**Section 1302(b)(4), 42 U.S.C.A. § 18022(b)(4), Essential health benefit requirements**

(4) Required elements for consideration

In defining the essential health benefits under paragraph (1), the Secretary shall--

(A) ensure that such essential health benefits reflect an appropriate balance among the categories described in such subsection,1 so that benefits are not unduly weighted toward any category;

(B) not make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life;

(C) take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups;

(D) ensure that health benefits established as essential not be subject to denial to individuals against their wishes on the basis of the individuals' age or expected length of life or of the individuals' present or predicted disability, degree of medical dependency, or quality of life;

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**42 U.S.C.A. § 300gg-1, Guaranteed availability of coverage**

**(a) Guaranteed issuance of coverage in the individual and group market**

Subject to subsections (b) through (e), each health insurance issuer that offers health insurance coverage in the individual or group market in a State must accept every employer and individual in the State that applies for such coverage.

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**42 U.S.C.A. § 300gg-2, Guaranteed renewability of coverage**

(a) In general

Except as provided in this section, if a health insurance issuer offers health insurance coverage in the individual or group market, the issuer must renew or continue in force such coverage at the option of the plan sponsor or the individual, as applicable.

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**42 U.S.C.A. § 300gg-3, Prohibition of preexisting condition exclusions or other discrimination based on health status**

(a) In general

A group health plan and a health insurance issuer offering group or individual health insurance coverage may not impose any preexisting condition exclusion with respect to such plan or coverage.

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**42 USC § 300gg-4, Prohibiting discrimination against individual participants and beneficiaries based on health status**

(a) In general

A group health plan and a health insurance issuer offering group or individual health insurance coverage may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan or coverage based on any of the following health status-related factors in relation to the individual or a dependent of the individual:

**(1)** Health status.
**(2)** Medical condition (including both physical and mental illnesses).
**(3)** Claims experience.
**(4)** Receipt of health care.
**(5)** Medical history.
**(6)** Genetic information.
**(7)** Evidence of insurability (including conditions arising out of acts of domestic violence).
**(8)** Disability.
**(9)** Any other health status-related factor determined appropriate by the Secretary.

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**Regulations:**

**45 C.F.R. § 156.125 Prohibition on discrimination.**

(a) An issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.

(b) An issuer providing EHB must comply with the requirements of § 156.200(e) of this subchapter; and

(c) Nothing in this section shall be construed to prevent an issuer from appropriately utilizing reasonable medical management techniques.

**45 C.F.R. § 156.200, QHP issuer participation standards.**

(e) Non-discrimination. A QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, sex, gender identity or sexual orientation.

**45 C.F.R. § 156.225, Marketing and Benefit Design of QHPs.**

A QHP issuer and its officials, employees, agents and representatives must—

(a) State law applies. Comply with any applicable State laws and regulations regarding marketing by health insurance issuers; and
(b) Non-discrimination. Not employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in QHPs.

§ 156.120(a), as they are not used in this section.

*Comment:* Some commenters requested use of a 2014 plan as the benchmark for 2016 rather than 2017. Several commenters suggested we use a 2015 plan as the benchmark for 2017, noting that the final regulations pertaining to the Mental Health Parity and Addiction Equity Act will not be effective until 2015.

*Response:* For the 2016 plan year, HHS expects to begin the certification process for QHPs in the FFEs in early spring of 2015. Because issuers are required to design QHP plans that provide EHB that are substantially equal to the EHB-benchmark plan, based on the base-benchmark plan chosen and supplemented as necessary by the State, it is not operationally possible for us to collect and publish new EHB-benchmark plans prior to the QHP certification process for the 2016 plan year if we allow States to choose a 2014 plan as their new base-benchmark plan and supplement if necessary. As codified in § 156.115(a)(3), an EHB-compliant plan must provide mental health and substance use disorder services, including behavioral health treatment services in compliance with MHPAEA and its corresponding regulations. While we agree that it would be easier for issuers to design plans if the base-benchmark plan chosen by the State were compliant with MHPAEA (that is, based on a 2015 plan), nothing in this rule negates the current requirement that EHB-compliant plans comply with MHPAEA and any associated regulatory requirements in effect at the time. Based on the timelines needed for issuers to design plans, if we permitted States to select 2015 plans as new base-benchmark plans, we do not believe that issuers would be able to design substantially equal EHB-compliant products until the 2018 plan year, based on those benchmarks, which we believe is not in consumers' best interest. Therefore, we are finalizing the re-codification of part of § 156.120 as proposed, as well as our proposal to allow issuers to design a plan that is substantially equal to the newly selected 2014 benchmark plan for the 2017 plan year.

*Comment:* Several States and other commenters requested more details on the process for selection and reassurance that they can supplement their benchmark plan.

*Response:* We did not propose to make changes to § 156.100(a) or (b); therefore, the options from which a base-benchmark plan may be selected remain the same. HHS issued a PRA package regarding collection of benchmark information on November 26, 2014.[48] As stated there, HHS proposes to obtain the certificate of coverage and other plan documents that describe covered services, exclusions, limitations, cost sharing, and all other terms and conditions of plan benefits that are provided to enrollees. States that select, or issuers in States that default to a benchmark due to lack of selection, would submit the documents securely via email. HHS intends to work collaboratively with States to identify responsive documents and to secure such documents during the second quarter of 2015. HHS then intends to publish selected and default benchmark plans and supporting documents. States retain the ability to supplement the base-benchmark plan, as codified in § 156.110(b)(1), and retain the ability to determine whether the base-benchmark plan covers the EHB category or whether supplementation is warranted. We also reiterate that supplementation is the addition of the entire category of such benefits to satisfy § 156.110(a), while substitution is the removal of one particular item or service for another actuarially-equivalent item or service within the same category. Supplementation ensures that all EHB categories are covered. Substitution, which is permitted within an EHB category at the issuer's discretion, allows for greater variety of plan designs.

*Comment:* Several States and other commenters requested further clarification regarding how new benchmark plan selection will affect our policy at § 155.170 pertaining to State-required benefits.

*Response:* We did not propose any changes to § 155.170. Therefore, only new State-required benefits enacted on or prior to December 31, 2011 are included as EHB, and States are expected to continue to defray the cost of State-required benefits enacted on or after January 1, 2012 unless those State-required benefits were required in order to comply with new Federal requirements. HHS intends to continue to publish a list of non-EHB State-required benefits on its Web site on an annual basis.

*Comment:* Some commenters expressed their desire for HHS to abandon the benchmark policy in the future, and specify a list of services that issuers must cover in each EHB category instead.

*Response:* To maintain State flexibility while ensuring comprehensive coverage, we believe that the benchmark policy continues to be the most appropriate at this time. Therefore, the benchmark policy will continue to establish EHBs through plan year 2017. Since the first EHB plan year just ended, we will examine how the policy affected enrollees and what changes, if any, should be made in the future. We believe that it is important to have a more complete sense of how EHB policy is working before proposing changes to the benchmark approach.

