Compliance and Ethics (§483.85)

Summary

**Effective date:** Providers will have to have a formal compliance and ethics program in place by November 28, 2017 at the earliest.

There is an inconsistency in the final rule on the implementation date of this section. The commentary section and implementation chart states that these requirements will be implemented in Phase 3 – by November 28, 2019.

The text of the regulatory language states the date of implementation as November 28, 2017. We will seek clarity on this from CMS.
### Compliance and Ethics (§483.85) Summary

- Organizations with 5 or more facilities have some additional requirements identified below.

### Elements of a Compliance Program for Skilled Nursing – Side-By-Side

<table>
<thead>
<tr>
<th>OIG Guidance</th>
<th>PPACA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementing written policies, procedures and standards of conduct</td>
<td>Established compliance standards and procedures</td>
</tr>
<tr>
<td>Designating a compliance officer and compliance committee</td>
<td>A senior-level compliance officer with sufficient resources and authority</td>
</tr>
<tr>
<td>Developing effective lines of communication (only in OIG guidance as an element)</td>
<td>Due care in delegating discretionary authority to individuals with a propensity for wrongdoing</td>
</tr>
<tr>
<td>Conducting effective training and education</td>
<td>Communicating standards and procedures to employee via training, publications</td>
</tr>
<tr>
<td>Conducting internal monitoring and auditing</td>
<td>Reasonable steps to achieve compliance by monitoring and auditing systems as well as a reporting system for employees</td>
</tr>
<tr>
<td>Enforcing standards through well-publicized disciplinary guidelines</td>
<td>Consistent enforcement/discipline, including employee discipline for failing to detect offenses</td>
</tr>
<tr>
<td>Responding promptly to detected offenses and developing corrective action</td>
<td>Reasonable responses to detected misconduct, including program modifications to prevent further similar offenses</td>
</tr>
<tr>
<td>Regular review of compliance program effectiveness (included in guidance by not as an element)</td>
<td>Periodic reassessment of the compliance program</td>
</tr>
</tbody>
</table>
Compliance and Ethics (§483.85)

Differences

NEW Section

We are requiring the operating organization for each facility to have in effect a compliance and ethics program that has established written compliance and ethics standards, policies and procedures that are capable of reducing the prospect of criminal, civil, and administrative violations in accordance with section 1128I(b) of the Act.

Compliance and Ethics (§483.85)

Key Actions

Requirements for all facilities:

• Each facility shall establish a written compliance and ethics program with standards, policies, and procedures capable of reducing the prospect of criminal, civil, and administrative violations of the Act and promote quality of care.

• Assignment of specific high-level personnel with responsibility to oversee compliance such as, but not limited to, the CEO, members of the board, or directors of major divisions in the operating organization.

• Dedicate sufficient resources and authority to the individual responsible to oversee the compliance and ethics program.
Compliance and Ethics (§483.85)
Key Actions

Requirements for all facilities:

• Providers must effectively communicate the standards, policies and procedures to their entire staff, individuals providing services under a contractual arrangement, and volunteers, consistent with their expected roles.

• Take steps to achieve compliance through audits and/or monitoring and have an anonymous reporting mechanism.

Compliance and Ethics (§483.85)
Key Actions

Requirements for all facilities:

• Enforce the program through appropriate disciplinary mechanisms.

• After a violation is detected, the organization must ensure all reasonable steps are taken to respond appropriately to the violation to prevent future similar incidents.

• Conduct an annual review of the compliance program.
Compliance and Ethics (§483.85)

Key Actions

Additional requirements for organizations with 5 or more facilities:

• Conduct mandatory annual staff training.

• Designate a compliance office that reports to governing body that is not subordinate to general counsel, chief financial officer, or chief operating officer.

• Designate a compliance liaison at each facility.

Compliance and Ethics (§483.85)

Next Steps

CMS will issue additional guidance on this section before the implementation date.

• Providers should start reviewing their existing compliance programs and compare them to the regulatory language.

• For those providers with 5 or more facilities, they may need to restructure their program to appoint a compliance officer and/or change the job description, reporting duties, or titles of an existing compliance professional.

• The organizations should also begin to identify potential liaisons at each community.
Compliance and Ethics (§483.85)

Next Steps

There are two existing CMS resources that provide guidance on compliance programs for nursing facilities that delineate the elements of an effective compliance program.

