Health Care Communiqué

Q4 2016

Summary: Final Rule Implementing Section 1557 of the Affordable Care Act

The Department of Health and Human Services (HHS) issued the Final Rule implementing the prohibition of discrimination under Section 1557 of the Affordable Care Act (ACA) of 2010.

The Final Rule, Nondiscrimination in Health Programs and Activities, will help to advance equity and reduce health disparities by protecting some of the populations that have been most vulnerable to discrimination in the health care context. The final rule explains consumers' rights under the law and provides covered entities important guidance about their obligations.

Section 1557 prohibits discrimination based on race, color, national origin, sex, age or disability in certain health programs and activities.

Section 1557 builds on long-standing and familiar Federal civil rights laws: Title VI of the Civil Rights Act of 1964 (Title VI), Title IX of the Education Amendments of 1972 (Title IX), Section 504 of the Rehabilitation Act of 1973 (Section 504), and the Age Discrimination Act of 1975 (Age Act). Most notably, Section 1557 is the first Federal civil rights law to prohibit discrimination on the basis of sex in all health programs and activities receiving Federal financial assistance. Section 1557 has been in effect since enactment of the ACA in 2010 and the HHS Office for Civil Rights (OCR) has been enforcing the provision since it was enacted.

Welcome Our New Experts, Medicare Compliance Solutions!

We are pleased to announce that Medicare Compliance Solutions (MCS) is now serving as our Medicare Advantage/Part D subject matter experts.

MCS is comprised entirely of seasoned Medicare Advantage and Part D experts, and have worked for Medicare health plans or with the Centers for Medicare and Medicaid Services (CMS).

The MCS team has specialized areas of expertise, from applications, appeals and grievances, to enrollment and disenrollment. MCS has also coached MA and PDPs through their CMS audits, created compliance and functional area training programs, and prepared applications for new Medicare managed care applicants, among other services.

For more information, visit:

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The rule covers:

- Any health program or activity, any part of which receives funding from HHS (such as hospitals that accept Medicare or doctors who accept Medicaid);
- Any health program that HHS itself administers;
- Health Insurance Marketplaces and issuers that participate in those Marketplaces.

Protections under the Rule

Section 1557 builds on prior Federal civil rights laws to prohibit sex discrimination in health care. The final rule requires that women be treated equally with men in the health care they receive and also prohibits the denial of health care or health coverage based on an individual's sex, including discrimination based on pregnancy, gender identity, and sex stereotyping. The final rule also requires covered health programs and activities to treat individuals consistent with their gender identity.

For individuals with disabilities, the final rule requires covered entities to make all programs and activities provided through electronic and information technology accessible; to ensure the physical accessibility of newly constructed or altered facilities; and to provide appropriate auxiliary aids and services for individuals with disabilities. Covered entities are also prohibited from using marketing practices or benefit designs that discriminate on the basis of disability and other prohibited bases.

Covered entities must take reasonable steps to provide meaningful access to each individual with limited English proficiency eligible to be served or likely to be encountered in their health programs and activities. In addition, covered entities are encouraged to develop and implement a language access plan. The final rule on Section 1557 does not include a religious exemption; however, the final rule does not displace existing protections for religious freedom and conscience.

Procedural Requirements

The final rule implementing Section 1557 requires covered entities with 15 or more employees to have a grievance procedure and a compliance coordinator. The final rule includes an Appendix that provides a model grievance procedure for covered entities. Entities with fewer than 15 employees are not required to have a grievance procedure or compliance coordinator.

The final rule requires that covered entities post notices of nondiscrimination and taglines that alert individuals with limited English proficiency to the availability of language assistance services. To reduce burden and costs, OCR has translated a sample notice and taglines for use by covered entities into 64 languages. For translated materials, visit www.hhs.gov/civil-rights/for-individuals/section-1557/translated-resources/index.html.

The final rule requires each covered entity to post taglines in at least the top 15 non-English languages spoken in the State in which the entity is located or does business. Those requirements are modified for small sized significant communications such as postcards; for these, the final rule requires entities to post a nondiscrimination statement and taglines in at least the top two non-English languages spoken by individuals with limited English proficiency in the State.

Enforcement

The existing enforcement mechanisms under Title VI, Title IX, Section 504 and the Age Act apply for redress of violations of Section 1557. These mechanisms include: requiring covered entities to keep records and submit compliance reports to OCR, conducting compliance reviews and complaint investigations, and providing technical assistance and guidance.

