

# Compliance and Ethics Programs for Nursing Facilities



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IHCA  
Convention  
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# Overview



1. New COPs re Compliance & Ethics Programs
  2. Issues to address in the Program
- Please ask questions or comment as we go along...

# Written Materials

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- .Ppt slides
  - Compliance and Ethics Program Rule, 42 CFR 483.85
  - HHS commentary to Rule, 81 FR 68812
  - OIG Compliance Program Guidance, 65 FR 14289
  - OIG Supplemental Compliance Program Guidance for Nursing Facilities, 73 FR 56832
  - CMS, Nursing Home Toolkit: Program Integrity and Quality of Care—An Overview for Nursing Home Providers
- ✓ Available on IHCA website

# Compliance and Ethics Program Requirements

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# History

- **1970's and 1980's:** high profile corporate fraud or misconduct.
- **1991:** DOJ sentencing guidelines factor compliance program.
- **2000:** OIG Compliance Program Guidance for Nursing Facilities (65 FR 14289)
  - **Voluntary**
- **2008:** OIG Supplemental Compliance Program Guidance for Nursing Facilities (73 FR 56832)
  - **Voluntary**
- **2010:** Affordable Care Act 6102
  - **Mandated compliance plans for nursing facilities**
- **2015:** Proposed rules for nursing facilities (80 FR 42217)
- **2016:** Final rules for nursing facilities at 42 CFR 483.85 (81 FR 68812)
- **2017:** Required compliance by **November 28, 2019** (81 FR 68688)
  - **No interpretive guidelines yet...**

# 42 CFR 483.85

- Beginning **November 28, 2019**, the operating organization for each facility must have in operation a compliance and ethics program for each facility.

(42 CFR 483.85(b))

- “Operating organization” = means the individual(s) or entity that operates a facility.
  - Owner?
  - Manager?
  - Administrative services company?

(42 CFR 483.85(a))

# 42 CFR 483.85

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## Compliance & Ethics Program

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1. Prevent and detect criminal, civil and administrative violations.
  2. Promote quality of care per regulations.

**After November 28, 2019, surveyors may issue citations for failure to have the required program (Ftag F895).**

# Compliance and Ethics Programs

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- Must be designed, implemented and enforced to be effective in:
  - preventing and detecting criminal, civil and administrative violations, and
  - promoting quality care.
- Compliance program extends to:
  - Operating organization's staff,
  - Contractors, and
  - Volunteers

(42 CFR 483.85(a))

# Compliance and Ethics Program

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- Good reasons to have one
  - Facilitates compliance by identifying and responding to problems early on.
  - Demonstrates commitment to integrity.
  - May mitigate penalties.
  - May improve performance.
    - facilitates prompt claims submissions
    - identifies undercoding as well as upcoding
    - reduces claim denials
    - improves medical record documentation
    - may identify and prevent resident care problems
  - Others?

# Compliance Program Elements

## All operating organizations

1. Written compliance program.
2. Assign responsibility.
3. Sufficient resources.
4. Do not delegate improperly.
5. Train personnel.
6. Ensure compliance, e.g.,
  - monitoring and auditing
  - appropriate reporting process.
7. Enforce program.
8. Respond appropriately.
- \* Annual review

## Organizations with 5+ facilities

9. Annual training.
10. Compliance officer.
11. Compliance liaison at each facility.

(42 CFR 483.85)

# <https://nvhca.org/wp-content/uploads/2019/02/ahca-preliminary-toolkit.pdf>

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## AHCA COMPLIANCE AND ETHICS PROGRAM TOOLKIT



### I. SURVEYORS WILL START ASSESSING COMPLIANCE AND ETHICS PROGRAMS STARTING NOVEMBER 28, 2019

Medicare and Medicaid participating nursing facilities (collectively referred to as “SNFs” or “facilities”) have been required to have a compliance and ethics program (“Compliance Program”) since March 23, 2013, under Section 6102 of the Affordable Care Act, but to date there has been no regulatory mechanism for the government to enforce this requirement, other than through corporate integrity agreements (“CIAs”) imposed by the Office of Inspector General (“OIG”) as a condition of settlement of certain federal investigations. The Centers for Medicare and Medicaid Services (“CMS”) did not issue final regulations for Compliance Programs until October 4, 2016, with an effective date of November 28, 2019. Starting November 28, 2019, CMS and state survey agencies will be authorized to issue survey deficiencies under federal Ftag F895 to facilities that do not have effective Compliance Programs.

AHCA has been at the forefront of encouraging facilities to implement Compliance Programs and many years ago developed a Compliance Manual and Sample Policies and Procedures for members that is available on its website at: [https://www.ahcancal.org/facility\\_operations/integrity/Pages/Compliance-Programs.aspx](https://www.ahcancal.org/facility_operations/integrity/Pages/Compliance-Programs.aspx). To help members better prepare for the new Compliance Program regulations that appear at 42 C.F.R. § 483.85, AHCA is providing this interim summary of the new requirements. AHCA will update this information as soon as CMS issues further interpretive guidance for F895.<sup>1</sup>

Facilities that do not already have a Compliance Program should begin putting one in place so that they are ready for survey enforcement. Facilities that have implemented Compliance Programs should review the new requirements against their existing programs and revise as necessary. The goal is to have an effective Compliance Program, with sufficient documentary evidence in place, to show surveyors who will be assessing the Compliance Program for substantial compliance with the new CMS regulations at 42 C.F.R. § 483.85, F895.

Starting November 28, 2019, surveyors will use the regulations at 42 C.F.R. § 483.85, F895, to determine whether a SNF’s Compliance Program is in substantial compliance with the regulations. CMS has not yet issued guidance about how F895 will be interpreted; it is likely CMS will release guidance in an updated State Operations Manual (“SOM”), Appendix PP within the next year or so. It is also possible that CMS will develop a Critical Element Pathway for Compliance Programs at some future date. Facilities should not wait for CMS to release any

# 1. Written Standards, Policies and Procedures

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- Must have written compliance and ethics standards, policies and procedures that:
  - Are reasonably capable of reducing criminal, civil and administrative violations; and
  - Promote quality of care.

(42 CFR 483.85(c)(1))

- Standards = the rules.
- Policies and procedures = how rules are to be achieved, addressed and enforced.

# Written Standards, Policies and Procedures

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- At a minimum, written policies must include:
  - Designation of appropriate compliance and ethics program contact to whom individuals may report suspected violations;
  - Alternative method to report anonymously without fear of retribution; and
  - Disciplinary standards that set out consequences for violations for:
    - Operating entity's entire staff,
    - Individuals providing services under contract, and
    - Volunteers, consistent with their expected roles.

(42 CFR 483.85(c)(1))

# Written Standards, Policies and Procedures

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- Consider
  - Coordinate standards, policies and procedures with:
    - Mission and values statement
    - Employee handbook
    - Contracts
    - Other key employee documents
  - Consider consolidating basic rules in a Code of Conduct.
    - More easily understood by staff and others
    - Separate from policies and procedures
  - Others?

## 2. Assign Compliance Responsibility to High-Level Person

- Assign to “high-level personnel” the responsibility to oversee compliance with program’s standards, policies and procedures.

(42 CFR 483.85(c)(2))

- “High-level personnel” = individual(s) who have substantial control over the operating organization or who have a substantial role in making policy, e.g.,
  - CEO,
  - Board members, or
  - Directors of major divisions.