The seven elements of an effective compliance program identified in the guidance are:

- Implementing written policies, procedures, and standards of conduct;
- Designating a compliance officer and compliance committee;
- Conducting effective training and education;
- Developing effective lines of communication;
- Enforcing standards through well publicized disciplinary guidance;
- Conducting internal monitoring and auditing; and
- Responding promptly to detected offenses and developing corrective action.

Compliance and Ethics (§483.85)

Additional Information

Section 1557

The nondiscrimination provision of the Affordable Care Act (ACA). The law prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs or activities. Section 1557 builds on longstanding and familiar Federal civil rights laws: Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973 and the Age Discrimination Act of 1975. Section 1557 extends nondiscrimination protections to individuals participating in:

- Any health program or activity any part of which received funding from HHS;
- Any health program or activity that HHS itself administers;
- Health Insurance Marketplaces and all plans offered by issuers that participate in those Marketplaces.
2000 OIG Compliance Program Guidance for Nursing Facilities

2000 Compliance Program Guidance

- The 2000 CPG addresses the following risk potential areas:
  - Quality of Care
  - Resident Rights
  - Billing and Cost Reporting
  - Employee Screening
  - Kickbacks, Inducements, and Self-Referrals
  - Creation and Retention of Records
Quality of Care

- Lack of comprehensive assessments of each resident’s functional capacity and a comprehensive care plan that includes measurable objectives and timetables to meet the resident’s medical, nursing, and mental and psychosocial needs
- Inappropriate and insufficient treatment and services to address residents’ clinical conditions, including pressure ulcers, dehydration, malnutrition, incontinence of the bladder, and mental or psychosocial problems
Quality of Care

- Failure to accommodate individual resident needs and preferences
- Failure to properly prescribe, administer and monitor prescription drug usage
- Policies for maintaining accurate drug records and tracking medications, processes that advance patient safety, minimize adverse drug interactions, and ensure that irregularities in a resident’s drug regimen are promptly discovered and addressed.

Quality of Care

- Inadequate staffing levels or insufficiently trained (inadequate clinical expertise) or supervised staff to provide medical, nursing, and related services or to meet the unique acuity levels of the residents
- Failure to provide appropriate therapy services
- Failure to provide appropriate services to assist residents with activities of daily living
- Failure to provide an ongoing activities program to meet the individual needs of all residents
Quality of Care

- Failure to report incidents of mistreatment, neglect or abuse to the administrator of the facility and other officials as required by law.
- Measures to ensure an interdisciplinary and comprehensive approach to developing care plans, meetings to accommodate the full interdisciplinary team, involving the residents’ family members or legal guardians, documenting the length and content of each meeting.
- Policies to facilitate participation by the attending physician, to ensure that a physician supervises care and involvement in the process.

Resident Rights
Resident Rights

- Discriminatory admission or improper denial of access to care
- Verbal, mental or physical abuse, corporal punishment and involuntary seclusion
- Inappropriate use of physical or chemical restraints

Resident Rights

Denial of a resident’s right to participate in care and treatment decisions

Failure to safeguard resident’s financial affairs

Failure to ensure that residents have personal privacy and access to their personal records upon request and that the privacy and confidentiality of those records are protected
Billing and Cost Reporting

Submitting claims for items or services not ordered
Knowingly billing for inadequate or substandard care
Submitting claims to Medicare Part A for residents who are not eligible for Part A coverage
Billing and Cost Reporting

Billing for items or services not actually rendered or provided as claimed.
Submitting claims for equipment, medical supplies and services that are medically unnecessary
Duplicate Billing
False Cost Reports
Credit Balances—failure to refund

Billing and Cost Reporting

Providing misleading information about a resident’s medical condition on the MDS or otherwise providing inaccurate information used to determine the RUG assigned to the resident

Upcoding the level of service provided
Billing for individual items or services when they either are included in the facility’s per diem rate or are of the type of item or service that must be billed as a unit and may not be unbundled
Billing and Cost Reporting

Billing for residents for items or services that are included in the per diem rate or otherwise covered by the third-party payor

Billing for visits to patients who do not require a qualifying service.

