WHAT TO EXPECT IF YOUR FACILITY RECEIVES A "G" LEVEL OR ABOVE DEFICIENCY

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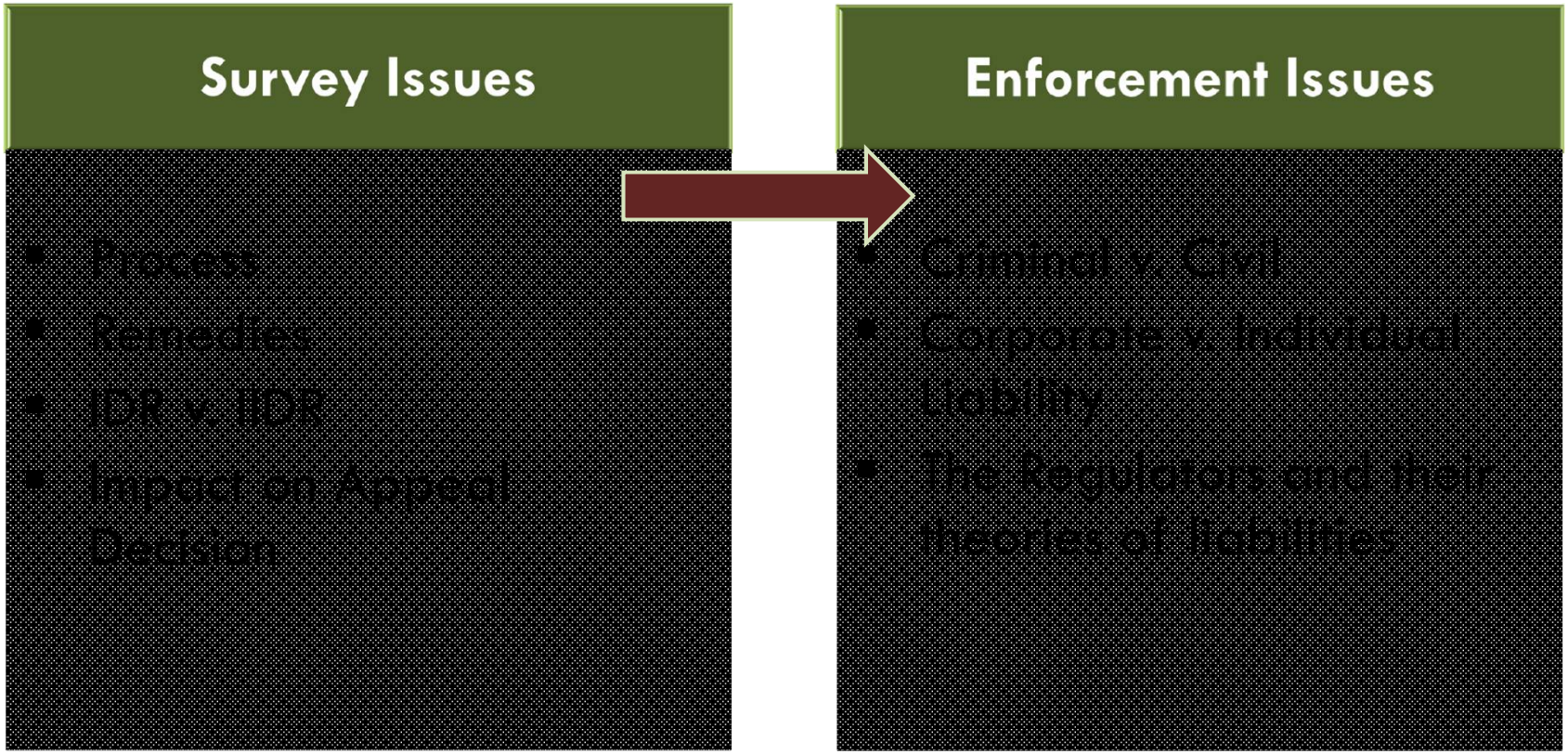
Challenging Regulatory Environment

- Aggressive and increasingly creative regulators
- Ever-increasing compliance demands and expectations
- Increasing penalties for missteps

Roadmap


Survey Issues
Process
Remedies
IDR v. IIOR
Impact on Appeal Decision
Enforcement Issues
Criminal v. Civil
Corporate v. Individual Liability
The Regulators and their theories of liabilities

Survey Process

- Survey
- Exit Conference
- If immediate jeopardy – DPH letter; possibly limited 2567 (addressing only IJ deficiencies)
- IJ lifted but Extended Survey
- Statement of Deficiencies (i.e. Form 2567) from Extended Survey issues with DPH letter
- Plan of Correction
- Re-survey (3 strikes)
- DPH substantial compliance letter
- CMS letters (timing and implications vary greatly)
- IDR and/or IIDR
- HHS Departmental Appeals Board (DAB) appeal

Where can signs of trouble arise?

