A Closer Look at Regulatory Developments on Health Plan Coverage and Reimbursement Decisions

A PART OF THE *FASTERCURES* VALUE AND COVERAGE ISSUE BRIEF SERIES

This issue brief, the fifth in a series prepared by Breakaway Policy Strategies for FasterCures, discusses regulatory developments relevant to coverage and reimbursement decisions of private commercial health plans. It provides information on key Affordable Care Act (ACA) regulations that address general coverage policy processes used by private payers. This brief also contains background information about the coverage appeals process, nondiscrimination protections for consumers, access to clinically necessary drugs, and standards for health plan network adequacy and medical loss ratios.

Introduction

In administering benefits, a health plan must make decisions as to what services and drugs will be covered by the plan and the amounts that the plan will pay for such benefits. (Note: For additional background on how plans make coverage decisions, please refer to *A Closer Look at Health Plan Coverage Policies and Approaches*, the first in the *FasterCures* Value and Coverage Issue Brief Series). There have been significant regulatory developments relevant to health plan coverage and reimbursement decisions since enactment of the ACA in 2010. The chart below identifies some of the key federal policies implemented under the ACA.

Regulatory Development	Description	Impact on Coverage
Interim Final Rule on Coverage and Appeals	Implements the requirements regarding internal claims and appeals and external review processes for group health plans and health insurance coverage in the group and individual markets under the ACA.[i]	Coverage appeals
Essential Health Benefits (EHBs) Final Rule	Sets forth the standards that plans must satisfy to be sold through the Marketplaces, including the requirement to provide the 10 categories of EHBs, including prescription drugs. In the case of prescription drugs, plans must provide the greater of one drug in every United States Pharmacopeial Convention category or class; or the same number of drugs in each category and class as the commercial plan that was used by the state as its benchmark. The rule requires plans to provide EHBs in a manner that does not discriminate against individuals based on their age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.	Nondiscrimination Drug coverage
2015 Letter to Issuers on Qualified Health Plans	Provides operational and technical guidance to insurance carriers wishing to offer Qualified Health Plans (QHPs) in the federally facilitated marketplaces.[ii] The letter outlines a new "reasonable access" standard for network adequacy, describes the new outlier analysis that the Centers for Medicare & Medicaid Services will use to determine whether benefits, including prescription drugs, are being provided in a nondiscriminatory manner, and encourages issuers to accommodate the needs of new enrollees by covering a transitional fill of non-formulary drugs.	Nondiscrimination Drug coverage; Network adequacy
Final Rule on Exchange and Market Standards	Requires plans have in place an expedited exceptions process to allow for coverage of prescription drugs for enrollees suffering from a health condition that may seriously jeopardize their life, health, or ability to regain maximum function, or when an enrollee is undergoing a current course of treatment using a drug not covered by the plan. The rule also finalizes various amendments to the medical loss ratio (MLR) provisions, including standards that would modify the timeframe for which issuers can include certain conversion costs in their MLR calculation and account for special circumstances related to the transition to the 2014 reformed market.[iii]	Drug coverage; Medical loss ratio

Regulatory Developments

Coverage Appeals & Reviews

Even before passage of the ACA, most individuals covered under fully insured health plans had the right to appeal denials of coverage. The ACA expanded this right, however, by requiring self-insured plans to afford individuals with appeals rights.[iv] On July 23, 2010, the Departments of Labor (DOL), Health and Human Services (HHS), and Treasury issued interim final regulations (Interim Final Rule) implementing the ACA's internal claims and appeals and external review requirements.[v]

When consumers enroll in private market health insurance, they must rely on a contract that defines the medical services covered and reimbursed by their health plans. As medical needs vary by patient and services vary by provider, patients may face denials or limitations on a particular treatment. The ACA requires group health plans and issuers to implement an internal claims and appeals process that ensures individuals receive a full and fair review of their claims. Among other things, plans must provide free of charge any new evidence related to a claim or new rationale for a decision as soon as possible before the appeal deadline so claimants have time to respond and ensure that all claims and appeals decisions avoid conflicts of interest and continue to provide coverage to the claimant until an internal appeal is resolved.