### d. Prescription Drug Benefits (§ 156.122)

#### i. § 156.122(a)

Under our regulations at § 156.122(a), EHB plans are required to cover the greater of one drug per United States Pharmacopeia (USP) category and class or the same number of drugs in each USP category and class as the State's EHB-benchmark plan. In the proposed rule, we proposed several revisions to this policy. First, we proposed to retain § 156.122(a)(2), with one modification to change ''drug list'' to ''formulary drug list'' for uniformity purposes for this section, and to renumber this paragraph from § 156.122(a)(2) to § 156.122(a)(1). Due to some concerns detailed in the proposed rule about the drug count standard under current § 156.122(a)(1), we proposed an alternative to the drug count standard. Specifically, we proposed that plans have a pharmacy and therapeutics (P&T) committee and use that committee to ensure that the plan's formulary drug list covers a sufficient number and type of prescription drugs. We proposed that the P&T committee standards must be met for the prescription drug coverage to be considered EHB. We stated our belief that the use of a P&T committee in conjunction with other standards that we proposed would ensure that an issuer's formulary drug list covers a broad array of prescription drugs. We noted that standards defined by the Medicare Part D Prescription Drug Program (Medicare Part D), the NAIC,[49] and other stakeholders, and we solicited comments on these standards and whether we should adopt them in lieu of or in addition to the standards we are proposing.

In the proposed rule, we proposed to specify P&T committee standards on

[48] CMS–10448; *http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10448.html.*

[49] Medicare Part D plans are required to maintain P&T committees by the Social Security Act section 1860D–4(b)(3)(G) codified at 42 CFR 423.120(b), 42 CFR 423.272(b)(2). NAIC has a Model Act entitled Health Carriers Prescription Drug Benefit Management Model Act (July 2003) that includes P&T Committee provisions at: *http://www.naic.org/store/free/MDL-22.pdf.*

membership, meetings, and establishment and development of a formulary drug list. For P&T committee membership, we proposed requiring the P&T committee to include members from a sufficient number of clinical specialties to adequately represent the needs of enrollees. For instance, we would expect that the P&T committee members include experts in chronic diseases and in the care of individuals with disabilities. We proposed that the majority of members be practicing physicians, practicing pharmacists, and other practicing health care professionals. Additionally, we proposed to require that members of the P&T committee that have a conflict of interest with the issuer or a pharmaceutical manufacturer would be permitted to sit on the P&T committee but would be prohibited from voting on matters for which the conflict exists. We also proposed that at least 20 percent of the P&T committee's membership have no conflict of interest with respect to either the issuer or to any pharmaceutical manufacturer. Under these standards, a member who holds more than one health care license, for example as a nurse practitioner and a pharmacist, would only count as one person. We also solicited comments on the percentage of committee members that should have no conflict of interest, and the proposed requirement that the members of the P&T committee with conflicts of interest should be permitted to sit on the P&T committee but would be prohibited from voting on matters for which the conflict exists. We considered requiring a set number of participants to be independent and have no conflicts of interest, but we were concerned that absent a limitation on the total number of committee members, requiring a specific number of committee members to be independent and not have a conflict of interest would have a variable impact, depending on the size of the P&T committee. We also proposed that the P&T committee would be responsible for defining a reasonable definition of conflict of interest and for managing the conflicts of interest of its committee members. As part of this standard, the P&T committee would require its P&T committee members to sign a conflict of interest statement revealing economic or other relationships with entities, including the issuer and any pharmaceutical manufacturers, affected by drug coverage decisions that could influence committee decisions. We solicited comments on this proposed standard, including the implementation of this conflict of interest standard, whether there are additional conflict of interest standards that should apply and what would constitute a conflict of interest. In particular, we sought comments on what could be considered a permissible relationship with respect to the issuer or a pharmaceutical manufacturer. We stated that we would consider providing further guidance regarding conflicts of interest.

We also proposed that the P&T committee must meet at least quarterly, and maintain written documentation of all decisions regarding development and revision of formulary drug lists. For formulary drug list establishment and management, we proposed that the P&T committee must develop and document procedures to ensure appropriate drug review and inclusion on the formulary drug list, as well as make clinical decisions based on scientific evidence, such as peer-reviewed medical literature, and standards of practice, such as well-established clinical practice guidelines. The P&T committee would be required to consider the therapeutic advantages of prescription drugs in terms of safety and efficacy when selecting formulary drugs and making recommendations for their formulary tier. The P&T committee would be required to review both newly FDA-approved drugs and new uses for existing drugs. We also proposed that the P&T committee would be required to ensure that an issuer's formulary drug list covers a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states and does not discourage enrollment by any group of enrollees.

Lastly, we proposed to require that issuers' formularies provide appropriate access to drugs that are included in broadly accepted treatment guidelines and which are indicative of and consistent with general best practice formularies in widespread use. Broadly accepted treatment guidelines and general best practices could be based on industry standards or other appropriate guidelines that are issued by expert organizations that are current at the time. For instance, broadly accepted treatment guidelines could include guidelines provided in the National Guideline Clearinghouse (NGC), which is a publicly available database of evidence-based clinical practice guidelines and related documents. As a result of this proposed policy, we would expect that a health plan's formulary drug list would ensure that appropriate access is being afforded to drugs in widely accepted national treatment guidelines and which are indicative of general best practices at the time. Given our proposal to use broadly accepted treatment guidelines and best practices, we would also expect that plans' formulary drug lists be similar to those formulary drug lists then currently in widespread use. We also noted that States have primary responsibility for enforcing EHB requirements and, if finalized, States would be responsible for the oversight and enforcement of the P&T committee standards. We sought comment on these proposed revisions to § 156.122(a), including on the oversight and enforcement of these standards, and whether other standards are needed for P&T committees.

As an alternative to, or in combination with, the above-proposed P&T committee requirements, we considered whether to replace the USP standard with a standard based on the American Hospital Formulary Service (AHFS). We sought comments on the proposed P&T committee standard, and whether we should consider adopting AHFS or another drug classification system, as well as on any other standards that may be appropriate for this purpose. For instance, for the AHFS system, we considered amending the minimum standard established in the EHB Final Rule that requires coverage of at least the greater of one drug in every USP category and class or the same number of drugs in each USP category and class as the State's EHB-benchmark plan to require at least the greater of one drug in each AHFS class and subclass or the same number of drugs in each AHFS class and subclass as the State's EHB-benchmark plan. We explained that if we were to finalize a P&T committee process in combination with a drug count standard based on either the AHFS system or the USP system, we would expect the health plan to establish and maintain its formulary drug list in compliance with the P&T committee standards, and in addition, the resulting health plan's formulary drug list would also need to comply with the drug count standard. We discussed continuing to use the existing USP drug count standard, and updating the USP drug count system to a more current version. We proposed to implement proposed § 156.122(a)(2) to start in the 2017 plan year, seeking comments on this proposed timing of implementation. Based on comments

received, as described in detail below, we are finalizing an approach that combines the use of a P&T committee (satisfying standards largely as proposed) with the current drug count standard that requires coverage of at least the greater of one drug per USP category and class or the same number of drugs in each USP category and class as the State's EHB benchmark plan.