Where noncompliance or threatened noncompliance cannot be corrected by informal means, available enforcement mechanisms include suspension of, termination of, or refusal to grant or continue Federal financial assistance; referral to the Department of Justice with a recommendation to bring proceedings to enforce any rights of the United States; and any other means authorized by law. The final rule also recognizes that an individual may bring a civil action to challenge a Section 1557 violation.

Responses to Comments on the Proposed Rule Reflected in the Final Rule

- Sexual orientation discrimination: While the final rule does not resolve whether discrimination on the basis of an individual's sexual orientation status alone is a form of sex discrimination under Section 1557, the rule makes clear that OCR will evaluate complaints that allege sex discrimination related to an individual's sexual

orientation to determine if they involve the sorts of stereotyping that can be addressed under Section 1557. HHS supports prohibiting sexual orientation discrimination as a matter of policy and will continue to monitor legal developments on this issue.

- No new religious exemption: The proposed rule sought comment on whether there should be an exemption for religious organizations in circumstances in which nondiscrimination obligations conflict with religious beliefs. As noted above, the final rule on Section 1557 does not include a religious exemption; however, the final rule does not displace existing protections for religious freedom and conscience.

- Benefit design in health coverage plans: OCR received comments that issuers would need time to come into compliance with the requirement prohibiting discrimination in benefit design. The final rule establishes that to the extent the provisions of the rule require changes to health insurance or group health plan benefit design, such provisions have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2017.

- Complaints against Third-Party Administrators (TPAs): The proposed rule noted that where an entity acts as a TPA for a health plan, OCR would engage in a case-by-case analysis to determine coverage under Section 1557. The final rule states that OCR will investigate the TPA when the alleged discrimination is in the administration of the plan; where the alleged discrimination is in benefit design, OCR will process the complaint against the employer/plan sponsor and typically will refer the matter to the Equal Employment Opportunity Commission (EEOC) if OCR lacks jurisdiction over the employer.

- Standards for single sex programs: The proposed rule sought comment on the standard for evaluating single sex health programs. The final rule allows these programs only where a covered entity has an exceedingly persuasive justification.

- Language access: Covered entities are encouraged to develop a language access plan.

For more information about Section 1557, including factsheets on key provisions and frequently asked questions, visit http://www.hhs.gov/civil-rights/for-individuals/section-1557.

Combating Fraud, Waste and Abuse: Are You Compliant?

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Fraud and abuse cost billions in wasteful payments - they drain resources from care for the needy (e.g., elderly and indigent beneficiaries of government programs), contribute to rising health care costs and compromise the integrity of Medicare and Medicaid. In 1977, Congress enacted the Medicare-Medicaid Anti-Fraud and Abuse Amendments P.L. 95-142 and provided funding for the establishment of Medicaid Fraud Control Units (MFCU).

Since 1995, Federal law requires each state to have a MFCU unless the state can demonstrate to the satisfaction of the HHS Secretary that it has a minimum amount of Medicaid fraud - and Medicaid beneficiaries are protected from abuse and neglect. Over the years, various legislations including the Medicare Modernization Act 2003 and Affordable Care Act 2010 have reinforced the focus and the ability to combat fraud, waste and abuse (FWA).

Consistent with the government's concern for program integrity and beneficiary protection, the Centers for Medicare & Medicaid Services (CMS) require plan sponsors to have comprehensive compliance measures to safeguard the Part D program from FWA. The requirements are spelled out in Chapter 9 of the Prescription Drug Benefit Manual or Chapter 21 of the Medicare Managed Care Manual:

- Monitor and audit your FDRs (first tier, downstream and related entities);
- Analyze data to detect and prevent potential fraud, waste, and abuse; and
- Have a unit, such as a Special Investigation Unit (SIU), specifically tasked with identifying and addressing fraud, waste, and abuse, or ensure that the responsibilities generally conducted by an SIU are conducted by a plan sponsor's compliance department.

Fraud is not easy to prove because intent has to be demonstrated and it takes time to investigate. For instance, even when one discovers a physician's ownership of a pharmacy located adjacent to the physician's practice, self-referral has to be evident to invoke the Stark

law (Phase III took effect in December 2007). Waste and abuse practices are easier to discern by scanning data. There are many examples:

1. Double billing of a drug in a medical claim and drug claim - drugs administered in the provider's office are submitted in CMS 1500 using a HCPCS code (or J code) or X12 837 electronic file. Due to the time lag between an office visit for administration of the drug and the submission of the claim and the different processes of adjudicating medical and drug claims, one has to be looking for these duplications through analytics. Injections such as DMARDs are at risk for double billing.