- Pre-survey incident (and facility self-report)
- Survey
- Exit Conference
- DPH internal review (pre-2567)
- 2567 and accompanying DPH & CMS remedies letter
- Acceptance/rejection of POC
- Re-survey

Scope and severity grid

Deficiency Severity	Deficiency Scope		
	Isolated	Pattern	Widespread
Immediate jeopardy to resident health or safety	**J** POC Required: Cat. 3 Optional: Cat. 1 Cat. 2	**K** POC Required: Cat. 3 Optional: Cat. 1 Cat. 2	**L** POC Required: Cat. 3 Optional: Cat. 2 Cat. 1
Actual harm that is not immediate jeopardy	**G** POC Required:* Cat. 2 Optional: Cat. 1	**H** POC Required:* Cat. 2 Optional: Cat. 1	**I** POC Required:* Cat. 2 Optional: Cat. 1 Temporary Management
No actual harm with potential for more than minimal harm that is not immediate jeopardy	**D** POC Required:* Cat. 1 Optional: Cat. 2	**E** POC Required:* Cat. 1 Optional: Cat. 2	**F** POC Required:* Cat. 2 Optional: Cat. 1
No actual harm with potential for minimal harm	**A** No POC No Remedies Commitment to Correct	**B** POC	**C** POC

■ = Substantial compliance

POC = Plan of correction

▭ = Non-compliance that is not substandard care.

Cat. = Remedy category

▭ = Substandard quality of care is any deficiency in 42 CFR § 483.13, Resident Behavior and Facility Practices, 42 CFR § 483.15 Quality of Life, or 42 CFR § 483.25, Quality of Care.

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. 42 CFR Part 489.3.
- Deficiencies at levels J, K or L

Substandard Quality of Care (SQC) is any deficiency at the following levels:

- **J, K, L** - IJ level deficiencies
- **H, I** - actual harm level (pattern and widespread)
- **F -** no actual harm/potential for more than minimal (widespread)

And also in one of the following categories:

- **42 C.F.R. §483.13,** Resident Behavior and Facility Practices
- **42 C.F.R. §483.15** Quality of Life or
- **42 C.F.R. §483.25,** Quality of Care

DPH Letter with Notice of Immediate Jeopardy finding

- At least limited detail regarding IJ deficiencies
- Sometimes accompanied by preliminary 2567
- May demand specific corrective actions
- Requires submission of Allegation of Removal of Jeopardy
- 23 Day Clock to avoid termination of Medicare/Medicaid participation

DPH IJ Letter (cont'd) - Penalties

- Generally includes recommended federal remedies:
  - Most common:
    - Termination of provider agreement mandatory if jeopardy not removed within 23 days
    - Denial of payment for new admissions
    - CMPs (IJ range is $3,050 - $10,000 per day)

DPH IJ Letter (cont'd) - Penalties

- Also possible:
  - Temporary management;
  - Denial of payment for all Medicare and/or Medicaid residents by CMS (rarely imposed);
  - State monitoring;
  - Transfer of residents (generally upon closure);
  - Directed plan of correction;
  - Directed in-service training; and
  - Alternative or additional State remedies approved by CMS.