*Comment:* Some commenters supported replacing the current drug standard with the P&T committee approach only, and some commenters recommended that we defer to a health plan's accreditation by the National Committee for Quality Assurance (NCQA) or URAC, or use Medicare Part D standards. Some commenters did not support the P&T committee approach because they were concerned it could result in plans with widely varying formularies, leading to consumer confusion. They also had concerns about oversight and enforcement. Several commenters supported combining the P&T committee with a drug count standard. Of those who commented on the drug count standard, some supported USP, some supported AHFS, and others supported the creation of a new standard. Some commenters recommended changes to the manner in which the drug count is calculated. For example, some commenters suggested that the drug count metric change to the greater of two drugs per category and class or the number of drugs in the benchmark. Other commenters sought clarification on the counting of chemically distinct drugs and the modes of delivery.

*Response:* We are finalizing an approach that combines the use of a P&T committee with the current drug count standard that requires coverage of at least the greater of one drug per USP category and class or the same number of drugs in each USP category and class as the State's EHB benchmark plan. We believe that a combination of a qualitative and quantitative approach will best ensure robust formulary design, because the two standards can complement each other. For instance, the requirement of the P&T committee to review new drugs addresses one of our concerns that the current drug count system does not incentivize coverage of new drugs. However, the drug count standard can provide a minimum standard for coverage.

For the P&T committee requirements, we considered deferring to other standards, such as those established by NCQA, URAC and Medicare Part D. However, § 156.122 establishes a market-wide standard, and not all plans are required to be accredited by those organizations. We also do not believe that some accreditation standards are as transparent as Medicare Part D standards—for example, some accreditation standards are proprietary and could be costly and burdensome for an issuer to implement. Further, stakeholders are already familiar with Medicare Part D's P&T committee standards and we believe that these standards will best ensure the P&T committee is able to ensure a robust formulary. For these reasons, we are finalizing P&T committee standards modeled on Medicare Part D's P&T committee standards that have been modified, as explained below, to better address the private health plan population and the needs of plans required to cover EHB. We also believe that adopting P&T committee standards that generally align with the existing Medicare Part D standards and guidance, where possible, will better ensure uniformity between standards to help reduce the burden on issuers. As explained below, we are finalizing the proposed conflict of interest standards. Although these standards are different than those adopted by Medicare Part D, we believe that these standards are similar to practices in the private insurance market.

We are retaining the USP drug count standard because stakeholders are now familiar with the USP system after using it for 2 years, and we were persuaded by the comments supporting the continued use of USP. Issuers have already developed 2 years of formularies based on it, States have already developed systems to review those formularies, and stakeholders are familiar with the system. Thus, while AHFS had the benefit of being updated more frequently and incorporating a broader set of classes and subclasses, commenters did not uniformly support its use because of several issues, including a lack of transparency, the need to supplement certain classes when compared with USP, and the complexity of the AHFS system. We also believe that retaining USP will reduce the administrative burden and costs on States and issuers in implementing a combined P&T committee process with a drug count standard. In implementing the revised § 156.122(a), we intend to use the most up-to-date version of the USP system available at the time that we build our formulary review tools for each plan year, starting with the 2017 plan year, and will refer to the version number in the methodology document that we update each year.[50]

To codify our final policy, we are retaining § 156.122(a)(1) (with one technical change to delete the ''and''), we are retaining current § 156.122(a)(2) (with one technical correction to replace ''drug list'' with ''formulary drug list'' and to add an ''and''), and we are adding a new § 156.122(a)(3). Under the new § 156.122(a)(3), a health plan must establish and maintain its formulary drug list in compliance with the P&T committee standards. These standards are in addition to the requirement that the health plan's formulary drug list comply with the drug count standard under § 156.122(a)(1) as the minimum standard of coverage, and the requirement that the health plan submit its formulary drug list to the Exchange, the State, or OPM. While issuers must have a P&T committee, nothing under § 156.122(a) precludes issuers from using the same P&T committee across multiple issuers. However, we recognize that using the same P&T committee across multiple issuers may be complex to administer. Because States are primarily responsible for enforcing EHB requirements, States will be responsible for the oversight and enforcement of the P&T committee standards and the drug count standard. We intend to work with States to implement these provisions and may consider developing additional tools and resources to assist States in reviewing formulary drug lists. New § 156.122(a)(3) will apply starting with the 2017 plan year to give States, issuers, and PBMs time to implement the new P&T committee standards.

*Comment:* Many commenters wanted the P&T committee membership to include certain types of representatives. Some commenters also wanted membership on the P&T committee to be limited to a certain number. Commenters supported limiting the P&T committee membership category for ''other practicing health professionals'' to ''other practicing health care professionals that can prescribe.'' Comments sought clarification that a practicing provider on the committee could be practicing part-time, and clarification on the P&T committee's documentation of its decisions. Some commenters supported the proposed conflict of interest standards, while other commenters were concerned it would be difficult to meet the standards. Others recommended other conflict of interest standards. Some commenters

[50] See the Essential Health Benefits (EHB) Rx Crosswalk Methodology at: *https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/ehb-rx-crosswalk.pdf.*

supported the conflict of interest percentage of 20 percent, and others recommended that it be 50 percent. Some commenters recommended implementing the Office of Inspector General's recommendations on conflicts of interest for Medicare Part D P&T committees,[51] and others sought transparency requirements for the operation and management of the P&T committee.

*Response:* We are finalizing the requirement that the P&T committee must be comprised of members that represent a sufficient number of clinical specialties to adequately meet the needs of enrollees. We would expect that the P&T committee membership include experts in chronic diseases and in the care of individuals with disabilities and that it would be composed of a diverse set of experts. We have established certain minimum standards for membership to ensure the integrity of the P&T committee and to allow flexibility to issuers in designing the P&T committee. However, we also expect the P&T committee would consult with experts in management of the relevant condition for each drug being considered. The P&T committee's membership is also required to include a majority of practicing physicians, practicing pharmacists, and other practicing health care professionals. The other practicing health care professionals on the P&T committee, excluding pharmacists, must be licensed to prescribe drugs. The practicing physicians, pharmacists, and other health care professionals on the P&T committee may be practicing part-time. However, under these standards, a member who holds more than one health care license, for example, as a nurse practitioner and a pharmacist, only counts as one member of the P&T committee.