2. Days' supply of drugs - the number of days' supply is often a calculated number input by the pharmacy; for a maintenance drug, the quantity and the days can be calculated based on usual dosing. For "as needed" drugs, the days' supply can be nebulous. By entering a number that can bypass the maximum daily dose or the refill threshold adjudication edit, more refills than clinically warranted may result. For instance, a 75% refill threshold allows refills every 22 days or 15+ refills in 12 months. By consistently submitting claims one day above the threshold, a member could receive refills in 12 months. But did the member actually receive 15 refills or was it a scam by the pharmacy? This can be prevalent with auto-fill practices of a pharmacy - the "tickler" system automatically processes the refills and the drug is not returned to stock even when the member did not pick up the supply. Such a pattern of potential abuse can only be detected through analytics;

3. The CMS 4159 F2 final rule is requiring pro-ration of dispensing fee for members in a skilled nursing facility (patient residence code 03/09) - some LTC pharmacies (pharmacy service type 05) would charge the payer the full dispensing fee even for less than 31 days or 14 days worth of supplies for generic and brand drugs, respectively. If one looks, one would find that the dispensing fee is higher than the ingredient cost of a generic drug when supply is less than 31 days;

4. Compound drugs have become the poster child of waste and abuse - different ingredients including extended release formulations of oral drugs mixed with topical anesthetic ointment or cream are favorites of compound pharmacies - not only is the efficacy of such concoctions not evidence-based but the costs of the compound far exceed the U&C costs of the individual ingredients. Even by implementing a cost edit for compound code 02 cannot prevent pharmacies from submitting the ingredients separately thus circumventing the compound cost edit.

The list of waste and abusive patterns for drug claims can go on and on. Their detection and prevention requires trained eyes and advanced analytics.

Medicare Compliance Solutions, has the clinical and analytical expertise to help a health plan combat FWA. Unnecessary or unsafe usage of drugs or medical services hinder quality of care and derail program integrity. It is everybody's responsibility, consumers included, to be on guard for FWA in medical and pharmacy claims.

Managing Drug Costs the Analytical Way

Yvonne Tso, PharmD, MBA

The revised annual percentage increase for Part D reported by the Centers for Medicare & Medicaid Services shows a reversal in 2015, after six consecutive years of decline between 2007 and 2013 and a negative increase in 2014.

The annual percentage increase for CY 2017 is double-digit (11.75%) for the first time in a decade. We all had sticker shock when Turing Pharmaceuticals announced the $750 cost per tablet for Daparim, a 62-year old anti-parasitic drug. While drugs for treatment of hepatitis C made headline news when the price tag was $1,000 a pill (it actually cost more at retail but payers receive rebates on the back end), several oncology drugs cost no less considering the length of therapy. The wholesale acquisition cost for Zytiga for late-stage/metastatic prostate cancer is about $7,540 a month compared to Xtandi for the same indication, which is $9,000 a month.

The difference between hepatitis C treatment and oncology is that cancer has become a chronic condition that needs treatment for months and years to maintain remission. Praluent, a new chemical moiety for lowering cholesterol costs $14,000 a year compared to a fraction of that for conventional statins. While generics have held down drug costs in the past, the pharmaceutical industry has also found ways to strategically price their generics – Daparim is the poster child for the pharmaceutical industry's pricing tactic, an old drug available from only one manufacturer or limited number of manufacturers. Glumetza, the brand name for metformin extended release formulation, retails for more than $7,000 (#60, 1000mg) when the average cost of metformin generic costs pennies a pill.

Another drug that troubles payers is H.P. Acthar, an anti-inflammatory drug marketed for infantile spasm, multiple sclerosis, nephrotic syndrome and rheumatologic conditions that used to cost $50 is now selling for $28,000.00 for a 5 mL vial, even though there is little evidence that Acthar is more effective than alternatives for those conditions that are far cheaper.[1]

How can we combat these exorbitant drug costs? The analytical way.

1. Mine your drug claim data to identify the cost drivers – this would require the organization of data for ready access.

2. Educate your providers with data. Oncologists and neurologists have expressed outcry at some of the previously mentioned prices.

3. Formulary exclusions and benefit design. Within the regulatory limits by the states and Medicare, drugs that do not have unique pharmacological properties should be tightly managed with UM edits such as prior authorization, step therapy, quantity limits and high refill thresholds (85% to 90% versus 75%) or exclusion from the formulary.