Altering documentation or forging a physician signature on documents used to verify that services were ordered and/or provided

Billing and Cost Reporting

Failing to maintain sufficient documentation to support the diagnosis, justify treatment, document the course of treatment and results, and promote continuity of care
Employee Screening

Investigate the background of employees by checking with all applicable licensing and certification authorities to verify that requisite licenses and certifications are in order.

Require all potential employees to certify that they have not been convicted of an offense that would preclude employment in a nursing facility and that they are not excluded from participation in the Federal health care programs.
Employee Screening

Require temporary employment agencies to ensure that temporary staff assigned to the facility have undergone background checks that verify that they have not been convicted of an offense that would preclude employment in the facility.

**Check the OIG’s List of Excluded Individuals/Entities and the GSA’s list of debarred contractors to verify that employees are not excluded from participating in the Federal health care programs.**

---

Employee Screening

Require current employees too to report to the nursing facility if, subsequent to their employment, they are convicted of an offense that would preclude employment in a nursing facility or are excluded from participation in any Federal health care program.

Periodically check the OIG GSA websites to verify the participation/exclusion status of independent contractors and retain on file the results of that query.
Kickbacks, Inducements, and Self-Referrals

Routinely waiving coinsurance or deductible amounts without a good faith determination that the resident is in financial need, or absent reasonable efforts to collect the cost-sharing amount.

Agreements between the facility and a hospital, home health agency, or hospice that involve the referral or transfer of any resident to or by the nursing home.
Kickbacks, Inducements, and Self-Referrals

Soliciting, accepting or offering any gift or gratuity of more than nominal value to or from residents, potential referral sources, and other individuals and entities with which the nursing facility has a business relationship

Conditioning admission or continued stay at a facility on a third-party guarantee of payment, or soliciting payment for services covered by Medicaid, in addition to any amount required to be paid under the State Medicaid plan

Kickbacks, Inducements, and Self-Referrals

Arrangements between a nursing facility and a hospital under which the facility will only accept a Medicare beneficiary on the condition that the hospital pays the facility an amount over and above what the facility would receive through PPS

Financial arrangements with physicians, including the facility’s medical director
Kickbacks, Inducements, and Self-Referrals

Arrangements with vendors that result in the nursing facility receiving non-covered items [such as disposable adult diapers] at below market prices or no charge, provided the facility orders Medicare-reimbursed products

Soliciting or receiving items of value in exchange for providing the supplier access to residents’ medical records and other information needed to bill Medicare

Joint ventures with entities supplying goods or services

Swapping

Creation and Retention of Records
Creation and Retention of Records

All records and documentation [e.g., billing and claims documentation] required for participation in Federal, State, and private health care programs, including the resident assessment instrument, the comprehensive plan of care and all corrective actions taken in response to surveys

All records, documentation, and audit data that support and explain cost reports and other financial activity, including any internal or external compliance monitoring activities

Creation and Retention of Records

All records necessary to demonstrate the integrity of the nursing facility compliance process and to confirm the effectiveness of the program

Secure information in a safe place

Maintain hard copies of all electronic or database documentation
Creation and Retention of Records

Limit access to such documentation to avoid accidental or intentional fabrication or destruction of records.

Conform document retention and destruction policies to applicable laws.

2008 Draft OIG Supplemental Compliance Program Guidance for Nursing Facilities
2008 Supplemental Compliance Program

In April 2008, the OIG posted a supplemental Compliance Program Guidance (CPG) for Nursing Facilities

The draft is meant to work with the March 2000 CPG to offer:

◦ "a set of guidelines that nursing facilities should consider when developing and implementing a new compliance program or evaluating an existing one"

2008 Supplemental Compliance Program

The 2008 CPG addresses the following risk potential areas:

◦ Quality of Care
◦ Submissions of Accurate Claims
◦ The Federal Anti-Kickback Statute
◦ The Stark Law
◦ Anti-Supplementation
◦ Medicare Plan D
◦ HIPAA Privacy and Security Rules
Quality of Care

Sufficient Staffing

- Federal Law (42 CFR 483.30) requires sufficient staffing in facilities to highest practicable overall well-being of their residents
- Facilities should assess their staff models considering:
  - Staff skill levels, Staff to resident ratios, staff turnover, staffing schedules, adverse event reports, payroll records, and timesheets
Quality of Care

Sufficient Staffing
- Facilities should ensure that their considerations reflect actual on-the-floor staff as opposed to the staff on paper
  - The facility should look to payroll records, which show actual hours being worked, rather than the theoretical staff schedules