(42 CFR 483.85(a))

# Assign Compliance Responsibility to High-Level Person

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- Consider
  - “Oversight” is not the same as making the person the effective compliance officer.
    - “Buck stops here”
  - Include compliance in job description or contract and compliance program documents.
  - Coordinate responsibilities with HIPAA privacy/security officer.
  - Others?

# 3. Sufficient Resources

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- Dedicate sufficient resources and authority to the specific individuals assigned to compliance to reasonably assure compliance with the standards, policies and procedures.

(42 CFR 483.85(c)(3))

# Sufficient Resources

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- Consider
  - Resources depend on circumstances, e.g., size of facility, number of facilities, etc.
  - Use facility assessment required by 42 CFR 483.70(e), i.e., specific line item re compliance.
  - Identify personnel.
    - Ensure they understand compliance is part of their job
    - Ensure others know of their authority
  - Establish budget.
  - Others?

## 4. Appropriate Delegation

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- Due care not to delegate substantial discretionary authority to individuals who the operating organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations under the Social Security Act.

(42 CFR 483.85(c)(4))

# Appropriate Delegation

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- Consider
  - Conduct and document background checks.
  - Check exclusion lists.
    - List of Excluded Individuals and Entities (“LEIE”), <https://exclusions.oig.hhs.gov/>
    - System for Award Management, <https://sam.gov/SAM/pages/public/index.jsf>
    - State Medicaid sites.
  - Others?

# 5. Train Personnel

- Take steps to effectively communicate the standards, policies, and procedures to:
  - Entire staff of the operating organization;
  - Individuals providing services under a contractual arrangement; and
  - Volunteers, consistent with the volunteers' expected roles.
- Must include, but is not limited to:
  - Mandatory participation in training as set forth at §483.95(f), or
  - Orientation programs, or
  - Disseminating info that explains in a practical manner what is required under the program.

(42 CFR 483.85(c)(5))

# Train Personnel

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- A facility must develop, implement, and maintain an effective training program for:
  - All new and existing staff;
  - Individuals providing services under a contractual arrangement; and
  - Volunteers, consistent with their expected roles.
- Among other things, training must explain the requirements of the compliance program.

(42 CFR 483.95(f))

# Train Personnel

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- **Consider**
  - Require personnel to participate in training programs.
  - Copies to vendors/contractors as part of the contracting process and annually thereafter.
  - Post compliance plan or code of conduct on intranet and internet.
  - Require that employees and others sign annual attestations that they have received and read and understand the code of conduct and/or compliance program.
  - Have employees, agents and volunteers sign in whenever compliance topics are discussed at meetings.

# Train Personnel

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- Consider
  - If you use electronic learning platforms, have a copy of compliance modules available for the survey team.
  - Track participation in compliance programs.
  - Discipline those who fail to participate.
  - Assign someone the task of conducting compliance interviews with staff, agents and volunteers on a random yet regular basis. Ask questions like:
    - Do you know if this facility has a compliance program?
    - What are you supposed to do if you have concerns?
    - To whom should you report concerns?

## 6. Steps to Achieve Compliance

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- Take reasonable steps to achieve compliance with the program, including but not limited to:
  - Monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations;
  - Having and publicizing a reporting system whereby individuals may report violations anonymously and without fear of retribution; and
  - Having a process to ensure the integrity of reported data.

(42 CFR 483.85(c)(6))

# Steps to Achieve Compliance

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- **Consider**
  - **Start with self-assessment or gap analysis to identify compliance risk areas.**
    - **Recent surveys and internal reports**
    - **Regulatory standards**
    - **OIG Compliance Program Guidance for Nursing Facilities, 65 FR 14289 (2000)**
    - **OIG Supplemental Compliance Program Guidance for Nursing Facilities, 73 FR 56832 (2008)**
  - **Establish compliance work plan to address identified deficiencies.**
  - **Follow up!**

# Steps to Achieve Compliance

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- Auditing and monitoring
  - Incorporate auditing and monitoring.
    - Auditing: systematic review.
      - Proactive
      - Reactive
    - Monitoring: watch to ensure systems are working.
  - Involve attorney to maximize attorney-client privilege or work-product doctrine.
  - Others?

# Steps to Achieve Compliance

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- Auditing and monitoring
  - CMS expects periodic audits focusing on:
    - Financial records
    - Quality of care issues
  - ACA Report and Repay rule requires repayment within 60 days.
    - Contemplates ongoing auditing or monitoring.
    - Knew or should have known standard.
  - Coordinate with Quality Assurance Performance Improvement (“QAPI”) programs.

# Steps to Achieve Compliance

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- **Effective reporting system**
  - Designate compliance officer or liaison.
  - Establish compliance hotline, e.g., 1-800 number.
  - Ensure reporting process is well-publicized, e.g., training, handbook, posters, internet, intranet, website, newsletters, admission packets, etc.
  - Publish strong no-retaliation policy.
  - Respond promptly to compliance concerns that are raised.
  - Maintain a log of complaints and timely responses.

# 7. Enforcement

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- Consistent enforcement of the standards, policies, and procedures through appropriate disciplinary mechanisms, including:
  - Discipline of those who violate program standards or policies; and
  - Discipline of those responsible for the failure to:
    - Detect a violation, and
    - Report a violation.

(42 CFR 485.85(c)(7))

# Enforcement

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- **Consider**
  - **Confirm discipline for compliance violations, up to and including termination.**
  - **Confirm obligation to report violations.**
  - **Coordinate compliance program with employee handbook, policies, contracts, etc.**
  - **Include acknowledgement of discipline in annual employee attestation.**
  - **Ensure discipline is applied fairly and consistently.**

## 8. Respond to Violations

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- After a violation is detected, the operating organization must ensure that all reasonable steps identified in its program are taken to respond appropriately to the violation and to prevent further similar violations, including any necessary modification to the operating organization's program.

(42 CFR 483.85(c)(8))

# Respond to Violations

- Consider
  - Ensure program documents require prompt action to address and correct noncompliance.
  - Compliance officer or designee coordinate any investigation, conclusions, and recommended corrective action.
  - Program should require all persons to cooperate in investigation.
  - Discipline as necessary.
  - Confirm obligation to report and repay, address violation of program, and modify policies or processes to avoid repeats.



## Additional Requirements for Operators with 5 or More Facilities

- **Smaller organizations may want to implement if able...**

## 9. Annual Training

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- Conduct mandatory annual training program on the compliance and ethics program that meets the requirements set forth in §483.95(f).

(42 CFR 483.85(d)(1))

- No specific direction concerning content, but likely should address:
  - Compliance program components.
  - Common or ongoing compliance issues.
  - Policies or procedures to address concerns.

# 10. Compliance Officer

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- Designate a compliance officer for whom the operating organization's compliance and ethics program is a major responsibility.
- Compliance officer must:
  - Report directly to the operating organization's governing body, and
  - Not be subordinate to the general counsel, chief financial officer or chief operating officer.

(42 CFR 483.85(d)(2))

# Compliance Officer

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- Consider
  - Conflicts of interest in appointing compliance officer, e.g.,
    - If compliance officer is also director of accounting.
    - If compliance officer is related to other high-level officer in operating organization.