4. Know your population by integrating results of health risk assessment (HRA) with drug claim data and performing predictive analytics. Drug claim data are available timely and in large volumes compared to other medical encounter data. They are sensitive to drug spend but not specific as to the medical conditions being treated (except for diabetes and oncology). Apply logic to identify the disease conditions that would progress to high utilization of medical services: diabetes, chronic obstructive respiratory diseases, behavioral health, immunological conditions and oncology; and

5. Monitor your PBM's paid claims. Any gaps in adjudication edits could leak thousands or even millions of dollars without the payer's knowledge. For example not all generic drugs are low cost; some NDCs cost more than others. Work with your PBM to ensure that MAC (maximum allowable cost) pricing is applied and selection of pricing outliers in NDC by network pharmacies is strictly discouraged or denied.

Medicare Compliance Solutions can help clients with all of the above.

Part D Drug Spend: Reimbursements

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Do you know if you receive all the reimbursements for Part D drug spend?

Prescription Drug Event (PDE) records are the official records used by the Centers for Medicare & Medicaid Services (CMS) for Part D revenue reconciliation, coverage gap discount payments, STAR measures, 1/3 financial audits, and CMS program audits. They are critical to your success in managing Part D of your Medicare Advantage Prescription Drug (MA-PD) Plan or your standalone Prescription Drug Plan (PDP). And PDEs may even be used for risk adjustment in the future. Drug plan sponsors have attested that they will:

- Submit timely PDE records (HPMS memo 05/16/2011),
- Submit original PDEs within 30 days following Date Claim Received or Date of Service (whichever is later),
- Resolve rejected records and re-submit within 90 days following receipt of rejected record status from CMS, and
- Submit adjustments and deletions within 90 days following discovery of issue requiring change.

Although PDE submission and resolution are not part of the CMS program audit, their accuracy and completion have both financial and regulatory consequences. Drug plan sponsors have received Notices of Non-Compliance (NONCs) when they omit PDE submission for more than 30 days. Managing PDE requires data administration capabilities and processes.

Auditing PDE requires knowledge of payment calculations (HPMS Memo December 2013, rules #1, #2, #3 and #5). Medicare Compliance Solutions, for example, has an application partner, Cadre360®, that provides a robust software application to:

- Verify PDE data files are submitted as processed in the adjudication systems and invoiced;
- Validate all the financial data elements (CPP, NPP, GDCA, GDCB, LICS and Reported Gap Discount Amounts);
- Track reprocessing PDE records and rejections including dashboard and graphic views of year-to-date PDE results so your finance department can reliably accrue for any deficiencies;
- Verify that True Out-of-Pocket (TrOOP) and Total Drug Spend Accumulation calculations are in accordance with CMS guidelines (so you can be ready for the 1/3 financial audit whenever the CMS auditors show up).

CMS TIMELINE

Nov. 14, 2016	NOIAs due for new MA or PDP contracts or service area expansions, to guarantee HPMS access to the online application when released in mid-January.
Dec. 2, 2016	Deadline to request HPMS access for new applicants
Jan. 10, 2017	2018 applications released by CMS
Jan. 1, 2017	Plan Benefit Period Begins
Mid Jan., 2017	Industry training on CY2018 applications
Jan. 1 – Feb. 14, 2017	Medicare Disenrollment Period
Jan. 17, 2017	Final deadline for NOIAs for CY2018
Feb. 15, 2017	CY2018 applications due to CMS

About UL Compliance to Performance

UL Compliance to Performance provides knowledge and expertise that empowers Life Sciences organizations globally to accelerate growth and move from compliance to performance. Our solutions help companies enter new markets, manage compliance, optimize quality and elevate performance by supporting processes at every stage of a company's evolution. UL provides a powerful combination of advisory solutions with a strong modular SaaS backbone that features ComplianceWire®, our award-winning learning and performance platform.

UL is a premier global independent safety science company that has championed progress for 120 years. It's more than 12,000 professionals are guided by the UL mission to promote safe working and living environments for all people

About our Authors

Medicare Compliance Solutions

Medicare Compliance Solutions believes in the power of teamwork and cooperation. We have assembled a 'best in class' Part C and D team comprised of senior level health plan and pharmacy benefit manager (PBM) professionals and former Centers for Medicare and Medicaid (CMS) regulators.

The MCS team is dedicated to solving the Medicare Part C and D Programs' unique regulatory and operational challenges. The team is comprised of senior level managed care professionals and former Center for Medicare and Medicaid (CMS) regulators who have worked at health plans, CMS and pharmacy benefit managers (PBMs).

For more information visit:
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