If a plan denies payment for a treatment or service, it must notify an individual of the reason for the denial and his or her right to an internal appeal. If an individual's claim is denied on an internal appeal, the plan must notify the individual of the right to have the claim externally reviewed by an outside, independent decision-maker.[vi] Model notices have been issued by the DOL and are available online.[vii] When an internal appeal for a denial is requested, the plan must provide its decision within: 1) 72 hours for urgent care claims, 2) 30 days for non-urgent care claims, and 3) 60 days for denials for services already received. Anyone receiving urgent care or an ongoing course of treatment may be allowed to proceed with an expedited external review at the same time as the internal appeal. While the Interim Final rule attempted to reduce the time limit for urgent care claims from 72 hours to 24 hours, the Amendment eliminated the 24 hours requirement.

If a state external review process that is binding on an issuer includes certain minimum consumer protections (as determined by HHS), then the issuer must comply with that state's process.

Nondiscrimination

Many of the ACA's significant reforms went into effect on Jan. 1, 2014, including the requirement that insurers comply with the ACA's consumer protections on nondiscrimination. "Discrimination" refers to the ways that insurers differentiate between individuals in designing and implementing private health insurance coverage, and can occur at the point of enrollment, in designing coverage options, and during an insurer's decision-making process when administering plan benefits.[viii] Prior to the ACA, federal and state law included some nondiscrimination protections, but most have had only a limited effect in ensuring that coverage meets consumer needs. Through its incorporation of these new standards, the ACA was designed to address this by prohibiting discrimination based on health status, disability, age, race, gender, and sexual orientation, among other things.

The ACA also prohibits insurers from making benefit design decisions that discriminate against individuals based on age, disability, or expected length of life.[ix] Essential health benefits must take into account healthcare needs of diverse segments of the population, including women, children, disabled individuals, and other groups.[x] The ACA requires that plans offered in the individual and small group markets, both inside and outside the Marketplaces, offer a comprehensive package of benefits and services including at least the 10 categories of EHBs: ambulatory services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services including oral and vision care. CMS implemented these statutory provisions in the EHB Rule on Feb. 20, 2013.[xi]

HHS later clarified the prohibition on discrimination rule in response to concerns it would prevent issuers from using traditional utilization management techniques. The agency said the prohibition would not preclude use of these techniques, but added language that they may only be implemented in a manner that does not discriminate on the basis of age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions "that are not based on nationally recognized, clinically appropriate standards of medical practice evidence or not medically indicated and evidence-based."[xii] For example, HHS added that "a reasonable medical management technique would be to require preauthorization for coverage of the zoster (shingles)

vaccine in persons under 60 years of age, consistent with the recommendations of the Advisory Committee on Immunization Practices."[xiii] This suggests that prior authorization criteria singling out a particular patient group must be clinically justified. Regarding enforcement, HHS cited section 2723 of the Public Health Service Act (PHS Act), which first looks to the states to enforce the nondiscrimination provisions and then to HHS where a state does not substantially enforce the rule.[xiv]

CMS' 2015 Issuer Letter restates that QHPs may not use discriminatory benefit designs. Though nondiscrimination is a market-wide standard enforced by the states with respect to the EHBs, CMS will conduct ongoing compliance review, including analysis of appeals and complaints. The Issuer Letter also stated it will continue to conduct outlier analyses with respect to cost-sharing for specific benefits—including but not limited to inpatient hospital stays, inpatient mental or behavioral health stays, specialist visits, emergency room visits, and prescription drugs—in order to identify discriminatory benefit designs. The agency will be looking specifically for plans that are outliers as far as subjecting an unusually large number of prescription drugs to prior authorization or step therapy requirements.

Prescription Drug Coverage

The ACA requires insurers to offer prescription drug benefits. Specifically, a plan must cover at least the greater of one drug from each United States Pharmacopeial Convention category or class, the number of drugs in each category as are covered by a state's EHB-benchmark plan. Plans may permit more than the minimum required number of drugs. The EHB Rule also notes that plans may implement tiering—or varying reimbursement for different categories of drugs—and other utilization management techniques for drug formularies so long as they are applied in a nondiscriminatory manner. Insurers will continue to rely on drug formularies to decide which prescriptions are covered and which are not.