(80 FR 42220)
  - Appropriate skills
    - Good communication and collaboration.
    - Understands organization's operations.
    - Objective and independent.
    - Others?

# 11. Compliance Liaison

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- Designate a compliance liaison located at each of the operating organization's facilities.

(42 CFR 483.85(d)(3))

- **Liaisons assist the compliance officer at each facility.**
- **Each organization has flexibility to determine the qualifications, duties and responsibilities for the liaisons.**

(81 FR 68816)



Bonus for  
all facilities

# Annual Review

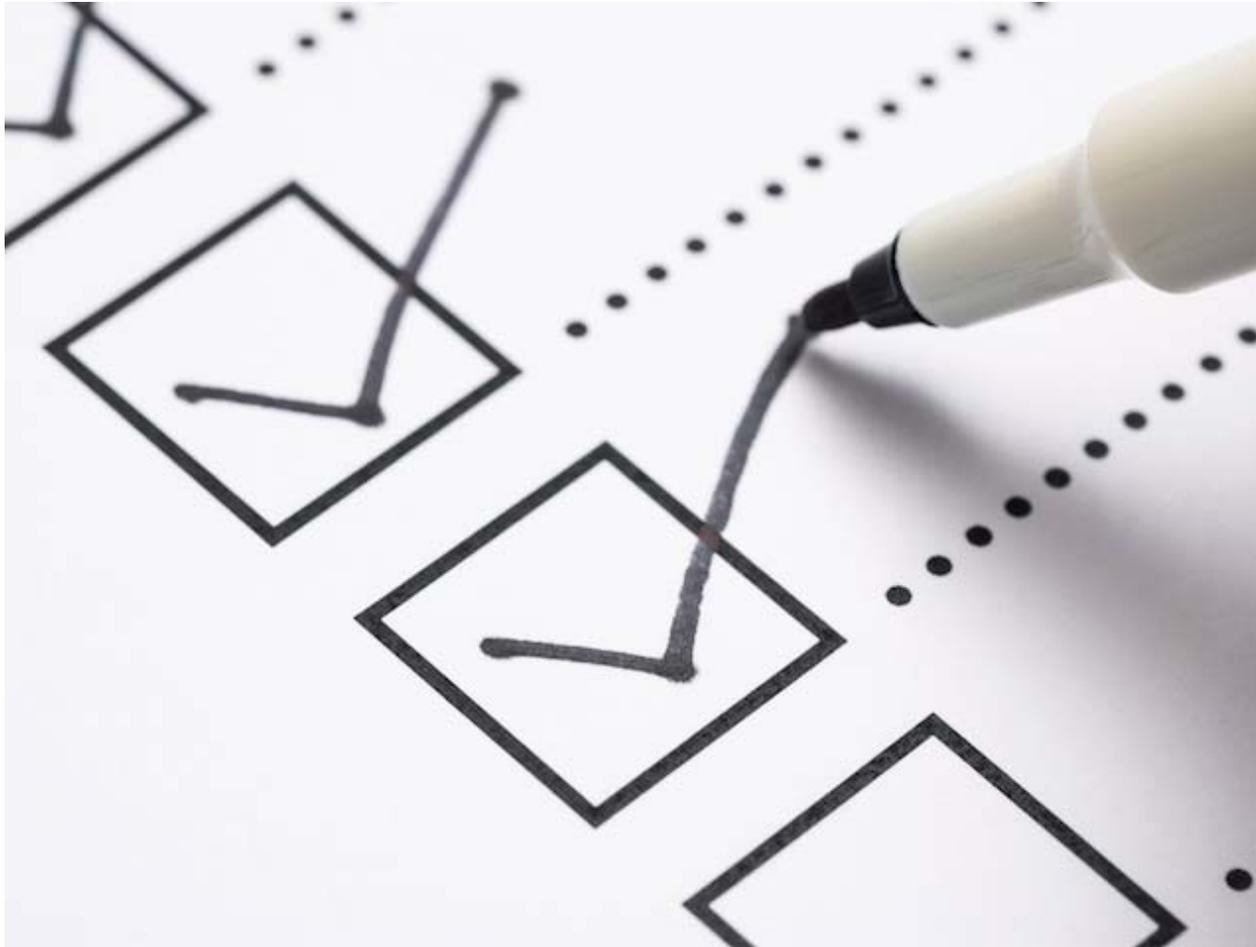
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- Operating organization for each facility must:
  - Review its compliance and ethics program annually, and
  - Revise its program as needed to reflect changes in all applicable laws or regulations and within the operating organization and its facilities to improve its performance in deterring, reducing, and detecting violations under the Act and in promoting quality of care.

(42 CFR 483.85(e))

➤ **Document annual review.**

# Issues to Address



# Issues to Address

- SNFs and NFs must comply with:
  - All applicable Federal, State, and local laws and regulations, and codes, and
  - Accepted professional standards and principles applicable to services in facilities.
- Specifically, facilities must comply with:
  - 42 CFR part 483;
  - Nondiscrimination on the basis of age, sex, race, color, national origin, or disability (45 CFR parts 45, 80, 84, 91, 92);
  - Protection of human subjects of research (45 CFR part 46);
  - Fraud and abuse (42 CFR part 455); and
  - Protection of individually identifiable health information (45 CFR parts 160 and 164).

(42 CFR 483.70(b)-(c))

# <https://www.oig.hhs.gov/compliance/compliance-guidance/index.asp>

Home > Compliance > Compliance Guidance

## Compliance Guidance

OIG has developed a series of voluntary compliance program guidance documents directed at various segments of the health care industry, such as hospitals, nursing homes, third-party billers, and durable medical equipment suppliers, to encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements.

The compliance program guidance documents are listed below.

**09-30-2008**

- Supplemental Compliance Program Guidance for Nursing Facilities (73 Fed. Reg. 56832; September 30, 2008)
- Compliance Program Guidance for Nursing Facilities (65 Fed. Reg. 14289; March 16, 2000)

**I'm looking for**

Let's start by choosing a topic

Select One

- Accountable Care Organizations
- Advisory Opinions
- Compliance Resource Portal
- Compliance Guidance
  - Compliance Resource Material
- Corporate Integrity Agreements
- Open Letters

# OIG Compliance Program Guidance for Nursing Homes

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## OIG Compliance Guidance (2000)

- **Quality of care**
- **Residents' rights**
- **Employee screening**
- **Vendor relationships**
- **Billing and cost reporting**
- **Record keeping and documentation**

(65 FR 14292)

## OIG Supplemental Guidance (2008)

- **Quality of care**
- **Submission of accurate claims**
- **Anti-Kickback Statute**
- **Physician Self-Referrals (“Stark”)**
- **Anti-supplementation**
- **HIPAA and Security Rules**

(73 FR 56833)

# Quality of Care

Nursing Home Toolkit: Program Integrity and Quality of Care—An Overview for Nursing Home Providers



The image shows a computer screen displaying a PDF document titled "Nursing Home Toolkit: Program Integrity and Quality of Care—An Overview for Nursing Home Providers". The document cover features a yellow background with the title "Nursing Home Toolkit" in white, arched text. Below the title is a blue banner with the subtitle "Program Integrity and Quality of Care—An Overview for Nursing Home Providers" in white text. The bottom half of the cover shows a photograph of three people: an elderly man with glasses on the left, a young woman with a stethoscope (nurse) in the center, and a woman with blonde hair (caregiver) on the right. The browser's address bar shows the URL: <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/nursinghome-provider-booklet.pdf>. The Windows taskbar at the bottom shows the time as 3:35 PM on 6/29/2019.