DPH IJ Letter (cont'd) - Penalties

- Will include any state remedies imposed:
  - Ban on all new admissions to facility
    - Includes re-admissions unless DPH consents
    - Generally imposed in IJ situations
      - Exception –retroactive IJ (i.e. past non-compliance/no POC required
  - Potential loss of DPH license
- Right to appeal state remedies
  - Notice of claim of adjudicatory hearing
  - 14 day deadline

Plan of Correction

- Corrective action begins immediately post-exit conference if possible
- Timely and aggressive response required
  - 23 day clock for IJ situation
  - 180 window to bring facility into substantial compliance
- Bring in outside/corporate resources if necessary to assist
- Important to ensure systemic checks to prevent recurrence
- DPH has rejected POCs on occasion – dialogue is critical

Revisits

- IJ – Generally need to get it right the first time because of limited time
- Be prepared as of date you allege removal of IJ (until re-survey)
- Often clear IJ but find that facility continues to not be in substantial compliance
  - Focus of visit is whether IJ is removed
  - **BUT** additional tags on revisit/extended survey are common

CMS Role

- CMS has ultimate authority
  - DPH as State Survey Agency (SSA) is only CMS' delegee to perform survey & regulatory functions re: Medicare rules
  - CMS has ultimate authority to determine violations
    - CMS can/does (rarely) overrule DPH
  - CMS can/does conduct its own surveys
  - CMS imposes federal remedies, including CMPs
- CMS issues letter(s) post-survey detailing violations/remedies/rights
  - Timing of CMS letters varies greatly

New CMS guidance – July 2016

"CMS is implementing national policy that requires the use of federal enforcement remedies when one or more residents suffer significant harm"

- Multiple categories of deficiencies now require immediate imposition of CMP with no opportunity to correct
  - All IJ deficiencies (i.e. J, K, L)
  - All Substandard Quality of Care (SQC) citations
  - All G Level Deficiencies in the SQC categories
    - (Resident Behavior; Quality of Life; Quality of Care)
  - G Level Deficiencies on Current Survey, plus actual harm citations on last standard survey OR actual harm citations on any intervening survey since last standard survey
  - Special Focus Facility (SFF) and F or higher level deficiency

Process when immediate CMPs required

- DPH enters survey results into ASPEN within 5 business days of notice to facility
- Immediate transfer to CMS Regional Office (RO) for review and sanction imposition
- CMS RO must impose CMPs
  - Factors taken into account include
    - Scope and severity
    - Relationship between deficiencies
    - Prior history of non-compliance
      - Generally
      - Specific survey citations

Remedies when immediate CMPs required

- DPH can both recommend and impose Category 1 remedies, including
  - Directed Plan of Correction
  - State monitoring
  - Directed in-service training
- CMS can impose the usual range of remedies
  - CMS can impose a state ban on admissions as to Medicare and Medicaid patients
    - But -- only DPH can impose a ban on admission of private pay patients

Immediate CMPs (cont'd)

- Once imposed (with proper notice), CMPs cannot be rescinded even if
  - Past non-compliance
  - IJ removed during the survey
  - IJ removed before 23rd day
- Exceptions:
  - Deficiency removed/reduced at IDR or IIDR
  - Successful appeal or settlement on appeal

CMS Post-survey letters

- May be initial and final letter
- Timing of issuance varies greatly
- Details violations and CMPs and other remedies
  - Different CMP amounts/periods for IJ and non-IJ deficiencies
- Details appeal rights and deadlines
  - Right to IIDR – 10 day deadline
  - Right to appeal to DAB –60 days from receipt of CMS letter
  - Right to 35% discount if waive appeal -60 days

IDR v. IIDR – Right to Review

IDR

- Informed of right to review by QIC (as SSA)
  - Longstanding process required by federal law
  - Permitted for essentially all deficiency citations
- 7 person panel
- Permitted review:
  - Factual findings that are predicated on evidence
  - Scope and severity – only if D or SQC
- Review not permitted:
  - Scope and severity – except as above
  - Remedy imposed by the enforcing agency
  - Survey process failures or differential treatment by surveyors
  - CMS actions generally or as applied

IIDR

- Informed of right to review by CMS
  - IIDR process created by PPACA in 2012
  - Available for all citations for which CMPs are assessed (D, SQC and G tags)
- 5 person panel
- Permitted review:
  - Factual findings that are predicated on evidence
  - Scope and severity – only if D or SQC
- Review not permitted:
  - Scope and severity – except as above
  - Remedy imposed by the enforcing agency
  - Survey process failures or differential treatment by surveyors
  - CMS or IIDR process generally or as applied

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IDR v. IIDR – Submission and processing