The Final Insurance Exchange and Market Standards Rule requires plans to have procedures in place that allow enrollees to request and gain access to clinically appropriate drugs not covered by the plan, including an expedited exceptions process for enrollees suffering from a condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function, or when an enrollee is undergoing a current course of treatment using a drug not covered by the plan. As part of the expedited process, plans must make coverage determinations within 24 hours after receiving the request, and must continue to provide the drug throughout the duration of the enrollee's medical issue.[xv]

As of 2014, issuers must provide a direct URL to their formularies. CMS specifies in the Issuer Letter that the URL must direct consumers to an up-to-date formulary where they can view the covered drugs that are specific to a given QHP. In addition, CMS plans to post formulary links for consumers on HealthCare.gov and require issuers to make the links easily accessible—consumers should not have to log on, enter a policy number, or otherwise navigate the issuer Web sites to locate links.

With new requirements for insurers to cover drug benefits and new limits on utilization management techniques, insurers are looking to prescription drug tiering to help control costs. Tiering shifts costs to consumers and may steer patients to one particular drug over another. Drugs in higher-level tiers, or specialty tiers, come at a higher cost to the patient. In many plans participating in the Marketplaces, specialty tier coinsurance is well above 30 percent of the cost of the drug. In some cases the rate is as high as 60 percent.

Network Adequacy

Qualified health plans must meet network adequacy standards to participate in a Marketplace.[xvi,xvii] (Note: Background on provider networks is discussed in more detail in *A Closer Look at Provider Networks,* the fourth brief in the *FasterCures* Value and Coverage Issue Brief Series). The ACA and subsequent regulations set minimum standards that plans must meet regarding network adequacy. Specifically, insurers must maintain a network that is sufficient in number and types of providers to assure that all services will be accessible without unreasonable delay. How network adequacy is reviewed depends on whether a Marketplace is a federally facilitated Marketplace, a state-based Marketplace, or a state-federal partnership.

CMS addressed concerns regarding the size and scope of the provider networks for plans sold through the Marketplaces in its 2015 Issuer Letter, which updates key provisions relating to plans offered through federally facilitated marketplaces through 2015.[xviii] One of the most significant changes for the 2015 plan year involves how CMS will enforce network adequacy standards. In 2014, CMS assessed adequacy based on accreditation status and network adequacy plans and deferred to a states' review process at least as stringent as federal standards. For 2015, CMS plans to assess adequacy using a "reasonable access" standard, which focuses only on certain providers, including hospital systems,

mental health providers, oncology providers, and primary care providers. CMS also said that insurers can expect to see additional changes to the network adequacy review process in the coming years as it gathers information from the QHP application process. CMS is considering potential formats for collection of provider network data that will allow it to assess network adequacy and enable it to create a provider search engine for consumers, which will be accessible through HealthCare.gov.

The Issuer Letter also outlines modifications to the network adequacy standards applicable to essential community providers (ECP). ECPs are providers that serve predominately low-income and medically underserved individuals. For 2015, QHP insurers must demonstrate that at least 30 percent of available ECPs in each plan's service areas participate in a provider network. It must offer a contract in good faith to all Indian health providers in the service area and at least one ECP in each ECP category in each county in the QHP's service area (where an ECP in that category is available). The categories include federally qualified health centers, Ryan White HIV/AIDS providers, family planning providers, Indian health providers, safety net hospitals, and other ECP providers. To assist issuers in identifying ECPs, CMS published a non-exhaustive list of available ECPs, which issuers may use to assess their satisfaction of the ECP standard.[xix]

In an effort to balance access to appropriate coverage with costs, while meeting the ACA standards required to participate in the Marketplaces, insurers have developed a range of health plan options for consumers. Offering plans with smaller networks of providers allows insurers to provide consumers with lower costing plans. CMS has said it will continue to monitor and evaluate the appropriate size and scope of these networks to ensure a plan's ability to deliver the benefits promised under the terms of the contract—which includes providing reasonable access to a sufficient number of in-network primary care and specialty physicians, as well as other healthcare services.

