice?

### Immediate Jeopardy

**Process:**
- Survey team
  - Consensus re: IJ
  - Notify Survey Agency
  - Evaluate whether other enforcement bodies should be notified
- Survey agency
  - Determine whether concurrence with Team findings
  - Notify CMS Regional Office
- Survey team
  - Verbal notice of IJ to HHA
  - Includes details of risk and identity of individual at risk
  - Prior to leaving HHA

### Immediate Jeopardy

**Survey Agency Documentation**
- Confirmation of Removal of Immediate Jeopardy
  - Onsite confirmation only
- Immediate Jeopardy Removed, Deficient Practice Corrected
  - Cite on deficiency on CMS-2567 including corrective action
- Immediate Jeopardy Removed, Deficient Practice Present at Condition Level
  - Cite condition-level deficiency and start 90 day termination cycle
- Immediate Jeopardy Removed, Deficient Practice Present at Standard or Elemental Level
  - Cite IJ deficiency at condition-level; cite remaining deficiency
- Immediate Jeopardy Not Removed
  - Inform HHA that RO will be notified
  - Begin IJ termination process
Immediate Jeopardy: 488.825

- CMS takes immediate action to remove the jeopardy and correct the deficiency
- Sanctions and/or termination
- Termination unless deficiency resolved within 23 days of survey
- 2 day notice (except CMPs)
- Termination “no later than” 23 days after survey
- If terminated, patients must be transferred within 30 days
- NB: In 2011, there were 11 IJ terminations out of 5500 surveys

Immediate Jeopardy
Termination Schedule

- Date of Survey
  - When survey is completed regardless of exit conference date
- Second Working Day
  - SA Telephones RO certifying noncompliance
  - Written notification to provider that termination is recommended to RO
  - Overnight express mail, FAX, or email
- Third Working Day
  - SA sends full record to RO
  - RO makes determination
- Fifth Working Day
  - RO notifies provider
    - at least 2 calendar days prior to effective date of termination
    - Press release to newspapers or alternatively radio and TV stations
    - Can be stopped if compliance is achieved prior to publication
    - Public notice of termination retraction
- Tenth Working Day
  - If no deficiencies exist, SA sends notice of such to HHA, RO, and State Medicaid Agency
  - Twenty-third Calendar Day
    - Termination takes effect unless compliance achieved or threat removed
    - If IJ removed but condition-level deficiencies continue, 90-day termination cycle continues (67 remaining days)

Alternative Sanctions: 488.800 et seq.

- Condition-level deficiencies only
  - Repeat standard-level deficiencies may trigger condition-level finding
- CMS developing detailed guidance on sanction process in SOM
  - Progressive action approach
- Sanction determinations made by CMS RO
  - Survey recommendations
  - State agency recommendations
  - No CMP funds can be used to finance survey activities
  - Avoids “bounty hunter” risk
General Sanction Provisions: 488.810

- Sanctions imposed only for condition-level deficiencies
- Accrediting Organizations report condition-level findings to CMS RO
- Sanctions lead CMS and SA to take over oversight and enforcement
- Branch deficiencies counted against parent
- Subunit deficiencies do not apply to parent
- All deficiencies require a Plan of Correction
- CMS approval required
- Written notification of intent to impose sanction
- Appeal rights under 42 CFR Part 498
  - Penalties accrue during appeal, but collection delayed

Sanction Factors: 488.815

- Choice reflects "the impact on patient care and the seriousness of the HHA's patterns on noncompliance"
- Whether deficiencies pose immediate jeopardy to patient health and safety
- The nature, incidence, degree, manner, and duration of the deficiencies
- The presence of repeat deficiencies; compliance history in general and specific to cited deficiencies
- Whether deficiencies directly relate to patient care
- Whether the HHA is part of a larger organization with documented problems
- Whether the deficiencies indicate system wide failure

Available Sanctions: 488.820

- Civil Money Penalties (CMP)*
- Suspension of payment on new admissions*
- Temporary management*
- Directed plan of correction**
- Directed in-service training**

* required by statute
** required by regulation
Condition-Level Deficiencies w/o Immediate Jeopardy: 488.830