IDR	IIDR
• 10 day deadline to submit from receipt of DPH letter	• 10 day deadline to submit from receipt of CMS letter
• IE recommendation to DPH • DPH makes determination re IDR; shares CMS agreement	• If DPH disagrees, it writes up basis for disagreement and sends IIDR panel materials and its objection to CMS
• If IDR denied, no change in deficiency citation • Unless successful IIDR or appeal or settlement on appeal • NOTE – IDR results can be introduced in DAB appeal	• If IIDR denied, no change in deficiency citation • Unless successful appeal or settlement on appeal • NOTE – IDR/IIDR results can be introduced in DAB appeal
• Facility can request (within 2 days) (required to submit revised POC) • CMS and other remedies followed by CMS as appropriate	• Facility can request (within 2 days) (required to submit revised POC) • CMS and other remedies followed by CMS as appropriate

Choosing IDR v. IIDR

- Will you have a right to IIDR?
- Can you have both?
  - Generally, a facility cannot have both IDR and IIDR on same matter
  - EXCEPTION: if the IDR proceeding is completed prior to CMS affording right to IIDR, a facility can proceed with IIDR.
- Advantages/Disadvantages of DPH involvement
  - Participation in panel and right to overrule v. direct objection to CMS

IDR v. IIDR Options

- Do Not seek IDR and wait for IIDR right to be afforded
- Seek IDR and proceed to completion if possible
- If seek IDR and CMS affords IIDR right before completion of IDR, facility can either:
  - Proceed with IDR or
  - Withdraw IDR request and seek IIDR
    - Rules require withdrawal of IDR request before or at the time the IIDR is submitted

Timing of IDR/IIDR and Appeal Strategy

- Harm if results stand
  - Cost of CMPs
  - Inconvenience of various remedies (e.g. NATCEP)
  - Effect on 5 star rating
- Probability of success in IDR, IIDR or on appeal
  - Possibility of settlement on appeal
- Cost/benefit analysis
  - Time and expenses of various options
  - Ability to take advantage of 35% discount for waiver of appeal
    - IDR <u>may</u> be completed by 60 day waiver deadline; IIDR probably <u>will not</u> be completed by 60 day waiver deadline

New State Initiatives re Oversight of Long-Term Care Facilities

- DPH intent to impose fines for violation of state licensure regulations
  - Effective April 11, 2016
  - $50/day until corrected
  - DPH "staffing up" to inspect for these issues (and others)

New State Initiatives re Oversight of Long-Term Care Facilities cont'd

- Most common areas (and expected DPH focus):
  - Documentation of staff qualifications and training
  - Physical environment in dementia care units
    - Finishes
    - Outdoor spaces
    - Noise control
  - Qualifications/limitations on therapeutic activity directors
  - PT and OT services in Level II care
  - Emergency electrical systems
  - Substance Use Disorder (SUD)

Non-survey Implications of a Poor Survey

- Criminal liability
  - Corporate
  - Individual
- Civil liability
- Administrative liability and sanctions
- Ancillary effects
  - Licensure
  - Ability to participate in/be employed by federal health care programs

Elder Justice Task Force Targeting Nursing Homes

- March 30, 2016 US Department of Justice Initiative
- Includes federal, state and local prosecutors, law enforcement, and agencies that provide services to the elder
  - Modeled on joint DOJ/OIG Health Care Fraud Prevention and Enforcement Action Team (HEAT)
- PURPOSE: to coordinate and enhance efforts to pursue nursing homes that provide grossly substandard care to their residents
- Ten areas in the US – does not include Massachusetts

Potential Criminal Exposure

- US Department of Justice (DOJ)/US Attorney
  - False Claims Act
  - Mail/Wire Fraud
- Massachusetts Attorney General
  - Medicaid Fraud Control Unit (MFCU)
    - State False Claims Act
    - Theft
    - Assault

Potential Civil Liability Exposure

- US DOJ/US Attorney
  - False Claims Act
- Recent very large settlements
  - Oct. 2016 — $145M unnecessary rehab services
    - Individual and corporate liability
  - Oct. 2016 — $28M pharmacy kickbacks
  - Oct. 2016 — $2.5M unnecessary rehab services
    - Individual and corporate liability
  - Sept. 2016 — $2.2M unnecessary rehab services
    - Individual and corporate liability
  - Aug. 2016 — $52.7M inadequate staffing; PT services
  - Jan. 2016 — $125M unnecessary rehab services

New Frontier – False Claims Act and Escobar case (from Massachusetts)