Quality of Care

Resident Care Plans
- Federal Regulations (42 CFR 483.20(k)) require that facilities develop comprehensive care plans for each resident in order to address their medical needs
  - These plans should include reasonable objectives and timetables
  - Plans should include all disciplines involved in the resident’s care
  - A full clinical team should be developed with the full clinical team in consideration
Quality of Care

Resident Care Plans
- Measures that should be taken
  - Schedule plan meetings so that the full medical care team can attend and complete all clinical assessments before the meeting concludes
  - Involve the resident’s family members
  - Documenting the length and content of each meeting

Quality of Care

Resident Care Plans
- Attending physicians should be involved in the resident’s care plan
- Facilities have a critical role to ensure that the physician supervisors each resident’s care
- Physicians should be visiting residents regularly
- Facility should have a process of informing attending physicians of any changes in a resident’s health
Quality of Care

Appropriate use of Psychotropic Drugs
- Facilities are responsible for the quality of drug therapy provided in the facility
- Psychotropic Medication should never be given to a resident for discipline or convenience purposes

Quality of Care

Appropriate use of Psychotropic Drugs
- If a resident requires psychotropic medication, the facility should give the resident gradual medication reductions and behavioral interventions aimed at reducing medication use
- Facilities should document, monitor, and review the use of these drugs
- Facilities should educate their providers regarding the proper way to document and review the use of these drugs
Quality of Care

Medication Management

◦ Facilities are required to provide pharmaceutical services to meet the needs of each resident (42 CFR 483.60)
◦ Facilities should have proper policies and procedures in place to ensure that the service needs of each resident are met

Quality of Care

Medication Management

◦ Procedures and Policies
  ◦ Obtain the services of a licensed consultant pharmacist
  ◦ Should review the drug regime of each resident at least once per month
  ◦ Should create a system of records for controlled drugs used
  ◦ Should ensure that controlled drugs are all accounted for and properly maintained
Quality of Care

Medication Management and Conflicts of Interest
- Pharmacist employed by long term care pharmacy
- Pharmacy has contract with pharmaceutical company that makes them prefer to give out one drug over another
- How does the facility handle this?

Quality of Care

Medication Management and Conflicts of Interest
- Facilities have to train and supervise those prescribing and administering drugs to residents
- Educate regarding the legal prohibition of accepting anything of value from a pharmaceutical company to influence the choice of drug for a resident
- Review the total compensation paid to consultant pharmacists to ensure that it is not structured in a manner that involves the volume or value of a particular drug prescribed for residents.
Quality of Care

Resident Safety
- Promoting Resident Safety
  - An effective compliance program recognizes the value of a demonstrated internal commitment to eliminating resident abuse
  - This includes policies and procedures to prevent, investigate, and respond to abuse, neglect, and misappropriation
  - Resident-on-Resident, Staff-on-Resident, and Injuries of unknown source should all be included in these policies and procedures

Quality of Care

Resident Safety
- Promoting Resident Safety
  - Facilities should have a confidential reporting system for anyone to make a report
  - Public notices should be found that encourage the reporting of incidents and tell individuals how they can make reports
  - Facilities should be CLEAR that they are committed to preventing and responding to abuse
Quality of Care

Resident Safety

- Resident Interactions
  - Facilities can address resident-on-resident abuse by:
    - Educating staff who are involved with hostile residents
    - Initial and periodic resident screenings
    - Proper staffing assignments
    - Care plans that reflect the additional attention these residents need

Staff Screening

- Cannot employ individuals found guilty of abusing, neglecting, or mistreating residents
- Conduct state required criminal background checks
- OIG recommends that facilities get a background check from every state in which an applicant has been previously employed
Submission of Accurate Claims

PROPER REPORTING OF RESIDENT CASE-MIX, THERAPY SERVICES, SCREENING FOR EXCLUDED INDIVIDUALS AND ENTITIES, AND RESTORATIVE AND PERSONAL CARE SERVICES

Submission of Accurate Claims

Facilities must submit accurate claims to Federal health care programs

Submitting false claims could result in:

- Criminal Prosecution
- Civil penalties including treble damages
- Exclusion from Federal health care programs
Submission of Accurate Claims