- "Incentives" for HHAs to achieve and maintain compliance
- 15 day notice of sanctions
- Termination and sanctions can be combined
- Sanctions continue until compliance or termination
- 6 month termination cycle
- Patient transfers within 30 days of termination

Temporary Management: 488.835

- When "deficiencies or the management limitations of the HHA are likely to impair the HHA's ability to correct deficiencies"
- CMS or agent appoints temporary management
- Termination of HHA if refusal to accept
- SA maintains list of recommended individuals
- At HHA expense
  - Prevailing salary
  - Other reasonable costs incurred
- Authority to hire, assign, fire staff, obligate HHA funds, change policies, manage HHA
  - Subject to HHA governing body
- No bond; no liability
- Failure to correct deficiencies within 6 months leads to termination

Suspension of Payments: 488.840

- Applies to new admissions after effective date of sanction
  - No greater than 6 months (termination if not corrected)
  - Written notice at least 2 days in advance in IJ and 15 days in other
  - HHA must notify prospective new patients of suspension
  - Charge to patient prohibited unless advance notice given
  - Suspension equals permanent loss of the payments, not just a hold on payment
  - Payment will be made on new episodes to existing patients
  - Mandatory with Immediate Jeopardy terminations
Civil Money Penalties: 488.845

- "per day" and "per instance" CMPs
  - "per day" = each day of noncompliance
  - "per instance" = single event corrected during the survey
- More than one CMP may be imposed during a survey
  - Per-day and per-instance not imposed simultaneously for same deficiency
- Total CMP cannot exceed $10,000 per day

Civil Money Penalties: 488.845

- Per instance CMPs: $1000-$10,000
- Per day CMPs: $500-$10,000; three tiers
- Factors considered
  - 488.5 factors
  - Size of the HHA
  - Accurate and credible resources such as PECOS, cost reports, claims information providing information on operations and resources of HHA
  - Evidence of built-in, self-regulating quality assessment and performance improvement system
  - Discretion to increase or decrease CMP at revisit

Civil Money Penalties: 488.845

- Three Tier System
  - Upper range: $8500-$10,000
    - Deficiency poses immediate jeopardy to patient health and safety
    - $10,000 per day where actual harm
    - $9,000 per day where potential harm
    - $8,500 per day for isolated employee incident in violation of HHA policy
Civil Money Penalties: 488.845

- Three tier system
  - Middle range: $1500-$8500 per day
    - Related of condition-level deficiencies that did not pose immediate jeopardy, but is directly related to poor quality patient care outcomes
  - Lower range: $500-$4000 per day
    - Repeated and/or condition-level deficiencies that did not constitute immediate jeopardy and were deficiencies in structures and processes that did not directly relate to poor quality patient care

### CMP fine ranges/Level of seriousness

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<thead>
<tr>
<th>CMP fine</th>
<th>ranges/amount</th>
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<tbody>
<tr>
<td>Immediate Jeopardy</td>
<td>$8,500-$10,000;</td>
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<tr>
<td>(Non-IJ) Patient Care Outcomes</td>
<td>2,500-$5,000;</td>
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<tr>
<td>Repeat Deficiency</td>
<td>8,500</td>
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<tr>
<td>42 CFR 484.18 Acceptance of Patients, Plan of Care, &amp; Medical Supervision</td>
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<td>42 CFR 484.30 Skilled Nursing Services</td>
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<td>42 CFR 484.34 Medical Social Services</td>
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<td>42 CFR 484.39 Home Health Aide Services</td>
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<td>42 CFR 484.55 Comprehensive Assessment of Patients</td>
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<tr>
<td>Structure or process issues</td>
<td>2,500</td>
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<tr>
<td>42 CFR 484.19 Patient Rights</td>
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<tr>
<td>42 CFR 484.12 Compliance With Federal, State and Local Laws, Disclosure and Ownership</td>
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<tr>
<td>Information, and Accepted Professional Standards and Principles</td>
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<tr>
<td>42 CFR 484.14 Organization, Services, and Administration</td>
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<tr>
<td>42 CFR 484.48 Clinical Records</td>
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</table>
Civil Money Penalties: 488.845