- FCA imposes liability on "any person who . . . knowingly presents or causes to be presented, a false or fraudulent claim for payment or approval"
- Dispute re meaning of falsity -- false certification liability
  - "Express false certification"
    - Factually false statement
    - Liability is clear
  - "Implied false certification"
    - Submission of claim as implied certification that claim is valid and provider entitled to payment
    - "conditions of participation" v. "conditions of payment"

Escobar (cont'd)

- US Supreme Court decision:
  - Implied false certification is a viable basis for liability at least where
    - The claim submitted requests payment and "makes specific representations about the goods and services provided" and
    - The provider's "failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths"
  - Key issue:
    - "What matters is . . . whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision"
    - Knowledge includes
      - Actual knowledge
      - Reckless disregard or
      - Deliberate indifference

Individual Liability and the Yates Memorandum

- Hold individuals responsible for corporate fraudulent activities
  - To obtain any "cooperation credit", corporations must provide all relevant facts relating to the individuals responsible for the misconduct;
  - Criminal and civil corporate investigations should focus on individuals from the inception of the investigation;
  - Absent extraordinary circumstances or approved departmental policy, the Department will not release culpable individuals from civil or criminal liability when resolving a matter with a corporation;
  - Inability to pay may not be sufficient to excuse individual liability
- Relevant to both criminal and civil liability
  - To date, liability has been imposed primarily in civil settlements

Civil liability and the Massachusetts Attorney General

- Franvale case
  - Billing while not in substantial compliance with program requirements
    - Especially while in IJ or SQC status
  - AG claims for violation of
    - Medicaid False Claims Act (G.L.c. 118E, §§40; 130 CMR 450.101)
    - Patient Abuse Prevention Act (G.L. c. 111, § 72F)
    - Patient Abuse Neglect, Mistreatment statute (G.L. c 265, §§ 13K, 38)
    - Long term care regulations (105 CMR 150.000; 42 CFR 483.1)
    - Breach of provider agreement

Civil liability and the Massachusetts Attorney General (cont'd)

- Recent AG Actions
  - Massachusetts Unfair Trade Practices Act, G.L. c. 93A
    - AG authority to
      - sue for injunctive relief
      - seek penalties of up to $5000 per violation, plus costs of investigation and reasonable attorney's fees
    - Very expansive interpretation of AG authority under statute:
      - Any violation of any existing state or federal statute, rule or regulation which provides protection to or for residents or prospective residents of long-term care facilities
    - Per the AG, the only limiting principle is the AG's discretion

Board of Registration

- Board of Registration of Nursing Home Administrators (NHA)
  - Many matters wind up at the board
    - Receive all surveys with IJ or SQC citations
    - Increasing use of "systems" tags and cross-tagging
  - Board looking to ensure that administrators are competent, knowledgeable and actively engaged in managing their facilities
- Board of Registration in Nursing
- Board of Registration in Medicine
- Board of Registration in Social Work

NOTE: License discipline could lead to exclusion from federal health care programs

Regulatory Priorities: Dementia Care

- DPH initiative: Dementia Care Units (DCU)
  - Special state requirements for facilities and operation of DCU
    - Specialized Training
    - Activities
    - Physical plant requirements
  - Constraints as to how non-DCUs can advertise their services

Regulatory Priorities: Dementia Care

- CMS initiative: Dementia Care Surveys
  - Focused surveys undertaken by federal contractor
- Priorities include
  - Assessment
  - Care planning
  - Activities
  - Antipsychotic medications
- Note that IDR/IIDR process for federal survey run by federal contractor
  - Completely paper process with no opportunity to see discussion by decision-makers

Regulatory Priorities: SUD

- Substance Use Disorder (SUD)
  - Particular challenges of dealing with substance users/abusers
    - Need for specialized training and staff
    - Need for substantial non-medical care planning
      - Psychosocial, etc.
    - Limited availability of treatment options
    - Challenges in obtaining treatment medications (i.e. suboxone or methadone)
    - Limitations posed by state and federal regulations
      - Limited ability to search residents or visitors
      - Limited ability to limit visitation
      - Limitations on ability to promptly discharge a resident
  - Need for caution in attempting to serve those with active or past history of substance use/abuse, especially if not in active treatment

What to Do

- Systematic review of policies and procedures
- Systematic review of actual practices
- Substantially enhance compliance programs and systems

Think about ways to adapt and replicate the types of systems that hospitals/large health care providers use

Questions?

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