Proper Reporting of Resident Case-Mix
◦ The assessment, reporting, and evaluation of resident case-mix data is a significant risk for facilities
◦ Facilities should:
  ◦ Train persons collecting data and those analyzing the data to ensure that they are informed of the purpose and utility of case-mix data
  ◦ Conduct internal and external validation of the data
  ◦ Scrutinize the quality-reporting data

Submission of Accurate Claims

Therapy Services
◦ Potential problems
  ◦ Improper utilization of therapy services to inflate the severity of RUG classifications and obtain additional reimbursement
  ◦ Overutilization of services billed on a fee-for-service basis to Part B under consolidated billing
  ◦ Stinting therapy services provided to residents covered by Part A PPS payment
Submission of Accurate Claims

Therapy Services
- Policies and Procedures
  - Require therapy contractors to provide complete documentation of each resident’s services
  - Regular reconciliation of the physician’s orders and the services actually provided
  - Assessment, with the ordering physician, of whether to services and medically necessary
  - Interview the family members of residents to ensure services are being provided

Submission of Accurate Claims

Screening for Excluded Individuals and Entities
- No Federal health care program payment may be made for items or services given by an excluded individual or entity
- Civil monetary penalties may be imposed against an individual who contracts with an excluded party, when they know should have known the party was excluded
Submission of Accurate Claims

Screening for Excluded Individuals and Entities
- Facilities should implement the following to avoid contracting with excluded parties
  - Screen all prospective owners, administrators, and agents against the OIG’s List of Excluded Individuals
  - Periodic screening of current contracted entities
  - Require potential vendors to disclose if they are excluded
  - Train human resource personnel of the effects of exclusion

Submission of Accurate Claims

Restorative and Personal Care Services
- Facilities are required to provide appropriate restorative and personal care to their residents
- OIG is currently aware of such services being billed, but not actually being rendered
- A failure to provide these services, after billing for them, will result in liability under fraud and abuse statutes
Submission of Accurate Claims

Restorative and Personal Care Services
- Facilities should implement the following policies
  - Comprehensive procedures to ensure that such services are afforded to each resident at the appropriate quality and level
  - Complete and contemporaneous documentation to ensure that these services are being rendered

Federal Anti-Kickback Statute

FREE GOODS AND SERVICES, SERVICE CONTRACTS, DISCOUNTS, HOSPICES, RESERVED BED ARRANGEMENTS
Federal Anti-Kickback Statute

Free Goods and Services
- OIG is substantially concerned that free goods and services are nothing more than a vehicle to confer the unlawful payment for referrals
- The provision of goods or services that have independent value to the recipient confers a benefit to the recipient → Such a benefit may constitute prohibited remuneration under anti-kickback

Federal Anti-Kickback Statute

Free Goods and Services
- Examples of arrangements getting scrutiny
  - Pharmaceutical consultant services
  - Infection control and Chart review from laboratories
  - Equipment (computers & software) of value to the facility
  - Durable Medical Equipment offered by DME suppliers
  - Hospice nurse providing nursing for non-hospice residents
Federal Anti-Kickback Statute

Service Contracts (Non-Physician Services)

- Obtaining goods and services at not fair market value presents a heightened risk of fraud
- Relationships where facilities arrange for goods and services to be provided for by outside suppliers should be closely scrutinized
- OIG recognizes that such relationships are a means to disguise kickbacks

Federal Anti-Kickback Statute

Service Contracts (Non-Physician Services)

- Ways to minimize risk in these relationships
  - Ensure that there is a legitimate need for the services or goods
  - Ensure that the compensation is at fair-market value in an arms length transaction
  - Ensure the goods or services are actually provided
  - The arrangement is not related in any manner to the volume or value of Federal health care program business
Federal Anti-Kickback Statute

Service Contracts (Physician Services)
- Physician services in facilities have to be closely examined to ensure that they are not arrangements to pay the physician for referrals to the facility

Federal Anti-Kickback Statute

Service Contracts (Physician Services)
- Ways to minimize risk in these relationships
- Same checklist as for Non-Physician Services
- Also the facility can:
  - Contemporaneous documentation of the arrangement with the physician
  - Compensation is appropriate with respect to the skill level and experience of the physician
  - Structure service arrangements to comply with the personnel services and management contracts safe harbor whenever possible
Federal Anti-Kickback Statute