# Quality of Care

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- **OIG recommends:**
  - **Statement that affirms commitment to high quality care.**
  - **Continually measure performance against applicable standards, including Medicare requirements.**
  - **Quality of care protocols.**
  - **Review resident outcomes and improve on outcomes.**
  - **Use current and past surveys to improve.**
  - **Assess vulnerabilities and risk areas.**

(OIG Compliance Guidance (2000))

# Quality of Care

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- Risk areas
  - No accurate assessment of resident's functional capacity or comprehensive care plan.
  - Inappropriate or insufficient treatment and services to address resident's clinical conditions, including
    - Pressure ulcers
    - Dehydration
    - Malnutrition
    - Incontinence
    - Mental or psychosocial problems

(OIG Compliance Guidance (2000); OIG Supplemental Guidance (2008))

# Quality of Care

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- Risk areas
  - Failure to accommodate individual resident needs and preferences.
  - Inadequate medication management.
  - Inappropriate use of psychotropic medications.
  - Inadequate staffing levels or insufficiently trained or supervised staff.
  - Failure to provide appropriate therapy services.

(OIG Compliance Guidance (2000); OIG Supplemental Guidance (2008))

# Quality of Care

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- Risk areas
  - Failure to provide appropriate services to assist residents with activities of daily living.
  - Failure to provide an ongoing activities program to meet individual needs.
  - Patient safety, including
    - Failure to report incidents of abuse or neglect
    - Failure to protect from other residents.
    - Failure to screen staff.

(OIG Compliance Guidance (2000); OIG Supplemental Guidance (2008))

# Resident Rights



# Residents Rights

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- Policies should address rights specified in:
  - Federal laws and regulations
    - 42 CFR part 483, including 483.10, 483.12, 483.15, etc.
    - Others?
  - State laws and regulations
    - IDAPA 16.03.02
    - Others?
  - Admission agreements?
  - Others?

# Residents Rights

- Rights include, but are not limited to:
  - Treated with dignity and respect.
  - Manage his/her own money or choose someone to manage it.
  - Use his/her own belongings so long as it does not affect others and space and safety permit.
  - Privacy and confidentiality.
  - Informed about services, patient condition and medication.
  - Refuse medications and treatments.
  - Participate in decisions and care planning.
  - Make independent choices, including re a physician.

(CMS, *Nursing Home Toolkit: Program Integrity and Quality of Care*)

# Residents Rights

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- Risk areas
  - Discriminatory admission or improper denial of access to care.
  - Verbal, mental or physical abuse, corporeal punishment, and involuntary seclusion.
  - Inappropriate use of physical or chemical restraints.
  - Failure to ensure that residents have personal privacy and access to their personal records.
  - Denial of right to participate in care or treatment.
  - Failure to safeguard resident's financial affairs.

(OIG Compliance Guidance (2000))

# Fraud and Abuse



- False Claims Act
- Anti-Kickback Statute (“AKS”)
- Ethics in Physician Referrals Act (“Stark”)
- Civil Monetary Penalties Law (“CMPL”)
- Eliminating Kickbacks in Recovery Act (“EKRA”)
- Travel Act
- Idaho False Claims Act
- Idaho Anti-Kickback Statute

# Increased Penalties

	Old Penalty	New Penalty
<b>False Claims Act</b>	<b>\$5,500 to \$11,000 /claim</b>	<b>\$10,781 to \$21,563 /claim</b>
• <b>Failure to repay</b>		<b>\$20,000 per claim</b>
<b>Anti-Kickback Statute</b>	<b>\$25,000 criminal penalty 5 years in prison</b>	<b>\$100,000 criminal penalty 10 years in prison</b>
	<b>\$50,000</b>	<b>\$100,000 civil penalty</b>
<b>Ethics in Patient Referrals ("Stark")</b>	<b>\$15,000 per claim</b>	<b>\$24,748 per claim</b>
• <b>Circumvention scheme</b>	<b>\$100,000</b>	<b>\$164,992</b>
<b>Civil Monetary Penalties Law</b>		<b>\$20,000 to \$100,000</b>
• <b>Induce beneficiaries</b>	<b>\$10,000</b>	<b>\$20,000</b>
• <b>Excluded individual</b>	<b>\$10,000</b>	<b>\$20,000</b>
<b>(See 45 CFR 102.3)</b>		

# False Claims Act

- Cannot knowingly submit a false claim for payment to the federal government.
- Must report and repay an overpayment within the later of 60 days after overpayment identified or date corresponding cost report is due.
- Penalties
  - Repayment plus interest
  - Civil monetary penalties of \$11,000 to \$22,000\* per claim
  - 3x damages
  - Exclusion from Medicare/Medicaid
  - Qui tam lawsuits

(31 USC 3729; 42 CFR 102.3; *see also* 18 USC 1347)

# Idaho False Claims Act

- **Cannot knowingly:**
  - Submit claim that is incorrect.
  - Make false statement in any document to state.
  - Submit a claim for medically unnecessary service.
  - Fail repeatedly or substantially to comply with DHW rules.
  - Breach provider agreement.
  - Fail to repay amounts improperly received.
- **Penalties**
  - Exclusion from state health programs, e.g., Medicaid.
  - Civil penalty of up to \$1000 per violation.
  - Referral to Medicaid fraud unit.

(IC 56-209h(6))

# Fraud and Abuse

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- Risk areas
  - Billing for items or services not provided as claimed.
  - Claims for medically unnecessary services or supplies.
  - Claims to Part A for residents who are not eligible.
  - Duplicate billing.
  - Failing to identify and refund credit balances.
  - Claims for items or services not ordered.
  - Billing for inadequate or substandard care.
  - Misleading info about resident's medical condition affecting reimbursement.

(OIG Compliance Guidance (2000); OIG Supplemental Guidance (2008))

# Fraud and Abuse

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- Risk areas
  - Upcoding.
  - Unbundling.
  - Billing residents for items in the per diem rate or that are otherwise covered by third-party payers.
  - Altering documentation or forging physician signatures to verify orders or services provided.
  - Insufficient documentation to support services.
  - False cost reports.

(OIG Compliance Guidance (2000))

# Anti-Kickback Statute

- Cannot knowingly and willfully offer, pay, solicit or receive remuneration to induce referrals for items or services covered by government program unless transaction fits within a regulatory safe harbor.

(42 USC 1320a-7b(b))

- “One purpose test”
  - Anti-Kickback Statute applies if one purpose of the remuneration is to induce referrals. (*U.S. v. Greber*, 760 F.2d 68 (3d Cir. 1985)).
  - Difficult to disprove.
- Ignorance of the law is no excuse.

# Anti-Kickback Statute

- Penalties
  - 10 years in prison
  - \$100,000 criminal fine
  - \$100,000 penalty
  - 3x damages
  - Exclusion from Medicare/Medicaid

(42 USC 1320a-7b(b); 42 CFR102.3)
- Anti-Kickback violation = False Claims Act violation
  - Lower standard of proof
  - Subject to False Claims Act penalties
  - Subject to qui tam suit.