We are finalizing the conflict of interest requirements as proposed. These conflict of interest standards are not the same as Medicare Part D's standards, but we believe that issuers are currently using similar practices in the private health insurance market. Members of the P&T committee that have a conflict of interest with respect to the issuer or a pharmaceutical manufacturer are permitted to sit on the P&T committee but are prohibited from voting on matters for which the conflict exists. We would expect that in implementing this standard, if a particular member of a P&T committee has to abstain from a majority of votes, that the P&T committee should consider removal of the member from the P&T committee. Additionally, at least 20 percent of the P&T committee's membership must have no conflicts of interest with respect to either the issuer or to any pharmaceutical manufacturer. We considered the comments we received on other P&T committee standards and on the requirements for the number and percentage of conflict free members. However, due to concerns about issuers' ability to meet a requirement with a higher threshold and concerns about setting a fixed number of members required to be conflict free when we did not also set the limit on the number of participants on the P&T committee, we believe that requiring 20 percent of the P&T committee's membership to be conflict free is a reasonable threshold in combination with § 156.122(a)(3)(i)(C). As part of this standard, the P&T committee members must sign a conflict of interest statement at least annually revealing economic or other relationships with entities affected by the committee's drug coverage decisions, including the issuer and any pharmaceutical manufacturers. The P&T committee is responsible for establishing a reasonable definition of conflict of interest and for managing the conflicts of interest of its committee members. We will consider providing further guidance regarding the P&T committee's management and oversight, including its operation and management of conflicts of interest, in the future.

*Comment:* Commenters generally supported the requirements regarding the establishment and management of the formulary drug list, and recommended specifying the timing of reviews for new drugs as well as other specified guidelines or best practices. Some commenters wanted the P&T committees' decisions to be binding on the plan, and others wanted the P&T committee's decisions to be advisory. Some commenters opposed the use of treatment guidelines or best practices, and some wanted clarification that the P&T committee can use pharmacoeconomic studies in formulary development. Commenters were concerned about the documentation requirements of P&T committees' decisions and others wanted additional standards, such as to require the P&T committee to have an appeals process for a consumer or provider to request a drug to be placed on the formulary.

*Response:* To ensure better uniformity of P&T committee practice, we are finalizing new § 156.122(a)(3)(iii), which generally aligns with the Medicare Part D standards and guidance on this subject. Under § 156.122(a)(3)(iii)(A), the P&T committee must develop and document procedures to ensure appropriate drug review and inclusion. This includes documentation of decisions regarding formulary development and revision and utilization management activities. P&T committee recommendations regarding which drugs are placed on the plan's formulary are binding on the plan. This clarification reflects practices by Medicare Part D. We also encourage P&T committees to be transparent about their operation and function, and while we are not requiring that P&T committees publicly post information on the P&T committee, we encourage issuers to consider providing this level of transparency to consumers. We are also finalizing a new § 156.122(a)(3)(iii)(B), which is consistent with Medicare Part D standards at 42 CFR 423.120(b)(1)(iv) and which requires the P&T committee to base clinical decisions on the strength of scientific evidence and standards of practice, and requires the P&T committee to assess peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate. Formulary management decisions must be based on scientific evidence, and may also be based on pharmacoeconomic considerations that achieve appropriate, safe, and cost-effective drug therapy. Under § 156.122(a)(3)(ii)(C), drugs' therapeutic advantages in terms of safety and efficacy must be considered when selecting formulary drugs. We are finalizing this provision, except we are not finalizing the requirement that drugs' therapeutic advantages be considered when placing the drugs on formulary tiers, to better align with 42 CFR 423.120(b)(1)(v).

We are also adding new § 156.122(a)(3)(iii)(D) through (F), which are consistent with Medicare Part D standards at 42 CFR 423.120(b)(1)(vi), (vii), and (ix), respectively. The new standard in § 156.122(a)(3)(iii)(D) will require the P&T committee to review policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, and therapeutic interchange. The purpose of finalizing these reviews, which is a typical practice by P&T committees, is to ensure that formulary management techniques do not undermine access to covered drugs.

The new standard in § 156.122(a)(3)(iii)(E) requires the P&T committee to evaluate and analyze treatment protocols and procedures

[51] See the Department of Health and Human Services' Office of the Inspector General Report on Gaps in Overview of Conflicts of Interest in Medicare Prescription Drug Decisions at: *http://oig.hhs.gov/oei/reports/oei-05-10-00450.pdf.*

related to the plan's formulary at least annually, which is also a typical practice of P&T committees today. Furthermore, under § 156.122(a)(3)(iii)(F), the P&T committee must review and approve all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each drug. P&T committee recommendations, with respect to a P&T committee's clinical appropriateness review of the practices and policies for formulary management activities, such as prior authorizations, step therapies, quantity limitations, and other drug utilization activities that affect access, are advisory only and not binding on the issuer, a standard that we believe reflects current practice in both the private health insurance and Medicare Part D markets. However, issuers must take the recommendations into good faith consideration. Similar to the new standards in § 156.122(a)(3)(iii)(D), the purpose of finalizing these reviews is to better ensure that formulary management techniques do not undermine access to covered drugs.

Under § 156.122(a)(3)(iii)(G), which was proposed as § 156.122(a)(3)(iii)(D), the P&T committee must review all new FDA-approved drugs and new uses for existing drugs. To implement this requirement, the P&T committee must make a reasonable effort to review a new FDA approved drug product (or new FDA approved indication) within 90 days, and make a decision on each new FDA approved drug product (or new FDA approved indication) within 180 days of its release onto the market, or a clinical justification must be documented if this timeframe is not met.

A health plan's formulary drug list, under § 156.122(a)(3)(iii)(H), must cover a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states and must not discourage enrollment by any group of enrollees. The formulary drug list must also ensure appropriate access to drugs in accordance with widely accepted national treatment guidelines and general best practices at the time. To comply with § 156.122(a)(3)(iii)(H), broadly accepted treatment guidelines and general best practices could be based on industry standards or other appropriate guidelines that are issued by expert organizations that are current at the time. For instance, broadly accepted treatment guidelines could include guidelines provided in the National Guideline Clearinghouse (NGC), which is a publicly available database of evidence-based clinical practice guidelines and related documents.

ii. Section 156.122(c)

Section 156.122(c) currently requires issuers of EHB plans to have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the plan. This requirement, commonly referred to as the ''exceptions process,'' applies to drugs that are not included on the plan's formulary drug list. As established in the EHB Final Rule (78 FR 12834) and the Market Standards Rule (79 FR 30240), such procedures must include a process that allows an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request an expedited review based on exigent circumstances. Exigent circumstances exist when an enrollee is suffering from a serious health 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 non-formulary drug. A health plan must make its coverage determination on an expedited review request based on exigent circumstances, and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 24 hours after it receives the request. A health plan that grants an exception based on exigent circumstances must provide coverage of the non-formulary drug for the duration of the exigency.

In the proposed rule, we proposed to build on the expedited exception process by proposing to also adopt similar requirements for the standard exception process. We also proposed to adopt standards for a secondary external review process if the first exception request is denied by the plan (regardless of whether the exception is requested using the standard process or the expedited process).