Discounts (Price Reductions)
◦ Anti-Kickback provides an exception for discounts offered to customers that submit claims to Federal health care programs
◦ The exception only covers price reductions in the product’s or service’s price

Federal Anti-Kickback Statute

Discounts (Price Reductions)
◦ In order to use the discounts safe-harbor facilities have to comply with it
◦ All discounts should be disclosed and reflected on cost reports filed with the Federal program
◦ Group Purchasing Organizations should be sure to document and report any discounts
Federal Anti-Kickback Statute

Discounts (Swapping)
- OIG is looking to see if the discount is tied or linked, directly or indirectly, to referrals of other Federal health care program business
- E.g. Facility accepts lower price from a supplier on an item covered by the facilities Part A per diem payment *in exchange for* the facility referring to the supplier other Federal health care plan business
- This is “swapping” violation

---

Federal Anti-Kickback Statute

Discounts (Swapping)
- The size of the discount is not the determinative factor for the OIG
- If any direct or indirect link exists *between a price offered for items or services the facility would normally pay out-of-pocket for* and *referrals for Federal health care plan business*, then there is a *violation* of anti-kickback
Federal Anti-Kickback Statute

Hospices
- Hospice services for residents inside the facility pose a risk for anti-kickback violations
- Facilities have to be mindful that requesting remuneration, *which influences their decision to do business with the hospice*, from a hospice may subject both parties to anti-kickback violations

Federal Anti-Kickback Statute

Hospices
- Practices that pose a substantial risk
  - Hospice offers free goods or services at below market value to induce referrals from the facility
  - Hospice paying room and board fees to the facility in access of what they would have received from Medicare
  - Hospice paying for additional services, or paying above market value for services, that Medicare considers does not consider to be part of its room and board payment to the facility
  - Hospice referring patients to the facility to induce referrals from the facility
Federal Anti-Kickback Statute

Reserved Bed Arrangements
- Hospitals providing remuneration to facilities to keep beds open for the hospital’s patients
- This can be a risk of an anti-kickback violation if the arrangement is there to induce referrals to the hospital
- Have to make sure these payments are not a disguise for referrals from the facility to the hospital

Federal Anti-Kickback Statute

Reserved Bed Arrangements
- Examples of problematic arrangements
  - Payments that are more than the actual cost to the nursing facility of holding an empty bed
  - Payments for “lost opportunity” calculated by considering the cost to the facility to hold an empty bed
  - Payment for more beds than the hospital needs
  - Payments should be for the exclusive purpose of securing needed beds
Physician Self-Referrals

The physician self-referral law (The Stark Law) prohibits entities that furnish “designated health services” (DHS) from submitting claims for DHS if the referral comes from a physician with whom the entity has a prohibited financial relationship.

Nursing facilities that bill Part B for lab services, physical therapy, and occupational services or DHS pursuant to the consolidated billing rules are considered DHS entities.
Physician Self-Referrals

Potential Self-Referral 3 Part Inquiry
- Is there a referral from a physician for a DHS?
  - Includes ordering a service for a resident
  - Does the physician have a direct or indirect financial relationship with the facility?
    - Can be created by ownership, investment, or compensation; its does not have to directly relate to the DHS
    - Does the financial relationship fit in an exception?

Is there a referral from a physician for a DHS?
- NO
- Yes
  - Does the physician have a direct or indirect financial relationship with the facility?
    - NO
    - Yes
      - Does the financial relationship fit into an exception?
        - NO
        - YES
          - No Violation
          - Yes
            - Self Referral Violation
Physician Self-Referrals
Polices to avoid self-referral violations
◦ Have written signed agreements with parties
◦ Ensuring and documenting that any services or items received are compensated with fair-market value
◦ Track non-monetary compensation provided annually to referring physicians

Anti-Supplementation
Anti-Supplementation

For covered items, a facility cannot charge a Medicare or Medicaid beneficiary any amount in addition to what is otherwise required to be paid under Medicare or Medicaid.

E.g. A facility may not accept supplemental payments from a hospital or other source merely because the facility believes the Federal payment to be inadequate.