(42 USC 1320a-7a(a)(7))
- OIG Self-Disclosure Protocol: minimum \$50,000 settlement.

# Idaho Anti-Kickback Statute

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- **Service provider (including providers of healthcare services) cannot:**
  - Pay another person, or other person cannot accept payment, for a referral.
  - Provide services knowing the claimant was referred in exchange for payment.
  - Engage in regular practice of waiving, rebating, giving or paying claimant's deductible for health insurance.
- **Penalties**
  - **\$5000 fine by Dept of Insurance**

(IC 41-348)

# Anti-Kickback Statute

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- Risk areas
  - Free or discounted goods or services.
    - Giving or receiving to induce referrals.
    - Beware hospices.
  - Services contracts with referring providers, medical directors.
    - Above fair market value.
    - Compensation varies based on referrals.
    - Contract for unnecessary services.
  - Waiver of copays or cost-sharing absent financial need.
  - Reserved bed payments.
  - Anything else of value that induces referrals.

(OIG Compliance Guidance (2000); OIG Supplemental Guidance (2008))

# Anti-Supplementation

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- **Must accept applicable Medicare/Medicaid payment (including copays) as complete payment for covered items and services.**
- **Cannot charge anyone (e.g., beneficiary, third party) any additional amount.**
- **Penalties**
  - **Violation of Medicare participation agreement.**
  - **Criminal penalties**

(42 USC 1395cc(a) and 1320a-7b(d); 42 CFR 489.20, -489.15, and 483.12(d)(3); *see also* OIG Supplemental Guidance (2008))

# Eliminating Kickbacks in Recovery Act ("EKRA")

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- Cannot solicit, receive, pay or offer any remuneration in return for referring a patient to a laboratory, recovery homes or clinical treatment facility unless arrangement fits within regulatory exception.
- Penalties
  - \$200,000 criminal fine
  - 10 years in prison

(18 USC 220)

# Ethics in Patient Referrals Act ("Stark")

- If a physician (or their family member) has a financial relationship with an entity:
  - The physician may not refer patients to that entity for designated health services, and
  - The entity may not bill Medicare or Medicaid for such designated health services ("DHS")

unless arrangement structured to fit within a regulatory exception.

(42 CFR 411.353)

# Stark

- Penalties
  - No payment for services provided per improper referral.
  - Repayment of payments improperly received within 60 days.
  - Civil penalties.
    - \$24,748 per claim submitted
    - \$164,922 per circumvention scheme

(42 CFR 411.353, 1001.102(a)(5); 1001.103(b); and 102.3)

- May also constitute Anti-Kickback Statute violation
- May trigger False Claims Act.

# Stark

- Applies to referrals for designated health services (“DHS”) payable in whole or part by Medicare.
  - Inpatient and outpatient hospital services
  - Outpatient prescription drugs
  - Clinical laboratory services
  - Physical, occupational, or speech therapy
  - Home health services
  - Radiology and certain imaging services
  - Radiation therapy and supplies
  - Durable medical equipment and supplies
  - Parenteral and enteral nutrients, equipment, and supplies
  - Prosthetics and orthotics
- Not services reimbursed by Medicare as part of composite rate (for example, SNF Part A payments, except if listed items are themselves payable through a composite rate (e.g., home health services or inpatient and outpatient hospital services)).

(42 CFR 411.351)

# Idaho Stark Law (kind of)

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- **Idaho Medicaid regulations allow DHW to “deny payment for any and all claims it determines are for items or services ... provided as a result of a prohibited physician referral under [Stark,] 42 CFR Part 411, Subpart J.”**

(IDAPA 16.05.07.200.01)

- **Not clear if this would create affirmative obligation to report and repay amounts received in violation of Stark.**

# Civil Monetary Penalties Law

Prohibits certain specified conduct, e.g.:

- Submitting false or fraudulent claims, misrepresenting facts relevant to services, or engaging in other fraudulent practices.
- Violating Anti-Kickback Statute or Stark law.
- Violating EMTALA.
- Failing to report and repay an overpayment.
- Failing to grant timely access.
- Misusing “HHS”, “CMS”, “Medicare”, “Medicaid”, etc.
- Failing to report adverse action against providers.
- Offering inducements to physicians to limit services.
- **Offering inducements to program beneficiaries.**
- **Submitting claims for services ordered by, or contracting with, an excluded entity.**

(42 USC 1320a-7a; 42 CFR 1003.200-1100)

# Inducements to Govt Program Patients

- **Cannot offer or transfer remuneration to federal program beneficiaries if you know or should know that the remuneration is likely to influence the beneficiaries to order or receive items or services payable by federal or state programs from a particular provider.**

- **Penalty:**

- **\$20,000 for each item or service.**
- **3x amount claimed.**
- **Repayment of amounts paid.**
- **Exclusion from Medicare and Medicaid.**

➤ **Also a likely violation of the Anti-Kickback Statute**

(42 USC 1320a-7a(a)(5); 42 CFR 1003 and 102.3)

# Excluded Entities

- **Cannot submit claim for item or service ordered or furnished by an excluded person.**
- **Cannot hire or contract with an excluded entity or arrange for excluded entity to provide items or services payable by federal programs.**
- **Penalties**
  - **\$10,000 per item or service.**
  - **3x amount claimed.**
  - **Repayment of amounts paid.**
  - **Exclusion from Medicare and Medicaid**

(42 USC 1320a-7a(a)(8); 42 CFR 1003.200; OIG Bulletin, Effect of Exclusion)

<https://exclusions.oig.hhs.gov/>

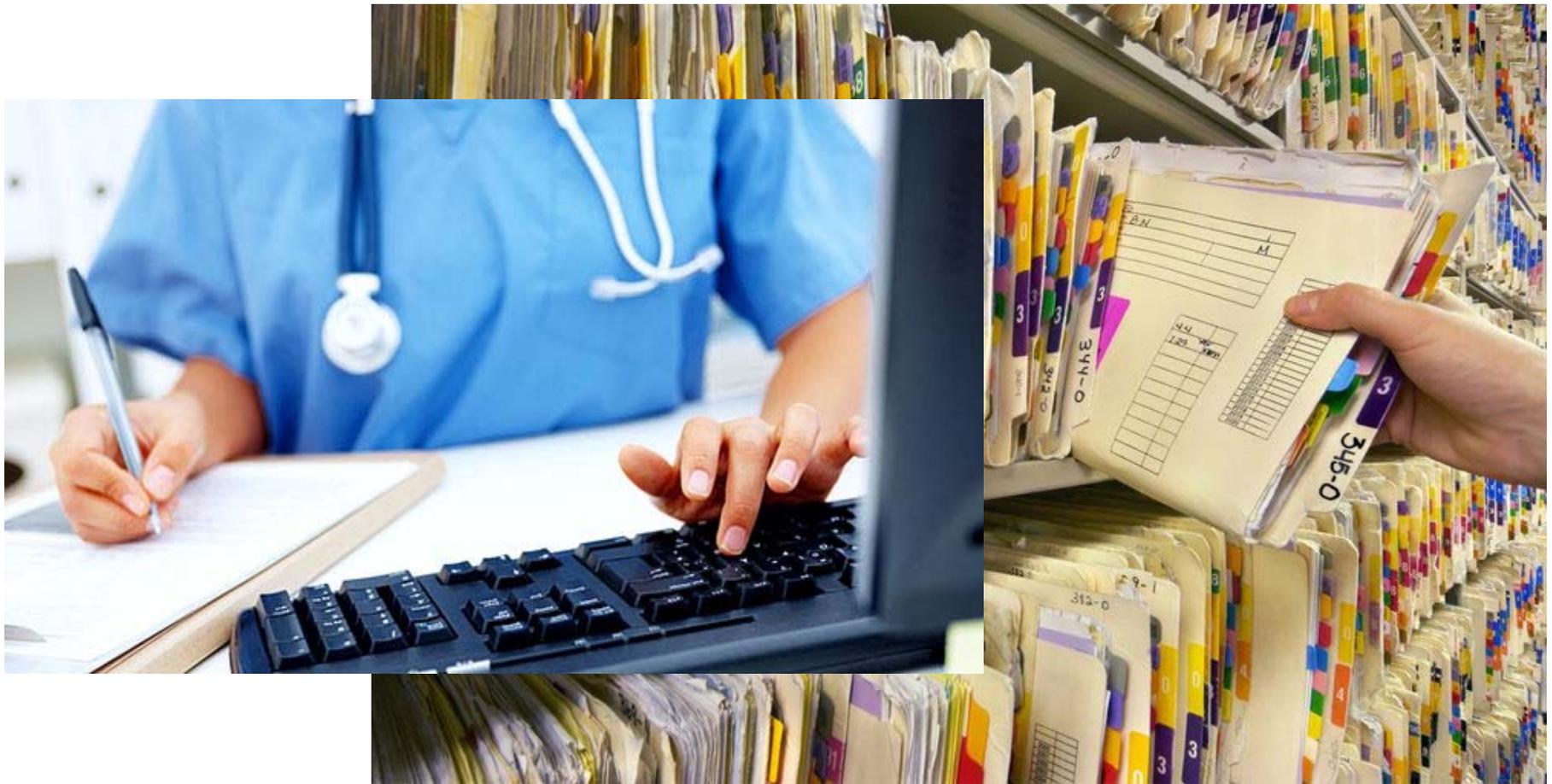
The screenshot shows a web browser window displaying the "Search the Exclusions Database" page. The browser's address bar shows the URL "https://exclusions.oig.hhs.gov". The page header includes a "REPORT FRAUD" button, navigation links (Home, FAQs, FOIA, Contact, HEAT, Download Reader), and social media icons. The main header features the Office of Inspector General logo and the text "Office of Inspector General, U.S. Department of Health & Human Services". A search bar is present with the placeholder text "Report #, Topic, Keyword.." and a "Search" button. Below the header is a navigation menu with links for "About OIG", "Reports & Publications", "Fraud", "Compliance", "Exclusions", "Newsroom", and "Careers". The main content area is titled "Search the Exclusions Database" and includes a sub-section "Search For An Individual" with options for "Search For Multiple Individuals", "Search For A Single Entity", and "Search For Multiple Entities". There are input fields for "Last Name" and "(and/or) First Name", along with "Search" and "Clear" buttons. A "Related Content" sidebar on the right lists links for "LEIE Downloadable Databases", "Monthly Supplement Archive", "Waivers", "Quick Tips", and "Background Information". The Windows taskbar at the bottom shows the time as 7:30 AM on 7/4/2019.

# Employee Screening

- Conduct appropriate background and reference checks before hiring.
  - Appropriate licensing boards.
  - Require certification of no convictions or exclusion.
  - Ensure temp agencies perform background checks.
  - Check the LEIE
- Require employees to report adverse action.
- Suspend employees upon credible allegations pending investigation.
- Prohibit continued employment if:
  - Criminal convictions.
  - Federal program exclusion.

(OIG Compliance Guidance (2000); OIG Supplemental Guidance (2008))

# Creation and Retention of Records



# Creation and Retention of Records

---

- Policies should address:
  - Accurate, complete and timely creation of records.
  - Retention of records.
  - Destruction of records when appropriate.
- Policies extend to:
  - Resident care records.
  - Records and document necessary to support claims.
  - Auditing and monitoring results.
  - Compliance program documents, including communications with Medicare or other agencies.
- Comply with security rule.  
(OIG Compliance Program Guidance (2000))

# Resident Privacy



- Resident rights
- HIPAA
  - Privacy
  - Security
  - Breach Notification

# Civil Penalties

(45 CFR 160.404; 42 CFR 102.3)

Conduct	Penalty	
Did not know and should not have known of violation	<ul style="list-style-type: none"><li>• \$114 to \$57,051 per violation</li><li>• Up to \$28,525 per type per year</li></ul>	<ul style="list-style-type: none"><li>• No penalty if correct w/30 days.</li><li>• OCR may waive or reduce penalty.</li></ul>
Violation due to reasonable cause	<ul style="list-style-type: none"><li>• \$1,141 to \$57,051 per violation</li><li>• Up to \$114,102 per type per year</li></ul>	
Willful neglect, but correct w/in 30 days	<ul style="list-style-type: none"><li>• \$11,182 to \$57,051 per violation</li><li>• Up to \$285,255 per type per year</li></ul>	<ul style="list-style-type: none"><li>• Penalty is mandatory.</li></ul>
Willful neglect, but do not correct w/in 30 days	<ul style="list-style-type: none"><li>• At least \$57,051 per violation</li><li>• Up to \$1,711,533 per type per year</li></ul>	

# Criminal Penalties

(42 USC 1320d-6(a))

- Applies if employees or other individuals obtain or disclose protected health info (“PHI”) from covered entity without authorization.

Conduct	Penalty
Knowingly obtain info in violation of the law	<ul style="list-style-type: none"><li>• \$50,000 fine</li><li>• 1 year in prison</li></ul>
Committed under false pretenses	<ul style="list-style-type: none"><li>• 100,000 fine</li><li>• 5 years in prison</li></ul>
Intent to sell, transfer, or use for commercial gain, personal gain, or malicious harm	<ul style="list-style-type: none"><li>• \$250,000 fine</li><li>• 10 years in prison</li></ul>

# HIPAA Privacy

## Confidentiality

- Don't access, use or disclose protected health info ("PHI") unless:
  - Treatment, payment or healthcare operations
  - Families or others involved in care + no objection
  - Govt function or public safety exceptions
  - Resident request or Authorization to disclose
- Minimum necessary rule
- Personal rep = resident  
(45 CFR 164.500-.530)

## Resident Rights

- Notice of privacy practices
- Alternative means of communication
- Access to info
- Amend info
- Accounting of disclosures

## Administrative

- Privacy and security officer
- Reasonable safeguards
- Training and sanctions
- Respond and mitigate

# HIPAA Security

- Conduct and update security risk assessment
- Implement safeguards
  - Administrative
  - Technical
  - Physical
- Execute business associate agreements

(45 CFR 164.300-.314)

## Beware

- Cybersecurity, especially
  - Phishing
  - Ransomware
- Social media, photos, etc.
- Unencrypted devices
  - Mobile devices (e.g., phones, tablets, etc.)
  - USB or other media
- Unencrypted e-mails, texts, photos

# HIPAA Breach Notification

- Must self-report “breach” of unsecured PHI to:
  - Affected individuals.
    - No later than 60 days.
    - Written letter
  - HHS.
    - Breach < 500 persons: 60 days after end of calendar year
    - Breach > 500 persons: when report to individual
    - <https://www.hhs.gov/hipaa/for-professionals/breach-notification/breach-reporting/index.html>
  - Local media.
    - Breach involves > persons in a state

(45 CFR 164.400-.410)

# Nondiscrimination



- ACA 1557, 42 CFR part 92
- Civil Rights Act of 1964, 42 USC 2000d, 45 CFR 80.3
- Section 504, Rehabilitation Act of 1973, 29 USC 701; 45 CFR 84.3
- Age Discrimination Act of 1975, 42 USC 6101
- Americans with Disabilities Act of 1990, 42 USC 12101
- Executive Order 13166 (8/00) and HHS Guidance re Persons with Limited English Proficiency (8/03)

# Nondiscrimination

- Do not discriminate on basis of race, color, national origin, sex, age, or disability.
- Provide language assistance to persons with limited English proficiency.
  - Interpreters
  - Translations of key documents
- Provide auxiliary aids to those with disabilities.
  - Depends on circumstances.
  - Allow service animals.
- Make newly constructed or altered facilities accessible to those with disabilities.
- Regulations concerning sex discrimination (gender identity) are enjoined; proposed rule issued 5/25/19.

# Nondiscrimination

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- Covered entities with 15 or more employees:
  - Appoint compliance coordinator.
  - Establish grievance procedure.

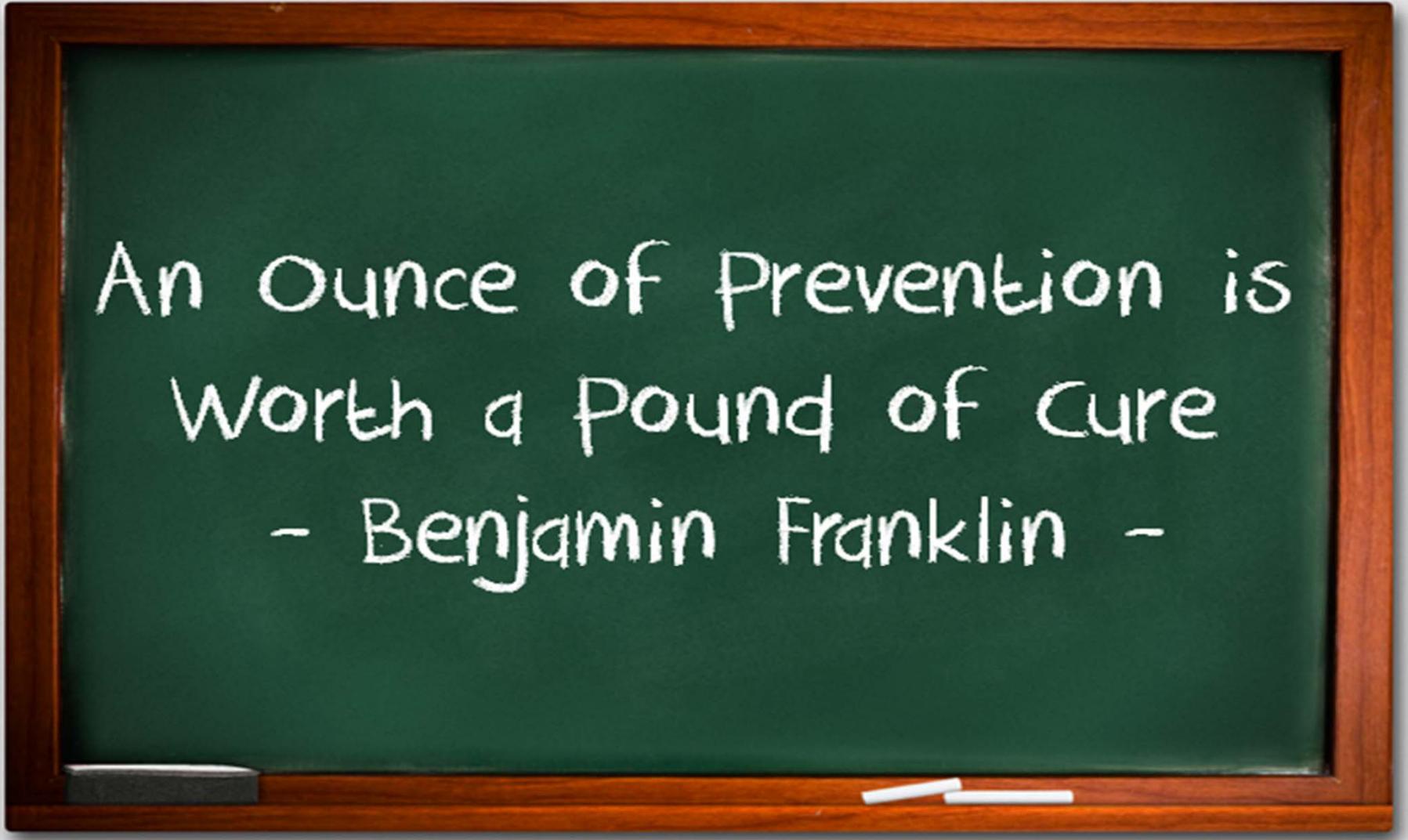
(42 CFR 92.7)

- Post notice of nondiscrimination.
- Include taglines and statements on significant documents.

➤ **On 3/24/19, HHS issued a proposed rule that would modify notice requirements.**

(42 CFR part 92)

## In conclusion...



An Ounce of Prevention is  
Worth a Pound of Cure  
- Benjamin Franklin -

# Additional Resources

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<https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/nursinghome-provider-booklet.pdf>

The screenshot shows a web browser window with the following elements:

- Browser Tab:** Nursing Home Toolkit: Program | x
- Address Bar:** <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/nursinghome-provider-booklet.pdf>
- Booklet Cover:**
  - Title:** Nursing Home Toolkit
  - Subtitle:** Program Integrity and Quality of Care—An Overview for Nursing Home Providers
  - Image:** A photograph of three people: an elderly man with glasses, a young woman with a stethoscope, and a woman looking at a document.
- Taskbar:** Windows taskbar with icons for Start, Search, File Explorer, Mail, Chrome, Word, OneNote, Edge, Lock, Clock, and PowerPoint. System tray shows network, volume, and date/time (3:35 PM, 6/29/2019).

# <https://oig.hhs.gov/compliance/compliance-resource-portal/>

Compliance Resource Portal | Off x +

https://oig.hhs.gov/compliance/compliance-resource-portal/

An official website of the United States government [Here's how you know](#)

U.S. Department of Health and Human Services  
**Office of Inspector General**

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RAT-STATS

Safe Harbor Regulations

## Compliance Resource Portal

[Highlights from Principal Deputy IG Joanne Chiedi's 2019 HCCA Compliance Institute Remarks](#)

- Toolkits +
- Provider Compliance Resources and Training +
- Advisory Opinions +
- Voluntary Compliance and Exclusions Resources +

Email your suggestions for new OIG compliance resources

This is not intended to be a formal agency solicitation. OIG welcomes ideas for new compliance resources that would be helpful to the health care community and that are consistent with OIG's mission, in any format. The receipt of a suggestion does not obligate OIG to take action, including responding to the suggestion, making suggestions public, or issuing public guidance. Members of the public are

3:37 PM 6/29/2019

# <https://www.hhs.gov/ocr/index.html>

The screenshot shows the HHS.gov Office for Civil Rights website. At the top, there is a blue header with the HHS.gov logo and the text "Office for Civil Rights" and "U.S. Department of Health & Human Services". Below the header is a search bar with the placeholder text "I'm looking for..." and a magnifying glass icon. To the right of the search bar is a link for "HHS A-Z Index".

Below the search bar is a row of six navigation buttons: "About OCR" (brown), "Filing with OCR" (purple), "Civil Rights" (maroon), "Conscience and Religious Freedom" (grey), "Health Information Privacy" (teal), and "Newsroom" (brown). Two large orange arrows point upwards from the bottom of the page towards the "About OCR" and "Civil Rights" buttons.

Below the navigation buttons is a breadcrumb trail: "HHS > Office for Civil Rights (OCR) Home". To the right of the breadcrumb trail are links for "size AAA", "Print", and "Share" (with Facebook and Twitter icons).

The main content area starts with the heading "Office for Civil Rights (OCR)". Below this heading is a section titled "I would like info on. . ." with a link for "Conscience Rule Effective Date Moved to Nov. 22, 2019". To the right of this link is a photograph of a stethoscope on a wooden surface. Further right is a dark grey box with the text "Proposed Rule on Section 1557".

[https://www.ahcancal.org/facility\\_operations/integrity/Pages/Compliance-Programs.aspx](https://www.ahcancal.org/facility_operations/integrity/Pages/Compliance-Programs.aspx)

Compliance Programs

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## Compliance Programs

Background

As part of the [Requirements of Participation \(RoP\)](#) published October 2016, nursing centers must have a Compliance and Ethics Program that meets certain requirements. Starting November 28, 2019, CMS and state survey agencies will be authorized to issue survey deficiencies under federal Ftag F895 to facilities that do not have an effective Compliance Program.

CMS has not yet issued guidance about how F895 will be interpreted, but AHCA encourages nursing centers to review the requirements at 42 CFR § 483.85 and begin making changes to comply.

### AHCA Provider Member Resources

- Center for Program Integrity
- CMS Integrity Contractors
  - Medicare Recovery Auditors
  - Medicare Administrative Contractors
  - Zone Program Integrity Contractors
- Supplemental Medical Review Contractors
- CERTs
- Unified Program Integrity Contractors
- Collaborating Agencies
- Voluntary Disclosures
- Exclusion Lists

# <https://nvhca.org/wp-content/uploads/2019/02/ahca-preliminary-toolkit.pdf>

https://nvhca.org/wp-content/uploads/2019/02/ahca-preliminary-toolkit.pdf

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rg

Go to Favorites Help

vert Select

## AHCA COMPLIANCE AND ETHICS PROGRAM TOOLKIT



### I. SURVEYORS WILL START ASSESSING COMPLIANCE AND ETHICS PROGRAMS STARTING NOVEMBER 28, 2019

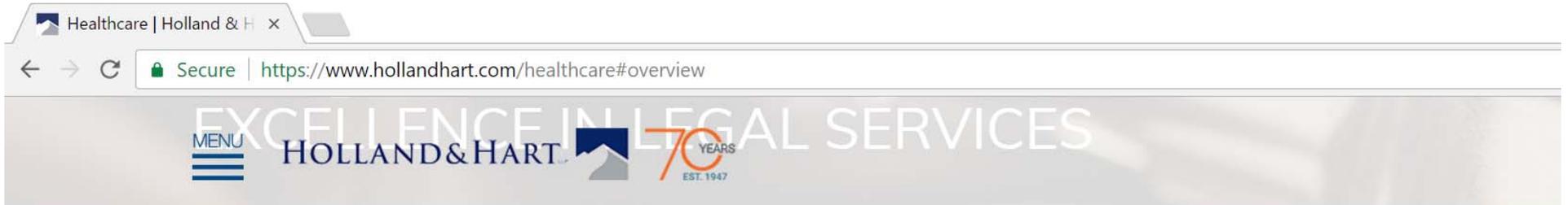
Medicare and Medicaid participating nursing facilities (collectively referred to as “SNFs” or “facilities”) have been required to have a compliance and ethics program (“Compliance Program”) since March 23, 2013, under Section 6102 of the Affordable Care Act, but to date there has been no regulatory mechanism for the government to enforce this requirement, other than through corporate integrity agreements (“CIAs”) imposed by the Office of Inspector General (“OIG”) as a condition of settlement of certain federal investigations. The Centers for Medicare and Medicaid Services (“CMS”) did not issue final regulations for Compliance Programs until October 4, 2016, with an effective date of November 28, 2019. Starting November 28, 2019, CMS and state survey agencies will be authorized to issue survey deficiencies under federal Ftag F895 to facilities that do not have effective Compliance Programs.

AHCA has been at the forefront of encouraging facilities to implement Compliance Programs and many years ago developed a Compliance Manual and Sample Policies and Procedures for members that is available on its website at: [https://www.ahcancal.org/facility\\_operations/integrity/Pages/Compliance-Programs.aspx](https://www.ahcancal.org/facility_operations/integrity/Pages/Compliance-Programs.aspx). To help members better prepare for the new Compliance Program regulations that appear at 42 C.F.R. § 483.85, AHCA is providing this interim summary of the new requirements. AHCA will update this information as soon as CMS issues further interpretive guidance for F895.<sup>1</sup>

Facilities that do not already have a Compliance Program should begin putting one in place so that they are ready for survey enforcement. Facilities that have implemented Compliance Programs should review the new requirements against their existing programs and revise as necessary. The goal is to have an effective Compliance Program, with sufficient documentary evidence in place, to show surveyors who will be assessing the Compliance Program for substantial compliance with the new CMS regulations at 42 C.F.R. § 483.85, F895.

Starting November 28, 2019, surveyors will use the regulations at 42 C.F.R. § 483.85, F895, to determine whether a SNF’s Compliance Program is in substantial compliance with the regulations. CMS has not yet issued guidance about how F895 will be interpreted; it is likely CMS will release guidance in an updated State Operations Manual (“SOM”), Appendix PP within the next year or so. It is also possible that CMS will develop a Critical Element Pathway for Compliance Programs at some future date. Facilities should not wait for CMS to release any

<https://www.hollandhart.com/healthcare#overview>



**OVERVIEW** ▶

PRACTICES/INDUSTRIES

NEWS & INSIGHTS

**CONTACTS**



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Salt Lake City



**The Healthcare Industry is poised to continue its rapid evolution. With this sector now making up close to 20 percent of GDP, our lawyers stand ready to help as changes unfold.**

Issues such as rising healthcare costs, healthcare reform, data and privacy security, and innovations in healthcare delivery, device and pharmaceutical designs are forefront in the minds of many of our clients. We are here to guide our clients through the challenges and opportunities that arise in this dynamic industry.

**Clients We Serve**

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- Managed care organizations (MCOs)
- Third-party administrators (TPAs)
- Health information exchanges (HIEs)
- Practice managers and administrators
- Veterans Affairs medical facilities
- Independent Practice Associations (IPAs)
- Imaging centers
- Ambulatory surgery centers
- Medical device and life science companies



# Questions?

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