We proposed at § 156.122(c), that a health plan providing EHB must have certain exception processes in place that allow an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request and gain access to clinically appropriate drugs not covered by the health plan, and when an exception requested under one of these processes is granted, the plan must treat the excepted drug as EHB for all purposes, including accrual to the annual limitation on cost sharing. Proposed § 156.122(c)(1) sets forth the standard exception process. Under this process, we proposed that a health plan have a process for an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request a standard review of a coverage decision for a drug that is not covered by the plan. We proposed that the health plan must make its coverage determination on a standard exception request and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 72 hours after it receives the request. We proposed to require a health plan that grants an exception based on the standard review process to provide coverage of the non-formulary drug for the duration of the prescription, including refills, and we stated that in such a case the excepted drug would be considered EHB for all purposes, including for counting towards the annual limitation on cost sharing. As stated in the EHB Rule, plans are permitted to go beyond the number of drugs offered by the benchmark without exceeding EHB. Therefore, if the plan is covering drugs beyond the number of drugs covered by the benchmark, all of these drugs are EHB and must count towards the annual limitation on cost sharing.

We proposed moving the language regarding the expedited exceptions process from § 156.122(c)(1) to new § 156.122(c)(2) and to replace ''Such procedures must include'' with ''A health plan must have'' in current (c)(1) proposed as a new paragraph (c)(2)(i).

In § 156.122(c)(3), we proposed that if the health plan denies an exception request for a non-formulary drug, the issuer must have a process for an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber, as appropriate) to request that an independent review organization review the exception request and the denial of that request by the plan. For this external exception review, we proposed to apply the same timing that applied to the initial review. Thus, if the enrollee requested the drug under the proposed standard process and the request was denied, then the independent review organization would have to make its determination and the health plan would have to notify the enrollee or enrollee's designee and the prescribing physician (or other prescriber, as appropriate) no later than 72 hours after the time it receives the external exception review request. Likewise, if the initial exception request is for an expedited review and that request is denied by the plan, then the independent review organization would

have to make its coverage determination and provide appropriate notification no later than 24 hours after the time it receives the external exception review request. We are finalizing the updated standards in § 156.122(c) as proposed, with an addition to clarify the duration of coverage of the excepted drug when accessed through the external review process.

*Comment:* Many commenters supported revising § 156.122(c), relating to the exceptions process. Some commenters wanted the same standards as Medicare Part D, and others wanted the same standards as the appeals process codified at § 147.136. Other commenters had concerns about conflict with State requirements, the definitions of expedited review and the current course of treatment, and the administrative cost of the exceptions process. Some commenters were concerned about time limits and wanted clarification on when the time limits begin, recommending that the time limits should be measured in business days instead of hours, or be different for the external review process. Others sought additional requirements related to the operation of the exception process such as requiring coverage of the non-formulary drug during the review process, requiring issuers to begin the external review if the original exception request is denied, and requiring issuers to submit or release information on its consideration of exception requests. Although some commenters recommended using a separate review organization for the external review, several commenters supported allowing issuers to use the same independent review organization for the external review as for the final external review decision under § 147.136. Commenters also supported requiring coverage of the excepted drug for the duration of the prescription, including refills, and others supported permitting the issuer to determine and notify the enrollees of the duration of the coverage for the excepted drug.

*Response:* The purpose of revising § 156.122(c) was to establish a more uniform exceptions process across plans and issuers providing EHB to help reduce consumer confusion in accessing, understanding, and using the exception process. We believe that uniform standards in this area will better ensure consumers' ability to understand and access this consumer protection. Because of the importance of this process in ensuring enrollee access to clinically appropriate medications, we are finalizing the 72-hour review period for the standard exception review, continuing the 24-hour review period for an expedited review, and applying the related timing standards to the external review periods. This exceptions process applies to drugs that are not included on the plan's formulary drug list, and § 147.136 applies if an enrollee receives an adverse benefit determination for a drug that is included on the plan's formulary drug list. Because these two processes serve different purposes, we believe they are not duplicative. Furthermore, while our exception process standards are not the same as those under Medicare Part D, they have similar elements. Since issuers that provide EHB are already required under our regulations to have formulary exceptions processes and procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the plan, we do not expect that these new requirements will significantly increase the administrative cost burden on issuers. Furthermore, to permit flexibility in implementing this policy for issuers, we have declined to establish additional requirements at this time, such as requiring issuers to begin the external review absent an enrollee request if the original exception request is denied, and requiring issuers' to submit or release information on its consideration of exception requests.

The 24-hour timing policy for the expedited review was adopted in the final rule on the Market Standards Rule (79 FR 30240), and we are finalizing the 72-hour standard review, as well as the timing for the external reviews, in this final rule. All of these timeframes begin when the issuer or its designee receives a request. An enrollee or the enrollee's prescribing physician (or other prescriber) should strive to submit a completed request; however, issuers should not fail to commence review if they have not yet received information that is not necessary to begin review. Therefore, we interpret new § 156.122(c) to mean that the review must begin following the receipt of information sufficient to begin review. Issuers should not request irrelevant or overly burdensome information. Issuers must be equipped to accept these requests in writing, electronically, and telephonically.

As part of the request for a standard review, the prescribing physician or other prescriber should support the request by including an oral or written statement that provides a justification supporting the need for the non-formulary drug to treat the enrollee's condition, including a statement that all covered formulary drugs on any tier will be or have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects.

Following a favorable decision on the standard or external review, the enrollee must be provided access to the prescribed drug without unreasonable delay. Therefore, issuers need to be prepared to communicate rapidly with pharmacies and pharmacy benefit managers, as applicable. At a minimum, we expect issuers to update certificates of coverage to reflect the availability of this process, and to be able to provide instruction to enrollees or their designees and providers or their designees on how to use the process.

For the external exception review, we are finalizing a standard under which the independent review organization that conducts the external review must be accredited by a nationally recognized private accrediting organization. As part of this process, the issuer should provide the independent review organization with all relevant information to conduct the review, including the initial denial of the exception request. The issuer may use the same independent review organization for the external review for the drug exception process under § 156.122(c)(3) that the plan contracts with for the final external review decision under § 147.136. As established in revised § 156.122(c), any drug covered through the exception process must be treated as an EHB, including by counting any cost sharing towards the plan's annual limitation on cost sharing and when calculating the plan's actuarial value. We believe that ensuring that an enrollee has the option to request an external review of a denied exception request and that a drug covered through the exception process count towards the plan's annual limitation on cost sharing are important consumer protections that help ensure enrollees' access to clinically appropriate medications.