Medicare Part D
Medicare Part D

“Under no circumstances should a nursing home require, request, coach, or steer any resident to select or change a plan for any reason”

Nor should it “knowingly and/or willingly allow the pharmacy servicing the nursing home” to do the same

-- CMS May 11, 2006 letter

Medicare Part D

Facilities have to be careful not to act in ways that would frustrate a beneficiary’s freedom of choice in choosing a Part D plan

Facilities and their employees and contractors should not accept any payments from any plan or pharmacy to influence a beneficiary to select a particular plan
Facilities that conduct electronic transactions governed by HIPAA are required to comply with the Privacy Rule adopted under HIPAA.

Facilities have flexibility under the rule to adopt their own procedures.

Make sure that procedures are in agreement with the rule’s requirements.
HIPAA Privacy and Security Rules

The HIPAA Security Rule
- As of April 2005, facilities that are covered entities were required to conform to the security rule
- Rule allows for flexibility when adopting procedures to conform
- Facilities should consider their organization and its capabilities when complying with the rule

Corporate Compliance Policy Audit & Crosswalk

The Crosswalk can be accessed at:

Resources

http://www.kitch.com/corporatecompliance/
  ◦ Kitch Compliance Website

  ◦ OIG Workplan

  ◦ CMS Survey and Certification Memos

Resources

https://oig.hhs.gov/reports-and-publications/oei/s.asp#skilled_nursing
  ◦ OIG Reports on Skilled Nursing Facilities

https://oig.hhs.gov/fraud/enforcement/index.asp
  ◦ OIG Enforcement Actions

https://oig.hhs.gov/compliance/advisory-opinions/index.asp
  ◦ OIG Advisory Opinions
(§483.85) Compliance and Ethics

Implementation Deadlines
• Phase 3: November 28, 2019

Seeking clarification—
There is an inconsistency in the final rule on the implementation date of this section. The commentary section and implementation chart states that these requirements will be implemented in Phase 3 – by November 28, 2019.

The text of the regulatory language states the date of implementation as November 28, 2017.

---

Final Rule: Nondiscrimination Notice in Health Programs and Activities

PRESENTED BY KIEL A. CHAMBERLAIN
Introduction

Section 1557 is the nondiscrimination provision of the Affordable Care Act (ACA)

The law, 45 CFR 92, prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs or activities

Applies to health programs and activities that receive federal financial assistance, such as Medicare or Medicaid

Key Provisions

Grievance procedure and compliance coordinator requirements for covered entities

Extends protections against sex discrimination to health coverage and care

Prohibits denial of health care or coverage based on sex, including discrimination based on pregnancy, gender identity, and sex stereotyping

Notice requirements for individuals with disabilities and individuals with limited English proficiency (LEP)
§92.8 Notice Requirements – Significant Publications

Notice of Nondiscrimination

- Covered entities must post a notice of nondiscrimination in significant publications or communications, including patient handbooks and notices pertaining to patient rights, “targeted to beneficiaries, enrollees, applicants, or members of the public”, in conspicuous physical locations, and in a conspicuous location on the home page of a covered entity’s Web site.

Notice of Nondiscrimination

The entity does not discriminate on the basis of race, color, national origin, sex, age or disability.

Appropriate auxiliary aids and services are available free of charge.

Language assistance services such as translated documents and oral interpreters are available free of charge and in a timely manner.

Information on how to obtain auxiliary aids or translations.

Contact information for the designated employee responsible for compliance.

Complaint procedures and how to file a grievance.

Information on how to file a discrimination complaint with the OCR.

A nondiscrimination tagline translated into at least 15 different languages.
Notice Requirements –
Taglines

Taglines must be posted in the top fifteen non-English languages spoken in the State in which the entity is located or does business.

ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1-xxx-xxx-xxxx (TTY: 1-xxx-xxx-xxxx).

Notice Requirements –
Small Publications

Exception to the full notice requirements for small printed publications

Statement of Nondiscrimination in lieu of the full Notice of Nondiscrimination

◦ [Name of covered entity] complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex.

Taglines
◦ Top two non-English languages
Final Rule
Enforcement Timeline

The final rule is effective 60 days after publication in the Federal Register
  ◦ July 18, 2016

Posting notices of consumer rights and taglines
  ◦ October 18, 2016

Provisions affecting health insurance plan benefit design
  ◦ January 1, 2017

Additional Resources

Sample notice, statement, and taglines for use by covered entities into 64 languages:

Lists of the top 15 non-English languages spoken by state: