

Final ROP: Things You Need To Do And Suggestions On How To Get Them Done

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Overview of Presentation

- Overview of Substantive Changes in the Final Rule
 - Person Centered Care;
 - Staffing & Competency;
 - Changing Patient Population And Care Needs;
 - Resident Rights;
 - New Grievances Requirements;
 - Discussion about Abuse, Neglect, and Incident Reporting, Timeframes, and Overlaps;

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Overview of Presentation

- Overview of Substantive Changes in the Final Rule
 - QAPI Requirements.
 - Compliance & Ethics;
 - Survey And Enforcement; and
- Policy Writing – Tips, Suggestions And Plan of Attack

Note: The presenters thank the American Health Care Association and in particular, Dr. David Gifford for permission to use various materials and slides with this presentation.

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Overview of Changes in Final Rule

Overview of Changes in Final Rule

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- ### Changes to ROP Sections Within Final Rule
- Basis & Scope(§ 483.1)
 - Definitions (§ 483.5)
 - Resident Rights (§ 483.10)
 - Abuse & neglect, (§ 483.12)
 - Admission, transfer, and discharge rights (§ 483.15)
 - Resident assessment (§ 483.20)
 - Comprehensive person centered Care planning (§ 483.21)
 - Quality of life (§ 483.24)
 - Quality of care § 483.25)
 - Physician services (§ 483.30)
 - Nursing services (§ 483.35)
 - **Behavioral health services (§483.40)**
 - Pharmacy services (§ 483.45)
 - Laboratory, radiology, and other diagnostic services (§ 483.50)
 - Dental services (§ 483.55)
 - Food & nutrition services (§ 483.60)
 - Specialized rehabilitative services (§ 483.65)
 - Administration (§ 483.70)
 - **Quality assurance and performance improvement (§483.75)**
 - **Infection control (§483.80)**
 - **Compliance and ethics (§483.85)**
 - Physical environment (§ 483.90)
 - Training requirements (§ 483.95)
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- ### Phase 1: *Effective Date* of the Final Rule (11-28-16)
- Phase 1
- Phase 1 (* this section is partially implemented in Phase 2 and/or 3)
- | | |
|---|---|
| <ul style="list-style-type: none"> - Resident Rights and Facility Responsibilities* - Freedom from Abuse Neglect and Exploitation* - Admission, Transfer and Discharge* - Resident Assessment - Comprehensive, Person-Centered Care Planning* - Quality of Life - Quality of Care* - Physician Services | <ul style="list-style-type: none"> - Nursing Services* - Pharmacy Services* - Laboratory, radiology and other diagnostic services - Dental Services* - Food and Nutrition* - Specialized Rehabilitation - Administration (Facility Assessment – Phase 2)* - Quality Assurance and Performance Improvement* - QAA Committee - Infection Control – Program* - Physical Environment* |
|---|---|
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Phase 2: 1 Year Delayed Effective Date (Nov. 2017)
Phase 3: 3 Year Delayed Effective Date (Nov. 2019)

Phases 2 and 3

Phase	Primary Implementation
Phase 2	<ul style="list-style-type: none">Behavioral Health Services*Quality Assurance and Performance Improvement* - QAPI PlanInfection Control – Facility Assessment and Antibiotic Stewardship **Physical Environment- smoking policies *
Phase 3	<ul style="list-style-type: none">Quality Assurance and Performance Improvement* - Implementation of QAPIInfection Control – Infection Control Preventionist *Compliance and EthicsPhysical Environment- call lights at resident bedside *Training *

*This section is partially implemented in other phases.

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Significant Changes

- Person Centered Care;
- Staffing & Competency;
- Changing Patient Population And Care Needs;
- Resident Rights;
- New Grievances Requirement and Documentation Risks
- QAPI Requirement and Survey Issues
- Discussion about Abuse, Neglect, and Incident Reporting, Timeframes, and Overlaps;
- Compliance & Ethics.

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Person Centered Care Person Centered Care

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Person Centered Care

- Resident Representative Changes;
- 48-Hour Baseline Care Plan;
- Comprehensive Care Plan;
- Discharge Planning Process.

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**Changes in Resident Representative
(§ 483.10(b)(1-4))**

- Representative has the right to exercise the resident's rights to the extent those rights are properly delegated to them;
- Resident retains those rights not delegated, including the right to revoke a delegation;
- Must treat Representative decisions as decisions of the Resident BUT not beyond what is required by court or delegated by Resident; and
- Must report concerns that Representative not acting in best interests of Resident.

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48-Hour Baseline Care Plan

- New requirement - Phase 2
- Initial set of instructions to facilitate smooth transition of care and to provide effective, person-centered care starting at admission

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48-Hour Baseline Care Plan

- Minimum of 6 key elements:
 - Initial goals based on admission orders;
 - All physician orders, including medications and administration schedule;
 - Dietary orders;
 - Therapy services;
 - Social services; and
 - PASARR recommendations, if PASARR completed.
- Could be replaced by the comprehensive care plan if done within 48 hours of admission.

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Comprehensive Care Plan (§ 483.21)

- Phase 1 requirement
- Develop and implement a comprehensive, person-centered care plan for each resident, consistent with the resident rights set forth in the ROPs:
 - Include measurable objectives and timeframes to meet resident's needs (medical, nursing, mental and psychosocial) as identified in the comprehensive assessment;
 - Describe at a high level services to be provided as well as resident's goals and preferences;
- Include summary of resident's strengths, goals, desired outcomes, life history, personal and cultural preferences, PASARR findings and specialized services needed.

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Comprehensive Care Plan

- Prepared and reviewed by IDT that now must include, in addition to attending physician and RN with responsibility for that resident, nurse aide and member of food and nutrition services:
 - Include resident and their representative(s) to the extent practicable; document an explanation if not practicable
- Reviewed or revised after comprehensive assessment and quarterly review assessment

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Comprehensive Care Plan

- Rooted in resident's rights (483.10(c))
 - Participate in developing the plan, be informed of the care to be provided, and participate in decision-making, in language he or she can understand;
 - Identify individuals and roles to participate, request meetings, request revisions to plan;
 - Participate in establishing goals and expected outcomes of care, including duration, frequency, type, and amount;
 - Be informed of care options, risks, benefits, alternatives.

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Comprehensive Care Plan

- Rooted in resident's rights (483.10(c)) (con't.)
 - Refuse or discontinue treatment;
 - Self-administer meds if IDT determines clinically appropriate;
 - Be informed in advance of changes to the plan;
 - Receive the services in the plan; and
 - Review and sign off on significant changes.

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Discharge Planning Process (§ 483.15)

Purpose & Intent

- Partner with the resident to maximize the likelihood that they may be able to return to the community, if they want to, without complications.

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Discharge Planning Process #1

Required steps

- Create an IDT which includes the resident;
- Evaluate the resident's discharge potential, goals, and needs;
- Document results of discharge plan;
- Create a discharge plan (see below for required content);
- Update discharge plan;
- Share discharge plan with the resident

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Discharge Planning Process #1 (con't.)

- Prepare resident & their representative for discharge;
- Notify Ombudsman of *all* discharges and transfers;
- Document reason for discharge or transfer
- Provide required information to receiving provider; and
- Complete a discharge summary.

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Information Accompanying Resident at Discharge or Transfer

- Ensure specified information is copied and available to go with resident:
 - Contact information of practitioner responsible for care;
 - Resident representative information;
 - Advance Directive Information;
 - Special instructions or precautions;

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Information Accompanying Resident at Discharge or Transfer

- Ensure specified information is copied and available to go with resident: (con't.)
 - Most recent comprehensive care plan goals;
 - Resident's discharge summary;
 - Other documents as needed; and
 - Resident's consent to share information.
- Develop checklist to ensure all required information is sent

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Discharge Summary Template: Phase 1 Requirement

- Key elements:
 - Recapitulation of stay (diagnoses, pertinent lab tests and results, course of illness/treatments/therapy);
 - Final summary of resident's status (specified items from comprehensive resident assessment, including needs, strengths, goals, preferences);

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Discharge Summary Template: Phase 1 Requirement

- Key elements: (con't.)
 - Medication reconciliation;
 - Post-discharge plan of care (where individual will reside, arrangements for follow-up care, consent to share discharge summary); and
 - Other elements as determined by facility.

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Staffing & Competency

Staffing & Competency

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**Staffing and Staff
Competency Requirements**

- Quality of Care (§ 483.25);
- Nursing Services (§ 483.35);
- Administration (§ 483.70); and
- Training Requirements (§ 483.95).

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Rule Text:

§ 483.25 Quality Of Care- "Quality of care is a fundamental principle that applies to all treatment and care provided to facility residents. **Based on the comprehensive assessment of a resident**, the facility must ensure that residents receive treatment and care in accordance with professional standards of practice, the comprehensive person-centered care plan, and the resident's choices, including but not limited to the following":*

- Vision & Hearing;	- Prostheses;
- Skin Integrity;	- Pain Management;
- Mobility;	- Dialysis;
- Incontinence;	- Trauma Informed Care;
- Assisted Nutrition & Hydration;	- Bed Rails
- Respiratory Care;	

* Emphasis supplied

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Quality Of Care

- Very specific requirements on addressing certain conditions;
- All implemented in Phase 1 except trauma informed care (Phase 3); and
- “Based on the comprehensive assessment of a resident”
–Common phrase throughout the rule.

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Rule Text on Resident/Facility Assessment

- § 483.35 (Nursing Services) - The facility must have sufficient nursing staff with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at 483.70(e).

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Rule Text on Resident/Facility Assessment

- § 483.70(e) Facility assessment. The facility must conduct and document a facility wide assessment to determine what resources are necessary to care for its residents competently during both day to- day operations and emergencies. The facility must review and update that assessment, as necessary, and at least annually. The facility must also review and update this assessment whenever there is, or the facility plans for, any change that would require a substantial modification to any part of this assessment. The facility assessment must address or include: [resident population, facility resources, and a facility and community based risk assessment, utilizing an all hazards approach.

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Competencies of Staff and Assessments

- Adds a “competency” requirement for determining the “sufficiency” of nursing staff, based upon facility assessment:
 - which includes but is not limited to the number of residents, resident acuity, range of diagnoses, and the content of individual care plans.

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Competencies of Staff and Assessments

- Facility must ensure staff competency in providing treatment and care in accordance with professional practice; and
- Must review the current processes around vision & hearing, skin integrity, mobility, incontinence, colostomy, urostomy & ileostomy, assisted nutrition & hydration, parenteral fluids, respiratory care, prostheses, pain management, dialysis, trauma informed care, and bed rails.

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Training Requirements (§ 483.95)

- Largely Phase 3, except Phase 1 requires:
 - Abuse/Neglect/Exploitation (c)
 - Dementia Management expanded beyond nurse aides to other direct staff (g)(2)
 - Care of the cognitively impaired (g)(4)
 - Feeding Assistant requirement. (See p. 68870)

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**Changing Patient Population
and Care Needs**
**Changing Patient Population
And Care Needs**

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**Changing Patient Population
and Care Needs**

- Physical environment must accommodate patient population and care delivery innovation;
- Physician services;
- Pharmacy needs addressed;
- Infection control; and
- Behavioral health.

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Physical Environmental (§ 483.90)

- Center must be equipped to allow residents to call for staff through a communication system which relays the call directly to a staff member or to a centralized staff work area from each resident's bedside;
- Establish policies regarding smoking, smoking areas and smoking safety that also considers non-smoking residents; and
- Conduct regular inspection of all bed frames, mattresses, and bed rails, to identify areas of possible entrapment.

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Physical Environmental (§ 483.90)

- Any facility newly certified or approved for construction (including remodeling) after November 28, 2016, must have bedrooms with no more than two residents AND must have a private bath including at least a toilet and sink for each resident room:
 - A bathroom that is located between two patient rooms and is accessible from each does not meet this requirement; and
 - For purposes of this requirement, a “renovated or remodeled area” means an area that requires residents to be moved out of the area to complete work:
 - For example, if a facility is conducting a major renovation on a wing and all patients must be relocated, included in that renovation must be eliminating any 4-bed rooms and ensuring that each patient room is equipped with its own bathroom including at least a sink and a toilet.

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**Physician Services (§ 483.30)
Phase 1**

- CMS Summary: We are allowing attending physicians to delegate dietary orders to qualified dietitians or other clinically qualified nutrition professionals and therapy orders to therapists.
- Additional Highlights:
 - The attending physician can delegate the writing of order to Dietician and to therapists per their state’s scope of practice; NPs and PAs and covering physicians cannot delegate authority; only the attending physician.

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**Physician Services (§ 483.30)
Phase 1**

- Additional Highlights:
 - Physician must approve an admission however an NP or PA can now write the admitting orders

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Intent & Purpose (§ 483.45)

Reduce medication prescribing and administration that increases the risk of adverse events in elderly

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Pharmacy Services (§ 483.45)

- The pharmacist must review a resident's medical chart during each monthly drug regimen review;
- Revision of existing requirements regarding "antipsychotic" drugs to refer to "psychotropic" drugs with requirements to reduce or eliminate their need;
- New MRR process where pharmacist must identify and documents "irregularities";

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Pharmacy Services (§ 483.45)

- Must provide a written report regarding irregularities to the attending physician, medical director, and DON; and
- The attending physician must document: that he/she reviewed the identified irregularity, the action taken to address the irregularity, or the reason for not changing the medication related to the identified irregularity.

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Drug Regime Review Process

Phase I

- Need a Drug regime review P&P
 - **psychotropic drug** defined;
 - “**irregularity**” defined;
- Training to staff and physicians/prescribing practitioners on monthly drug regimen (review P&P and new regulatory requirements);

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Drug Regime Review Process

- Audit monthly DRR, medication error rates to be consistent with policies, procedures and regulatory requirements; and
- Must Incorporate identified areas for process improvement into QAPI.

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“Irregularity” Defined

What is considered an irregularity (e.g. including, but not limited to, unnecessary drug criteria):

- Excessive dose (including duplicate drug therapy);
- Excessive duration;
- Without adequate monitoring;
- Without adequate indications for its use; and
- Use in presence of adverse consequences which indicate dose should be reduced or discontinued.

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Change Psychotropic Medication

A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories:

- (i) Anti-psychotic;
- (ii) Anti-depressant;
- (iii) Anti-anxiety; and
- (iv) Hypnotic.

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Infection Control (§ 483.80)

▪ CMS Summary: We are requiring facilities to develop an Infection Prevention and Control Program (IPCP) that includes an Antibiotic Stewardship Program and designate at least one Infection Preventionist.

- Additional Highlights:
- Expanded required elements of facility IPCP.
 - Annual review of facility IPCP and update program as necessary.

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Infection Control

- Additional Highlights: (con't.)
- Specific qualification requirements for Infection Preventionist.

 - Infection Preventionist must be member of QAA committee and report on IPCP on a regular basis.