We do not believe that enrollees should have to continue to make requests under § 156.122(c) to access a refill of the same clinically appropriate drugs that they initially obtained through the exceptions process. Therefore, we are finalizing a standard under which non-grandfathered health plans in the individual and small group markets that must provide coverage of the essential health benefit package under section 1302(a) of the Affordable Care Act must cover a drug accessed through the standard exception process for the duration of the prescription, including refills. To provide further clarification on the operation of the external review process, we are also finalizing a new standard under which,

if a health plan providing EHB grants an external exception review of a standard exception request, the health plan must provide coverage of the non-formulary drug for the duration of the prescription, including refills. Likewise, if a health plan grants an external exception review of an expedited exception request, the health plan must provide coverage of the non-formulary drug for the duration of the exigency. Nothing under this policy precludes a State from requiring stricter standards in this area. Issuers will be required to comply with the new standard exception process and external review process requirements starting with the 2016 plan year.

iii. Section 156.122(d)

Under § 156.122(d), we proposed adding a requirement to the EHB prescription drug benefit that a health plan must publish an up-to-date, accurate, and complete list of all covered drugs on its formulary drug list, including any tiering structure that it has adopted and any restrictions on the manner in which a drug can be obtained, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Exchange, HHS, OPM, and the general public. We also solicited comment on whether the formulary tiering information should include cost sharing information, such as the enrollee's applicable pharmacy deductible (for example, $100), copayment (for example, $20), or cost-sharing percentage for the enrollee (for example, 20 percent). We proposed that a formulary drug list be considered easily accessible when the general public is able to view the formulary drug list on the plan's public Web site through a clearly identifiable link or tab and without creating or accessing an account or entering a policy number. The general public should be able to easily discern which formulary drug list applies to which plan if the issuer maintains multiple formularies, and the plan associated with each formulary drug list should be clearly identified on the plan's Web site. As a result of this proposed requirement, we would expect the issuers' formulary drug list to be up-to-date, meaning that the formulary drug list must accurately list all of the health plan's covered drugs at that time. We solicited comments on this timing. Also, the formulary drug list URL link under this section should be the same direct formulary drug list URL link for obtaining information on prescription drug coverage in the Summary of Benefits and Coverage, in accordance with § 147.200(a)(2)(i)(K). We proposed that this requirement would be effective beginning with the 2016 plan year. We solicited comments on these proposed requirements, including whether we should require that additional types of information be included in the formulary drug list.

As part of this proposed requirement that issuers' formulary drug list must be made available to the general public, we considered requiring issuers to make this information publicly available on their Web sites in a machine-readable file and format specified by HHS. The purpose of establishing machine-readable files with the formulary drug list data would be to provide the opportunity for third parties to create resources that aggregate information on different plans. As an alternative, we considered whether the formulary drug list information could be submitted to HHS though an HHS-designed standardized template, while recognizing that there could be challenges with keeping this type of template information updated. We solicited comments on these options. We are finalizing these requirements largely as proposed, with language to clarify that the requirement to publish an up-to-date, accurate and complete list of all covered drugs applies beginning with the 2016 plan year, and to require that QHPs in the FFEs make available this information to HHS in a format and at times determined by HHS beginning with the 2016 plan year.

*Comment:* Most commenters generally supported the proposed standards regarding the ease with which consumers should be able to view formulary drug lists on issuers' Web sites, and some recommended requirements on the format for the formulary drug list on the Web site. Many commenters wanted detailed cost-sharing information to be included on the formulary drug list, including deductible, copay, and specific coinsurance dollar amounts. Others opposed providing that level of detail on the formulary drug list because of difficulties in keeping the formulary drug list up to date and potential consumer confusion because every plan design, including each silver plan variant, would need a separate formulary drug list. Other commenters sought clarification on definitions, including all covered drugs and any restrictions on the manner in which the drug can be obtained. Others supported or opposed the proposed definition of ''up to date.''

*Response:* The purpose of § 156.122(d) is to improve the transparency of formulary drug lists for plans required to cover the essential health benefits by requiring accurate, complete and up-to-date information on the drugs that the plan covers to assist consumers. Thus, while we recognize the value in providing consumers with detailed cost-sharing information on the formulary drug list (such as the enrollee's applicable pharmacy deductible, copayment, or cost-sharing percentage for the enrollee), our goal with this provision is to ensure that the formulary drug list is accurate, complete, and up-to-date. Providing detailed cost-sharing information on the formulary drug list is not a typical practice in the private health insurance market. Therefore, we are finalizing § 156.122(d) as proposed at this time. Issuers' formulary drug lists must include any tiering structure that it has adopted and any restrictions on the manner in which a drug can be obtained, and while we are not requiring detailed cost-sharing information under § 156.122(d) at this time, we encourage issuers to provide this level of transparency on the formulary drug list where feasible to help consumers make more informed decisions about their health insurance coverage. In general, consumers should be able to use the formulary drug list in conjunction with the summary of benefits and coverage or other plan documents to determine their applicable cost sharing. For example, a formulary drug list would list which drugs are in Tier 1 (or similar category of prescription drug coverage), and the SBC would indicate that drugs in Tier 1, or similar category, have a $20.00 copayment. While the SBC must list any applicable coinsurance and major limitations or exceptions, an issuer's SBC would not list the specific dollar amounts an enrollee would pay for a drug that is subject to coinsurance, given that the SBC is only a summary of cost-sharing features. For the purpose of this section, references to the URL have been removed to clarify that our standards apply to the actual formulary drug list, not the Web address.

For the purpose of § 156.122(d), for a formulary drug list to be considered complete, the formulary drug list must list all drugs that are EHB and when the formulary drug list specifies all drug names that are currently covered by the plan at that time. This requirement means that issuers are prohibited from listing only the most commonly prescribed medications. The formulary drug list does not have to list every covered formulation for each covered drug, but the issuer should be prepared to provide information on the specific formulations upon request to the plan's enrollees, prospective enrollees, the State, the Exchange, HHS, OPM, and the

general public. Issuers must also include accurate information on any restrictions on the manner in which the drug can be obtained in the formulary drug list, including prior authorization, step therapy, quantity limits, and any access restrictions related to obtaining the drug from a brick and mortar retail pharmacy, such as only being accessible through a mail-order pharmacy because the drug requires special handling. The formulary drug list must be up-to-date, which means that the formulary drug list must accurately list all of the health plan's covered drugs at that time. To meet this requirement, we would expect that the issuer would make any coverage changes simultaneously with updating the formulary drug list and therefore, if an issuer makes a change to its formulary, it would not implement the change until the issuer has posted the change to the formulary drug list on its Web site. We understand that our standard for updating the formulary drug list is stricter than is the case for the typical private market plan, but we believe that the value of increased transparency to consumers is critically important to ensuring that consumers are making informed decisions about their health care. Issuers are prohibited from limiting the updates to their formulary drug list to only formulary changes that negatively impact enrollees, such as removal of drugs from the formulary drug list. Also, the URL that takes a consumer to the issuer's formulary drug list on its Web site must be the same direct formulary drug list URL link for obtaining information on prescription drug coverage in the SBC, in accordance with § 147.200(a)(2)(i)(K), and for QHPs on the Exchanges, this link must be the same link displayed to prospective enrollees on the applicable Exchange Web site. As discussed in the preamble to § 156.250, in addition to the requirements imposed by § 156.250, QHP issuers may also have duties to make this information accessible to individuals with disabilities and individuals with LEP under Federal civil rights laws that also might apply, including section 1557 of the Affordable Care Act, section 504 of the Rehabilitation Act of 1973, and Title VI of the Civil Rights Act. For the FFEs, this URL must be the one that issuers provide through the QHP application for display on HealthCare.gov. While these regulations do not prohibit issuers from providing their drug lists in a searchable or dynamic format on their Web sites, consumers should not have to create an account, be an enrollee in the plan, or navigate multiple Web pages to view the formulary drug list. Specifically, the link needs to be the direct link to the formulary drug list. Further, if an issuer has multiple formulary drug lists, consumers should be able to easily discern which formulary drug list applies to which plan. Also, the Web page should clearly list which plans the formulary drug list applies to using the marketing name for the plan, which for Marketplace plans would be the marketing name used on HealthCare.gov. The revised § 156.122(d) is effective beginning with the 2016 plan year, and we expect that most issuers already have a formulary drug list available via a URL link and will only need to make certain minor modifications to its link to be in compliance with the new § 156.122(d)(1).