- Non-IJ Structure/process............................. 500-4,000
- Repeat Deficiency at revisit or from prior survey.... 4,000
- 42 CFR 484.11 Confidential OASIS Information....
- 42 CFR 484.16 Group of Professional Personnel...
- 42 CFR 484.20 Reporting OASIS Information....
- 42 CFR 484.52 Evaluation of the agency's program.
- First time deficiency................................. 500-3,000
- 42 CFR 484.11 Confidential OASIS Information....
- 42 CFR 484.16 Group of Professional Personnel...
- 42 CFR 484.20 Reporting OASIS Information....
- 42 CFR 484.52 Evaluation of the agency’s program.
- Other structure or process issues.................... 500-3,000
- Non patient care issues 42 CFR 484.34 Medical Social Services...
- 42 CFR 484.38 Qualifying to Furnish Outpatient Physical Therapy or Speech Pathology Services...

Civil Money Penalties: 488.845

- Written notice on intent to impose
  - Amount
  - Effective date
  - Final notice
  - Amount due
  - Interest rate
  - Nature of noncompliance
  - Statutory basis
  - Criteria considered
  - Date penalty accrues
  - When penalty would stop
  - When penalty collected
  - Appeal rights

Civil Money Penalties: 488.845

- Penalty start
  - Per-day: day of the survey that identified noncompliance
- Penalty ends: date of correction of all deficiencies/date of termination
  - Correction=revisit survey finding date
Civil Money Penalties: 488.845

- Appeal Rights: 42 CFR Part 498
- CMPs held pending outcome, but still accruing during appeal
  - Payment due 15 days after final administrative decision
- Written request for hearing w/in 60 days of notice
- Waiving right to appeal reduces CMP 35%
  - Payment due w/in 15 days of waiver request receipt
- IDR option
  - Request w/in 10 days of notice of penalty
- CMP may be offset against Medicare or Medicaid payments

Directed Plan of Correction: 488.850

- Requires HHA to take specific actions
  - If HHA fails to submit an acceptable Plan of Correction
- Sets out:
  - Outcomes to be achieved
  - Corrective actions needed
  - Specific date for performance
- If compliance not achieved in timeframes, other sanctions imposed

Directed In-Service Training: 488.855

- Where staff performance resulted in noncompliance
- May be imposed in combination with other sanctions
- Requires use of qualified instructors
  - No specific required training locations, but recommendations
- At HHA cost
Continuation of Payments: 488.860

- Payments may continue for up to 6 months for noncompliant HHA conditioned upon:
  - Survey agency finds more appropriate to impose alternative sanctions rather than terminate
  - HHA submits a Plan of Correction and it is approved by CMS/SA
  - HHA agrees to repay federal payments if corrective action not taken by time of revisit

Termination: 488.865

- Ends all payments and sanctions
- Termination if:
  - HHA failed to correct condition-level deficiencies w/in 6 months (non-IJ)
  - HHA failed to submit an acceptable Plan of Correction
  - HHA failed to relinquish control to the temporary manager, if applicable
  - HHA failed to meet qualifications for continued payments under 488.860

Provider Appeal Rights

- 42 CFR Part 498
- Informal Dispute Resolution
- Reconsideration
- Administrative Law Judge hearing
- Departmental Appeals Board
Informal Dispute Resolution: 488.745

- Informal opportunity to resolve disputes
- Available with condition-level deficiencies only
- CMS/state will provide written notification of deficiencies and IDR opportunity
- HHA must request IDR in writing
- Specify disputed deficiencies
- w/in 10 days of notice
- IDR does not delay enforcement process
- CMS to develop timeframes for action
- Left to State/CMS to design IDR
- Effective 7/1/14

IDR Implementation

- State Operations Manual, Chapter10 Section 10009
- IDR conducted by party that conducted survey (SA or RO)
- Process must be in writing and available for public review
- Counsel permitted
- Mandatory elements
  - Request in writing
    - w/in 10 calendar days
  - Not available to challenge survey process, severity assessment, sanction imposed, or immediate jeopardy decision
  - Limited to whether a condition-level deficiency exists

CONCLUSION

- Involuntary terminations on the rise slightly, including Immediate Jeopardy
- Alternative sanctions are serious!
  - Risk of a condition-level deficiency increased as penalties not limited to termination
- 2% of HHAs had condition-level deficiencies in 2011; 11 of 5500 subject to involuntary termination
- The operating guidelines in the SOM will be key