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Laboratory, Radiology, and Other Diagnostic Services (§ 483.50)

- Facility must promptly notify the ordering physician, PA, NP, or clinical nurse specialist of lab results that fall outside of clinical reference ranges in accordance with facility policies and procedures for notification of a practitioner or per the ordering physician's orders; and
- Physician extenders can order radiology and other diagnostic services and must be promptly notified of results falling outside of clinical reference ranges in accordance with facility policies and procedures.

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Behavioral Health Services (§ 483.40)

- Develop and implement process to meet requirements at § 483.40 (b)(1) and (b)(2) related to providing services to a resident to correct an assessed problem related to mental disorder or psychosocial adjustment difficulty and, if an assessment did not reveal a mental or psychosocial adjustment difficulty, prevent an occurrence of such in a resident if clinically unavoidable;
- Facility must provide medically-related social services for highest practicable well-being as necessary; and
- Also dementia training to all direct staff (see § 483.95).

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Resident Rights

§ 483.10 Resident Rights

- Reasonable access to electronic communication
- Advance directives § 483.10(b)(8)
- Develop Grievance policy with “grievance official”
- Revise visitation rights;
- Accommodate needs of LGBT residents and same sex spouses;
- Pre-dispute Arbitration Prohibition???

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Resident Rights – Facility Responsibilities

- Planning and implementing care: Places much more emphasis on person-centered care and the inclusion of residents in the care planning process;
- Affirmative action to inform residents of a change of physician;
- Written policies and procedures regarding visitation and restrictions visitation rights, including any clinically necessary or reasonable restriction or limitation or safety restriction or limitation when consistent with the regulations;

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Resident Rights – Facility Responsibilities

- New rules regarding deposit of residents’ funds and notices;
- 3 years of survey and complaint documents available;
- Posting of a list of agencies and advocacy groups; and
- 60 days advance notice when there are changes in charges.

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Grievances and Grievance Process

**Grievances and Grievance Policies
(§ 483.10(j))**

- Incorporates the facility responsibilities at existing § 483.10(f) and require that facilities ensure that residents know how to file grievances;
- Must establish a grievance policy to ensure the prompt resolution of grievances;
- Identify a Grievance Officer;
- Provide a copy of this policy upon request, as well as make information about filing grievances available to residents;

**Grievances and Grievance Policies
(§ 483.10(j))**

- Written Grievance Decisions –
 - Date grievance received and summary of resident's grievance;
 - Steps taken to investigate the grievance;
 - Summary of the pertinent findings or conclusions regarding concerns;
 - Statement as to whether the grievance was confirmed or not confirmed;
 - Any corrective action taken or to be taken by the facility as a result of the grievance; and
 - Date of written decision.

**Grievances and Grievance Policies
(§ 483.10(j))**

Facility *required to take a number of actions in response to a grievance*, including:

- Preventing further violations of resident rights during an investigation;
- *Immediately reporting allegations* of neglect, abuse (including injuries of unknown source), and/or misappropriation of resident property, by anyone furnishing services on behalf of the facility, to the administrator of the facility and as required by state law;

**Grievances and Grievance Policies
(§ 483.10(j))**

- Ensuring that all *written grievance decisions* include the required information;
- Taking *appropriate corrective action* in accordance with state law if the alleged violation of the residents' rights is confirmed by the facility or if an outside entity having jurisdiction confirms a violation of any of these residents' rights within its area of responsibility; and
- Maintain *3 years of decisions* (... "evidence demonstrating the resolution of complaints and grievances").

**42 C.F.R. § 483.10(j) –
Grievances and Grievance Policies**

- Develop Policy and Procedure related to Grievance policy; and
- Establish a process for responding to grievances by family and or residents.

Reporting on Allegations of Abuse / Neglect / Exploitation / Injuries of Unknown Origin (A/N/E/loUO)

Knowledge Check

- The new rule says reasonable suspicion of a crime and all allegations of A/N/E must be reported in how long:
 - A) All A/N/E immediately, and crimes within 24 hours;
 - B) Abuse within 2 hours and crimes within 5 days;
 - C) It depends on how serious the crime or A/N/A allegations are;
 - D) None of the above.

Freedom From Abuse, Neglect, and Exploitation (A/N/E) (§ 483.12)

- Facilities Obligations:
 - Have a process for ensuring that residents are free or at the least restrictive level of chemical restraints;
 - Have a process for ensuring that staff are qualified and in good standing;
 - Develop P&P related to the prohibition of abuse, neglect and exploitation; and
 - Train staff on abuse, neglect and exploitation.

New Definitions Around Abuse, Neglect, and Exploitation (A/N/E)

- “abuse”
- “adverse event”
- “exploitation”
- “misappropriation of resident property”
- “mistreatment”
- “neglect”
- “person-centered care”
- “resident representative”
- “sexual abuse”

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Freedom From Abuse, Neglect, and Exploitation (A/N/E/loUO) (§ 483.12)

Note change in reporting timing:

(c)(1) In response to allegations of abuse, neglect, exploitation, or mistreatment, the facility must ... Ensure that all alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property, are *reported immediately, but not later than 2 hours after the allegation is made, if the events that cause the allegation involve abuse or result in serious bodily injury*, or not later than 24 hours if the events that cause the allegation do not involve abuse and do not result in serious bodily injury, to the administrator of the facility and to other officials (including to the State Survey Agency and adult protective services where state law provides for jurisdiction in long-term care facilities) in accordance with State law through established procedures.