*Comment:* Several commenters supported the proposal for issuers to make the formulary drug list information available in a machine-readable file or a format specified by HHS, stating that this would improve transparency and foster development of additional tools to help consumers make informed decisions about their coverage. Commenters recommended types of information that should be included and the development of tools similar to tools developed by the Medicare Part D program. Others supported allowing various options on how to search for covered drugs, such as by the drug name or listing alphabetically. Conversely, some commenters opposed the proposal, expressing concerns about data integrity, accuracy, confidentiality, and managing third parties' use of this data. Some commenters were concerned that the machine-readable data collection would be duplicative, and noted that implementing any standard would be time-consuming and requested the opportunity to provide additional stakeholder feedback. Some commenters suggested use of an application programming interface (API) to support making formulary drug list information more transparent.

*Response:* We believe a machine-readable file or a format specified by HHS will increase transparency by allowing software developers to access this information and create innovative and informative tools to help enrollees better understand plans' formulary drug lists. Based on the comments received asking us to make formulary drug list information more transparent and accessible to consumers, HHS is finalizing this rule by adding § 156.122(d)(2) to require QHPs in the FFEs to make available the information on the formulary drug list on its Web site in a HHS specified format and also submit this information to HHS, in a format and at times determined by HHS. We agree with commenters that creating a vehicle for consumers to easily determine which plans cover which drugs will help consumers select QHPs that best meet their needs. We recognize that this will require issuer resources, and will provide further details about the specific data elements, frequency of updates, file types, and other crucial information in future guidance.

iv. Section 156.122(e)

Under § 156.122(e), we proposed to require that enrollees be provided with the option to access their prescription drug benefit through retail (brick-and-mortar or non-mail order) pharmacies. This requirement would mean that a health plan that is required to cover the EHB package cannot have a mail-order only prescription drug benefit. This proposed requirement would still allow a health plan to charge a different cost-sharing amount when an enrollee obtains a drug at an in-network retail pharmacy than he or she would pay for obtaining the same covered drug at a mail-order pharmacy. However, as a part of these requirements, we proposed to clarify that this additional cost sharing for the covered drug would count towards the plan's annual limitation on cost sharing under § 156.130 and would need to be taken into account when calculating the actuarial value of the health plan under § 156.135. Additionally, under this proposed policy, issuers would still retain the flexibility to charge a lower cost-sharing amount when obtaining the drug at an in-network retail pharmacy. While this proposal requires coverage of a drug at an in-network retail pharmacy, for plans that do not have a network, the enrollee would be able to go to any pharmacy to access their prescription drug benefit and those plans would, therefore, be in compliance with this proposed standard.

As part of this proposed policy, we proposed that the health plan may restrict access to a particular drug when: (1) The FDA has restricted distribution of the drug to certain facilities or practitioners (including physicians); or (2) appropriate dispensing of the drug requires special handling, provider coordination, or patient education that cannot be met by a retail pharmacy. If the health plan finds it necessary to restrict access to a drug for either of the two reasons listed above, we proposed that it must indicate this restricted access on the formulary drug list under § 156.122(d). We are finalizing these policies as proposed with a technical edit to § 156.122(e)(2) to replace

''higher'' cost sharing with ''different'' cost sharing.

*Comment:* Several commenters supported proposed § 156.122(e) as helping to ensure that plans do not discourage enrollment by, and thus discriminate against, transient individuals and individuals who have conditions that they wish to keep confidential and discussed other cases in which obtaining a prescription from a mail-order pharmacy is difficult for an enrollee, such as cases where an enrollee with a serious health condition may be unable to wait for the prescription to be filled via a mail-order pharmacy. Other commenters opposed these requirements, stating that it would be costly, limit consumer choice of plans that use mail-order benefits, be contrary to specialty drug market practices, not account for the quality standards used by specialty pharmacies, be contrary to precedent from other Federal programs, and be duplicative. Some commenters were concerned that the issue is outside the scope of EHB, is not reflective of a typical employer plan, does not take into account existing privacy laws, and should require additional rulemaking that, for instance, takes into account the NAIC's pending model act on network adequacy. Other commenters wanted clarification that preventive services drugs must be covered at no cost sharing at retail pharmacies, and other commenters discussed similar and overlapping State requirements. Several commenters wanted additional exceptions, such as an exclusion related to specialty drugs and pharmacies, and some commenters supported implementing this provision in 2016 while others supported a 2017 implementation date.

*Response:* The intention of § 156.122(e) is to ensure all enrollees in plans required to cover EHB are able to use the prescription drug benefit if needed, and is intended to expand options for these enrollees. Thus, the purpose of this policy is not to limit the ability of issuers to use mail-order pharmacies—issuers can continue to influence consumer choice through cost sharing. The issuers need only provide enrollees with the option to access drugs that are not exempted under § 156.122(e)(1)(i) and (ii) at an in-network retail pharmacy. There are instances in which obtaining a drug through a mail-order pharmacy may not be a viable option, such as when an individual does not have a stable living environment and does not have a permanent address, or when a retail pharmacy option better ensures that consumers can access their EHB prescription drug benefit on short notice. In such cases, we do not believe that making drugs available only by mail order constitutes fulfilling the obligation under section 1302(b)(1)(F) of the Affordable Care Act to provide prescription drug coverage as part of EHB. We also believe that making drugs available only by mail order could discourage enrollment by, and thus discriminate against, transient individuals and individuals who have conditions that they wish to keep confidential. We also believe that this provision is important to ensure uniformity in benefit design and consumer choice. Therefore, we are finalizing § 156.122(e) as proposed and with a clarification that this policy will be effective beginning with the 2017 plan year.

Issuers retain the ability to charge different cost sharing for drugs obtained at a retail pharmacy, but for non-grandfathered health plans in the individual and small group markets that must provide coverage of the essential health benefit package under section 1302(a) of the Affordable Care Act, all cost sharing, including any difference between the cost sharing for mail order and the cost sharing for retail, must count towards the plan's annual limitation on cost sharing in accordance with § 156.130(a) and must be taken into account when calculating the actuarial value of the health plan in accordance with § 156.135. We are clarifying that these issuers can apply higher or lower cost sharing, that is, nothing requires an issuer to use higher cost sharing for drugs obtained from a retail pharmacy. As a result, some or all of the costs associated with this option may be passed on to the consumer who chooses to use it. However, nothing in this provision supersedes State law that may apply other cost sharing standards to mail-order pharmacies. For plans that do not have a network, enrollees should be able to go to any pharmacy to access their prescription drug benefit, and those plans would, therefore, be in compliance with this standard. In addition, this requirement is not intended to disrupt or supersede the rules regarding cost sharing for preventive service benefits when such coverage includes drugs.