Medical Loss Ratio

The ACA imposes a new federal, minimum medical loss ratio requirement on fully funded health plans—plans where the insurance company assumes the full risk for medical expenses incurred.[xx] The MLR measures the share of a healthcare premium dollar spent on medical benefits, as opposed to company expenses such as overhead or profits. For example, if an insurer spends $85,000 on medical out of a total of $100,000 received in premium dollars, the MLR would be 85 percent. The ACA sets the minimum required MLR at 80 percent for the individual and small group markets and 85 percent for the large group market. The MLR requirement allows insurers to add certain quality improvements to the health benefits calculation, while letting companies disregard certain taxes, fees and other expenses when calculating non-claims expenses.

HHS issued several regulations since 2010 implementing the ACA's statutory MLR provisions, which took effect in calendar year 2011.[xxi] In July 2012, HHS announced that, based on 2011 performance, insurers covered by the law would be required to issue approximately $1.1 billion in rebates to 12.8 million individuals by Aug. 1, 2012.[xxii] The MLR requirement is intended to provide "greater transparency and accountability around the expenditures made by health insurers and to help bring down the cost of health care."[xxiii]

The ACA imposes separate MLR standards for Medicare Advantage plans—those that provide private insurance options to Medicare beneficiaries enrolled in both Medicare Parts A and B—including that they achieve a minimum MLR of 85 percent. Plans that do not meet this standard will have to pay HHS a set amount, and if they fail to meet the standard for three consecutive years, their enrollment in Medicare will be restricted. The MLR requirement does not apply to self-funded plans—those that are offered by businesses in which the employer assumes the financial risk for medical care—or to long-term care, dental, vision, or retiree health insurance.

The Exchange and Market Standards Final Rule changed several MLR reporting and rebate requirements. Specifically, the Final Rule allows insurers in the individual and small group market that implemented the transitional policy to increase their incurred claims and quality improvement expenses incurred for 2014 by a factor of 1.0001. Insurers are also allowed to increase their claims and quality improvement costs for their entire individual and small group book of business, including plans off the Marketplaces by 1.0004, in recognition of the increased burden born by Marketplace plans due to problems with the launch in 2014.

Requiring insurers to devote a specific portion of the premium toward actual health benefits—as opposed to administrative costs—provides an added protection for consumers, ensuring that they are receiving the full value of their covered benefits.

Conclusion

The ACA provided for numerous coverage requirements and consumer protections, including rights to an appeals and external review process, protections against nondiscrimination, access to clinically appropriate prescription drugs, adequate provider networks, and new medical loss ratio. These standards, which have been implemented through federal regulations and other guidance, will likely be modified and improved upon in coming years. It will be up to the states and the federal government to assess the performance of plans operating under these new rules and modify regulations as necessary to improve coverage and ensure that consumers have access to appropriate care.

[i] Federal Register. "Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and External Review Processes under the Patient Protection and Affordable Care Act." 23 July 2010. Web. April 2014. <https://www.federalregister.gov/articles/2010/07/23/2010-18043/interim-final-rules-for-group-health-plans-and-health-insurance-issuers-relating-to-internal-claims>.

[ii] "2015 Letter to issuers in the federally-facilitated marketplace (FFM)," *CCIO.* CMS, n.d. Web. April 2014. <http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2015-final-issuer-letter-3-14-2014.pdf>.

[iii] HHS. Final Rule. "Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond." 45 CFR 146-148, 153, 155, 156, 158. 13 May 2014. PDF file. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/508-CMS-9949-F-OFR-Version-5-16-14.pdf

[iv] "ACA Requirements for Claims and Appeals and External Review." *Health Care Reform Updates.* Herrernan Insurance Brokers, 2014. Web. April 2014. <http://www.healthcarereform-updates.com/appeals-process>.

[v] Federal Register. "Interim final rules for group health plans and health insurance issuers relating to internal claims and external review processes under the Patient Protection and Affordable Care Act." 23 July 2010. Web. April 2014. <https://www.federalregister.gov/articles/2010/07/23/2010-18043/interim-final-rules-for-group-health-plans-and-health-insurance-issuers-relating-to-internal-claims>.