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Reporting Requirements – Keeping Them Straight

- The final rule has included Elder Justice Act reporting obligations, as well as reporting obligations in situations of abuse, neglect, exploitation, mistreatment, injuries of unknown origin and misappropriation; and
- Time frames to report to State Agency abuse and serious bodily injury is much shorter than was previously the case.

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Elder Justice vs State Reporting Obligations

ELDER JUSTICE ACT REPORTING TO THE STATE AGENCY AND LAW ENFORCEMENT	TIMEFRAME FOR REPORTING ABUSE, NEGLIGENCE, ETC to the STATE AGENCY ENFORCEMENT
Must report to Law Enforcement and The State Agency events which cause reasonable suspicion that a crime has been committed which results in serious bodily injury within two 2 hours .	Alleged violations of abuse or events which result in serious bodily injury must be reported immediately to the State Agency, but not later than two (2) hours after the allegation is made.
Must report to Law Enforcement and the State Agency events which cause reasonable suspicion that a crime has been committed which does not result in serious bodily injury within twenty-four (24) hours.	Alleged violations of neglect, exploitation, mistreat, including injuries of unknown origin or allegations that do not involve abuse or result in serious bodily injury must be reported to the State Agency not later than twenty-four (24) hours after the allegation is made

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Examples

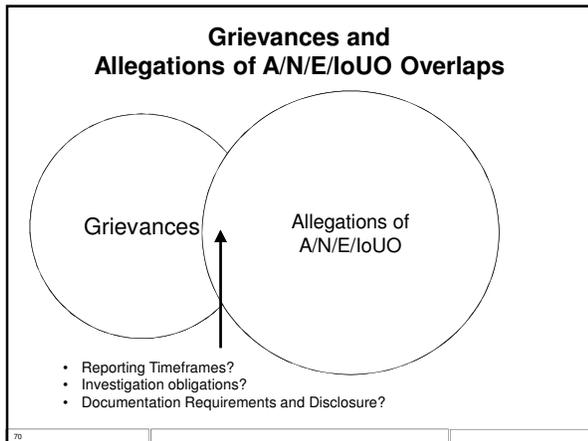
EXAMPLES	ELDER JUSTICE ACT	STATE AGENCY REPORTING
Theft of money	Yes, within 24 hours	Yes, within 24 hours
Assault with serious injury	Yes, within 2 hours	Yes, within 2 hours
Unwitnessed Fall without serious injury	No, unless suspicion of a crime	Yes, within 24 hours
Small bruise	Yes, if suspicion of a crime. No, if no suspicion of a crime	Yes, within 24 hours
Damage to wheelchair	Yes, if suspicion of a crime (intentional damage to property), No, if damage does not create reasonable suspicion of a crime	No

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Examples

EXAMPLES	ELDER JUSTICE ACT	STATE AGENCY REPORTING
Resident left on bed pan for three hours	No, unless suspicion of a crime (criminal neglect?)	Within 2 hours if serious bodily injury. Within 24 hours if no injury
Alleged verbal abuse	Yes, within 24 hours	Within 2 hours
Resident fails to receive medication	No, unless suspicion of a crime (criminal neglect?)	Within 24 hours, unless serious bodily injury

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QAPI (Quality Assurance and Performance Improvement)

Quality Assurance and Performance Improvement (§ 483.75)

- CMS Final Rule (Phase 3 implementation November 2019):
 - “We are requiring all LTC facilities to develop, implement, and maintain an effective comprehensive, data-driven QAPI program that focuses on systems of care, outcomes of care and quality of life.”
- CMS explains in the preamble discussion that proposed 42 C.F.R. § 483.75 would “establish [the] programmatic standards” “relating to facilities’ QAPI program[s]” required by Section 6102 of the Affordable Care Act (“ACA”).

Quality Assurance and Performance Improvement (§ 483.75)

- 483.70(d) Governing body.
....(3) The governing body is responsible and accountable for the QAPI program, in accordance with § 483.75(f). [§ 483.70(d)(3) will be implemented beginning November 28, 2019 (Phase 3)]

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Quality Assurance and Performance Improvement (§ 483.75)

- QA&A committee – all provisions except the inclusion of the infection prevention control officer (note: this term varies throughout the rule and AHCA will request clarification from CMS);
- State may not require disclosure of the records of the committee except related to requirements of the committee (e.g., who is on committee; that committee meets as required; etc.); and
- Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.

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QAPI – Documentation and Survey Access To It

- (a) ...The facility must—
- 1) *Maintain documentation and demonstrate evidence of its ongoing QAPI program that meets the requirements of this section. This may include but is not limited to systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events; and documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities;*
 - 2) Present its QAPI plan to the State Survey Agency no later than 1 year after the promulgation of this regulation;

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QAPI – Documentation and Survey Access To It

- (a) ...The facility must— (con't.)
- 3) Present its QAPI plan to a State Survey Agency or Federal surveyor at each annual recertification survey and upon request during any other survey and to CMS upon request; and
 - 4) *Present documentation and evidence of its ongoing QAPI program's implementation and the facility's compliance with requirements* to a State Survey Agency, Federal surveyor or CMS upon request.

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CMS Excerpts in Response to Final Rule Comments (p.68805-7)

- We have attempted to strike an appropriate balance between concerns about inappropriate use of QAPI materials and our obligation to provide effective oversight of Medicare and Medicaid participating facilities.
- The expectation that facilities will implement a QAPI program that meets those standards is clear, and facilities must be able to demonstrate that they have implemented their QAPI plan and have an effective, ongoing QAPI program.

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CMS Excerpts in Response to Final Rule Comments (p.68805-7)

- It is not our intent that a facility lose existing protections for QAA documents, including those established under state law, nor do we intend to create a punitive environment or increase litigation. At the same time, we cannot ignore our obligation to ensure that facilities implement their QAPI plan, and continue to modify and implement that plan over time. What we require is satisfactory evidence that a facility is implementing its QAPI plan and maintaining an ongoing QAPI program. We further articulated in the proposed rule what sort of evidence and documentation we believe may be necessary to demonstrate compliance.

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<p>Compliance & Ethics</p>
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<p>Compliance and Ethics Program (§ 483.85) Phase 3</p>
<ul style="list-style-type: none">▪ Must have written standards for compliance and clear reporting path for suspected violations of compliance and ethics; ▪ Must designate a compliance and ethics contact; ▪ Must identify a high level person to oversee with the program; ▪ Sufficient resources and authority to oversee compliance;
<p>80</p>

<p>Compliance and Ethics Program (§ 483.85) Phase 3</p>
<ul style="list-style-type: none">▪ Effective communication of compliance standards to all staff; ▪ Audit and monitoring system; ▪ Publicize a reporting system; ▪ Annual review of compliance and ethics program and its efficacy;
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**Compliance and Ethics Program (§ 483.85)
Phase 3**

- Consistent enforcement through appropriate disciplinary action;
- Mandatory annual training on compliance and ethics; and
- Designate Compliance liaisons in each facility.

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Survey and Enforcement

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Terminology

- CMP – Civil money penalty
- CMS – Centers for Medicare and Medicaid Services
- DPNA – Denial of payment for new admissions
- IJ – Immediate jeopardy
- PD – Per day
- ROPs - Requirements of Participation
- S/S –Scope and Severity
- SNF – Skilled nursing facility
- SQC – Substandard quality of care
- SSA – State survey agency
- 2567 – Statement of deficiencies

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Poll

- Should Compliance be involved in the survey process?
- Do you get survey information?
- Does your Board get survey information?

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Increased Enforcement a Reality

- Marked increase in citations and sanctions
- *Marked increase in CMS civil money penalties*



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Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015

- Intended to improve “effectiveness” of CMPs and maintain “deterrent effect” of CMPs
- Requires annual “adjustment” of CMPs using October Consumer Price Index for all Urban Consumers (CPI-U)
- First increase was in 2016; most recent increase effective February 3, 2017 (82 Fed. Reg. 9174, 2/3/2017)

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Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015

- Secretary of covered agency may provide lesser CMP by less than the new formula through a rulemaking only if:
 - Secretary finds that increasing penalty by required amount will have a negative economic impact or that the social costs outweigh the benefits and
 - Director of the Office of Management and Budget (OMB) concurs with this analysis

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Impact of Inflation Adjustment Act

- CMS CMPs for surveys have increased astronomically

	Pre-August 2016	August 1, 2016	February 3, 2017
Cat.2 Per Day	\$50 - \$3,000	\$103 - \$6,188	\$105 - \$6,289
Cat. 2 Per Instance	\$1,000 - \$10,000	\$2,063 - \$20,628	\$2,097 - \$20,965
Cat. 3 Per Day	\$3,050 - \$10,000	\$6,291 - \$20,628	\$6,394 - \$20,955
Cat. 3 Per Instance	\$1,000 - \$10,000	\$2,063 - \$20,628	\$2,097 - \$20,965

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Federal Scope and Severity Grid

	Isolated	Pattern	Widespread
Immediate Jeopardy To Resident Health Or Safety	PoC: Required: Cat. 3 Optional: Cat. 1 Optional: Cat. 2	J PoC: Required: Cat. 3 Optional: Cat. 1 Optional: Cat. 2	K PoC: Required: Cat. 3 Optional: Cat. 1 Optional: Cat. 2
Actual Harm That Is Not Immediate Jeopardy	PoC: Required: Cat. 2 Optional: Cat. 1	G PoC: Required: Cat. 2 Optional: Cat. 1	H PoC: Required: Cat. 2 Optional: Cat. 1 Optional: Temporary Mgmt
No Actual Harm With Potential For More Than Minimal Harm That Is Not Immediate Jeopardy	PoC: Required: Cat. 1 Optional: Cat. 2	D PoC: Required: Cat. 1 Optional: Cat. 2	E PoC: Required: Cat. 2 Optional: Cat. 1
No Actual Harm With Potential For Minimal Harm	No PoC No remedies Commitment to Correct Not on CMS-2567	A PoC: No remedies	B PoC: No remedies
Substandard Quality of Care (F221-226; F240-258; F309-334)			
Out of Compliance			
Substantial Compliance			

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Federal Remedies Categories

Category 1 (Cat.1)	Category 2 (Cat.2)	Category 3 (Cat.3)
Directed Plan of Correction; State Monitor; and/or Directed In-Service Training <i>Note: If CMP >\$10,4830 or SQC, automatic loss of Nurse Aide Training Competency Evaluation Program (NATCEP)</i>	Denial of Payment for New Admissions; Denial of Payment for All Individuals imposed by CMS; Termination; Temp. Mgmt and/or Civil Money Penalties: Old: \$50 - \$3,000/day \$1,000 - \$10,000/ instance New: * \$105 - \$6,289/day \$2,097 - \$20,628/ instance	Temp. Mgmt.; Termination; Civil money penalties <i>Old:</i> 3,050-\$10,000/day \$1,000 - \$10,000/ instance New: * \$6,394 - \$20,965/day \$2,097 - \$20,965/ instance

* Updated effective Feb. 3, 2017

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Mandatory Criteria for Immediate Imposition of Federal Remedies

Mandatory Criteria for Immediate Imposition of Federal Remedies	Immediate Jeopardy on current survey	Deficiencies of SOC that are not U on current survey	Any G level deficiency on current survey in §483.13, §483.15, §483.25	Deficiencies of actual harm on current survey AND U OR actual harm on any survey between current survey and last standard survey	Special Focus Facility AND "F" level or higher on current survey
Remedy(ies) considered for immediate imposition by CMS in addition to the CMPs when U is cited, mandatory 3 month DPNA for new admissions or mandatory 6 month termination, as required. NOTE: Multiple remedies may be imposed	Termination CMPs must be imposed immediately DDPNA Temp. Mgmt. State Monitoring Directed Plan of Correction Denial of Payment for All Individuals	Termination CMPs DDPNA Directed Plan of Correction Directed In-service Training Denial of Payment for All Individuals	Termination CMPs DDPNA Directed Plan of Correction Directed In-service Training Denial of Payment for All Individuals	Termination CMPs DDPNA Temp. Mgmt. State Monitoring Directed Plan of Correction Directed In-service Denial of Payment for All Individuals	Termination CMPs DDPNA Temp. Mgmt. State Monitoring Directed Plan of Correction Directed In-service Denial of Payment for All Individuals

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Areas of Potential Substandard Quality Of Care

- Major Expansion
- Resident Rights § 483.10
 - Resident Rights
 - Exercise of Rights
 - Respect and Dignity
 - Self-Determination
 - Safe Environment
- F Tags
 - F221 – F226
 - F240 – F258
 - F309 - F334

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New CMS CMP Analytic Tool

- New approach to federal per day (PD) CMPs
- Begin CMP on 1st day noncompliance is documented, *even if that date precedes the first day of the current survey*
 - Unless facility can demonstrate that it corrected the noncompliance prior to the current survey (past noncompliance)

CMS Survey & Certification Memo, "Civil Money Penalty (CMP) Analytic Tool and Submission of CMP Tool Cases," S&C: 15-16-NH (Dec. 19, 2014)

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Starting the PD CMP

- Calculate the start date for the proposed CMP with the "first supportable date of noncompliance, as determined by the evidence documented by surveyors in the statement of deficiencies (CMS form 2567)"
- Surveyors instructed to "determine the earliest date for which supportable evidence shows that the non-compliant practice began"

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Ambiguity About Start of Deficient Practice

- CMS analysts will contact state agency if start date is ambiguous or not clearly identified and supportable, to see if start date can be determined
- CMS analysts required to document their discussions and conclusion with the state agency

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If Start Date Not Determinable

- If start date cannot be determined, then PD CMP would start on 1st day during the survey on which the survey team identified the noncompliant practice
- If the team cannot document the first day of noncompliance, then the CMP should start on the day the noncompliance was observed and documented at the time of the current survey

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CMP Culpability Add-Ons

- Neglect, indifference, or disregard for resident care, comfort or safety
 - SNF responsible and culpable for actions of its management and staff, and contract staff
- Failure to act culpability amount up to \$500
 - If management officials, e.g., administrator, director of nursing, facility owners, and/or the facility's governing body knew of problems but failed to act

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CMS: Past Noncompliance

- Reduce a CMP by 50% if:
 - (i) self-reported noncompliance to CMS or State before it was otherwise identified by or reported to CMS or State; and
 - (ii) correction of the self-reported noncompliance occurred within 15 days of the incident. 42 C.F.R. § 488.438

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**Get Credit for Correcting
Past Noncompliance**

- Treat any incident that results in reporting to SSA as you would if it was on your 2567
- Develop corrective action and document monitoring and auditing for ongoing compliance
- Give evidence to surveyors at the time of the survey that a monitoring plan was implemented and maintained to assure continued compliance

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How to Read the 2567

- What are the deficiencies?
- What are the regulatory violations?
 - Federal
 - State
- What is the best way to respond?

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“Required” POC Elements

- What corrective action(s) will be accomplished *for residents affected by the deficient practice*?
- How will you identify *other residents* having the *potential to be affected by the same deficient practice* and corrective actions?
- What measures will be put in place or system changes will you make to ensure that the *deficient practice does not recur*?

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“Required” POC Elements

- How will the corrective action be monitored to ensure the *deficient practice will not recur, i.e.*, what quality assurance programs will be established?

- Dates when the corrective action will be completed.

Strategies for Preparing Effective POCs

- Less is more

- Read the F Tags *and* the state tags

- Don't be afraid to have your POC rejected

- Be responsive and responsible
 - Don't overpromise
 - Don't admit liability

Strategies for Preparing Effective POCs

- Don't go overboard with policies, procedures and plans of correction

- Keep your date of compliance as short as possible
 - Begin implementing corrective action during the survey and document corrections (*e.g.*, in servicing of staff)

**Best Practices for Evaluating,
Writing, Revising and Deleting
Facility Policies**

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Possible Action Plan Outline

- Executive Level Briefing on the Rule and Requirements
 - Time Table
 - See Attachment
- Team Development – Create and Set Up Your Team
- Identify Affected Facility and Company Policies

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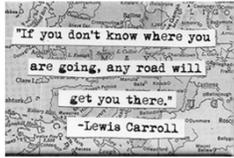
Possible Action Plan Outline

- Identify Affected Positions, Job Descriptions, or Needed New Positions
- Training (Lots of it!)
- Compliance and Ethics Program
- QAPI

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Best (and Worse) Practices

- Before you start walking, you better know where you are going !!!



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Best Practice – What Do You Have / What Do You Need

- You need to have an inventory of the Facility's current policies
- Need a listing:
 - “New” policies that are needed because of new regulations/additions
 - Policy revisions that are needed because of regulation changes
- AHCA Playbook provides much of that listing

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Best Practice – Understand What Is Required (Exactly)

- You can't draft a new policy or revise a policy if you have not read AND are not looking at the regulatory text while you do it.
- It also will help to know what changed in the new regulation and (sometimes) why CMS thought they should change the rule.
- The revised text is found in the Compliance Tool.
- The Fed. Reg. contains CMS's response to comments, S & C 17-07 has the SOM revisions, and the CMS handout has areas of emphasis.

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Best Practice – Teamwork

- Not in a dark room
- Consider a policy Committee
- A interdisciplinary staff team is needed because:
 - Too much work for a single person
 - Many changes affect multiple areas and their input is critical (nursing and CNA, Physician and nursing, etc.)
 - Two, three, four or ten heads are better than one
 - You need buy in and investment from key staff
 - BUT – There needs to be a CAPTAIN in charge of all policies and then each policy or policy area



Basic Policy Elements

- Policy Title
- Rationale – briefly explains why the policy exists or why a new policy was made/changed
- Definitions – key words and terms to prevent misunderstandings
- Scope statement – explains whether the policy is limited to certain individuals, certain areas, or is applicable to whole Facility

Basic Policy Elements

- Policy Language or Requirements
- Reference Documents – Any regulations or cross-references to Facility or company policies
- Revision and Accountability Information

Best Practice – Policy Content

- KEY– WHAT IS REQUIRED (FOR NOW ONLY THAT!!!)
- Do you even need a “new” policy ? Eliminate unnecessary or duplicate documents if you can.
- Addition through subtraction - Do you have opportunities to combine policies under the new regs?
- Don't reinvent the wheel, but know enough to know if your riding on a flat tire.

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Best Practice – Policy Content

- Use formatting to increase readability – Section headings, bullets or lists, images or tables
- Create (and then use) a Single Template
- Limit policies to one or two pages ideally (or divide)
- Use bullets and lists

1
1
6

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Best Practice – Policy Content

- Make sure the title describes the content accurately
- Keep sentences short (RoFt – 21 words) and paragraphs short (RoFt – 4 to 6 lines)
- AVOID use long multi-syllable words
- CAREFULLY USE vague modifiers like proper, appropriate, timely, normal, reasonable, etc.

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Best Practice – Policy Draft Review

- Draft should be reviewed by multiple individuals
- Does the Policy Comply with text of regulation?
- Can the policy be implemented by the staff you have with the staff you have ?

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Best Practice – Policy Draft Review

- Try to ensure these initial policies don't only work if your staff become super-humans overnight
- What ever you do – DO NOT OVERPROMISE!!!!
- Track the revisions and versions of your current and new policies

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Best Practice – Policy Implementation

- Your (nice and shiny) new policy does not help the Facility at all if no one knows it exists
- There should be standard process for informing staff of new policies or revisions
- Policy also doesn't help if staff are not training on what the policy does or requires

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Best Practice – Policy Implementation

- Training will be critical to success
- Do you have process or tool to assess staff's understanding and knowledge?
- What is the remedial "loop" when policies are not known, understood, or properly implemented?

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Final ROP: Things You Need To Do And Suggestions On How To Get Them Done

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