[vi] "External Appeals." *CCIIO.* CMS, n.d. Web. April 2014. <http://www.cms.gov/CCIIO/Programs-and-Initiatives/Consumer-Support-and-Information/External-Appeals.html>.

[vii] "Affordable Care Act Regulations and Guidance." *United States Department of Labor.* n.p.,n.d. Web. April 2014. <http://www.dol.gov/ebsa/healthreform/regulations/internalclaimsandappeals.html>.

[viii] Rosenbaum S. "Insurance Discrimination on the Basis of Health Status: An Overview of Discrimination Practices, Federal Law, and Federal Reform Options." *Georgetown University Law Center O'Neill Institute for National and Global Health Law.* (2009): 6-7.

[ix] ACA § 1302(b)(4)(B).

[x] ACA § 1302(b)(4)(C).

[xi] Federal Register. "Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation." 45 CFR 147, 155, 156. 25 February 2013. PDF file. <http://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf>.

[xii] Federal Register. "Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation." 45 CFR 147, 155, 156. 25 February 2013. PDF file. <http://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf>.

[xiii] Federal Register. "Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation." 45 CFR 147, 155, 156. 25 February 2013. PDF file. <http://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf>.

[xiv] Federal Register. "Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation." 45 CFR 147, 155, 156. 25 February 2013. PDF file. <http://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf>.

[xv] HHS "Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond." 45 CFR 146-148, 153, 155, 156, 158. 16 May 2014. PDF File. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/508-CMS-9949-F-OFR-Version-5-16-14.pdf

[xvi] "42 U.S. Code § 18021 - Qualified health plan defined." *Cornell University Law School.* Legal Information Institute, n.d. Web. April 2014. <http://www.law.cornell.edu/uscode/text/42/18021>.

[xvii] Federal Register. "Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation." 45 CFR 156.230. February 2013. PDF file. <http://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf>.

[xviii] "2015 Letter to issuers in the federally-facilitated marketplace (FFM)." *CCIIO.* CMS, n.d. Web. April 2014. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2015-final-issuer-letter-3-14-2014.pdf.

[xix] "Qualified Health Plans." *CCIIO.* CMS, n.d. Web. April 2014. <http://cciio.cms.gov/programs/exchanges/qhp.html>.

[xx] ACA, P.L. 111-148, as amended.

[xxi] "Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act; Interim Final Rule," December 1, 2010, http://www.gpo.gov/fdsys/pkg/FR-2010-12-01/pdf/2010-29596.pdf; "Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act; Corrections to the Medical Loss Ratio Interim Final Rule With Request for Comments," December 30, 2010, http://www.gpo.gov/fdsys/pkg/FR-2010-12-30/pdf/2010-32526.pdf; "Medical Loss Ratio Rebate Requirements for Non-Federal Governmental Plans; Interim Final Rule," December 7, 2011, http://www.gpo.gov/fdsys/pkg/FR-2011-12-07/pdf/2011-31291.pdf; Medical Loss Ratio Requirements Under the Patient Protection and Affordable Care Act, Final Rule," May 16, 2012, http://www.gpo.gov/fdsys/pkg/FR-2012-05-16/pdf/2012-11753.pdf; Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Under the Patient Protection and Affordable Care Act; Correcting Amendment," May 16, 2012,

http://www.gpo.gov/fdsys/pkg/FR-2012-05-16/pdf/2012-11773.pdf.

[xxii] Department of Health and Human Services, "The 80/20 Rule: Providing Value and Rebates to Millions of Consumers," http://www.healthcare.gov/law/resources/reports/mlr-rebates06212012a.html#individual.

[xxiii] Federal Register. "Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements under the Patient Protection and Affordable Care Act." 75 CFR 74864. 1 December 2010. Web. April 2014. <https://www.federalregister.gov/articles/2010/12/01/2010-29596/healthinsurance-issuers-implementing-medical-loss-ratio-mlr-requirements-under-the-patient>.