In response to comments, we considered an exceptions process under which an enrollee could make a request to obtain the prescription at a brick and mortar retail pharmacy. However, we are concerned that if we allow an exception process, the issuer would retain the option to deny the request, and such a process could be seen as burdensome on the enrollee. In particular, an exception process could be burdensome for enrollees with complex health conditions if they had to seek an exception request for each of their prescription drugs that they take.

We understand that specialty pharmacies provide more integrated services, aimed at improving clinical outcomes while limiting costs relating to the delivery and management of the product, than a typical mail-order pharmacy or a brick and mortar retail pharmacy. We understand that drugs on the specialty tier of a formulary are not necessarily the same drugs that a specialty pharmacy would provide. Our intention with this policy was not to disrupt the specialty pharmacy market, and we understand that exceptions will be needed for many drugs that are only accessible via a specialty pharmacy. For these reasons, we are finalizing the exceptions that allow a health plan to restrict access to certain drugs in limited circumstances. As part of this requirement, a health plan may restrict access to mail order, which may include specialty pharmacies, for a particular drug when: (1) The FDA has restricted distribution of the drug to certain facilities or practitioners (including physicians); or (2) appropriate dispensing of the drug requires special handling, provider coordination, or patient education that cannot be met by a retail pharmacy. For instance, certain drugs have a Risk Evaluation and Mitigation Strategy (REMS) that includes Elements to Assure Safe Use that may require that pharmacies, practitioners, or health care settings that dispense the drug be specially certified and that may limit access to the drugs to certain health care settings.[52] If the health plan finds it necessary to restrict access to a drug for either of the reasons listed above, it must indicate this restricted access on the formulary drug list that plans must make publicly available under § 156.122(d). The provisions at § 156.122(e)(1)(i) and (ii) allow an issuer to restrict access to certain drugs at a retail pharmacy for the specific reasons noted in those paragraphs. Although issuers may subject these drugs to reasonable utilization management techniques, the fact that these drugs have restricted access should not in and of itself be a justification for applying these techniques to these drugs.

Issuers must implement the revised § 156.122(e) no later than for the start of

[52] FDA requires a Risk Evaluation and Mitigation Strategies (REMS) for certain drugs to ensure that the benefits of a drug or biological product outweigh its risks. The following is FDA's list of currently approved REMS at: *http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm111350.htm.*

the 2017 plan year, and we have added this clarification to the regulation.

v. Other Comments on the Preamble to § 156.122

In addition to the proposed provisions above, we urged issuers to temporarily cover non-formulary drugs (including drugs that are on an issuer's formulary but require prior authorization or step therapy) as if they were on formulary (or without imposing prior authorization or step therapy requirements) during the first 30 days of coverage. We encouraged plans to adopt this policy to accommodate the immediate needs of enrollees, while allowing the enrollee sufficient time to go through the prior authorization or drug exception processes.

*Comment:* Some commenters sought clarification about coverage of medical drugs and preventive service drugs. Others recommended requiring limits to formulary changes during the plan year. Several commenters recommended that we require issuers to temporarily cover non-formulary drugs during the first 30 days of coverage or longer and other commenters were against this policy, stating that it is not a typical requirement in the private market, and that it is costly and counterintuitive to formulary transparency. Other commenters supported transition policies, but acknowledged the importance of flexibility for issuers in developing these policies.

*Response:* Preventive services, including preventive service drugs, are required to be covered as part of EHB. Non-grandfathered group health plans and health insurance coverage must provide benefits for preventive health services, including preventive service drugs, without cost sharing, consistent with the requirements of section 2713. Similarly, the rules set forth under § 156.122 are specific to coverage of drugs under the prescription drug EHB category. Issuers could cover drugs administered as part of another service (such as during an inpatient hospitalization or a physician service) under the EHB category that covers that service, in addition to covering the drug under the prescription drug EHB category. We believe this clarification reflects the current practice of issuers.

We are also concerned about issuers making mid-year formulary changes, especially changes that negatively affect enrollees. We are monitoring this issue to consider whether further standards are needed. We also note that, under guaranteed renewability requirements and the definitions of ''product'' and ''plan,'' issuers generally may not make plan design changes, including changes to drug formularies, other than at the time of plan renewal. We recognize that certain mid-year changes to drug formularies related to the availability of drugs in the market may be necessary and appropriate.

We are not requiring coverage of a transitional fill at this time. As stated in the proposed rule, we will consider whether additional requirements may be needed in this area. We remain concerned that new enrollees may be unfamiliar with what is covered on their new plan's formulary drug list and the process and procedures under the plan. Further, some new enrollees whose drugs are covered by the plan's formulary may need to obtain prior authorization or go through step therapy to have coverage for their drugs, and others may need time to work with their provider to determine which formulary drug the individual should be transitioned to. For these reasons, we urge issuers to temporarily fill drugs that are not on the formulary (or are on an issuer's formulary but require prior authorization or step therapy) as if they were on formulary (or without imposing prior authorization or step therapy requirements) during the first 30 days of coverage. We encourage plans to adopt this policy to accommodate the immediate needs of enrollees, while allowing the enrollee sufficient time to go through the prior authorization or drug exception processes.

*Comment:* Some commenters recommended that we implement the prescription benefit requirements in 2017 or later. Others recommended that all of the prescription drug benefit changes be implemented in 2016. Some had separate recommendations for the timing or only commented on the timing for certain requirements.

*Response:* We recognize that certain prescription benefit changes under § 156.122 will be easier to implement than others. For that reason, we are finalizing our proposal effective dates for § 156.122(c) and new § 156.122(d), such that they are effective for plan years beginning or after January 1, 2016. These requirements are typical of the current market and would require updating and modifying of systems and procedures to align with the finalized policy. We are finalizing our proposed effective dates for the revisions to § 156.122(a) and new § 156.122(e) such that they are effective for plan years beginning on or after January 1, 2017 to better ensure a smooth transition in implementing these policies.

e. Prohibition on Discrimination (§ 156.125)

Section 1302(b)(4) of the Affordable Care Act directs the Secretary to address certain standards in defining EHB, including elements related to balance, discrimination, the needs of diverse sections of the population, and denial of benefits. We have interpreted this provision, in part, as a prohibition on discrimination by issuers providing EHB. Under § 156.125, which implements the prohibition on discrimination provisions, an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.

As described in the proposed rule, since we finalized § 156.125, we have become aware of benefit designs that we believe would discourage enrollment by individuals based on age or based on health conditions, in effect making those plan designs discriminatory, thus violating this prohibition. Some issuers have maintained limits and exclusions that were included in the State EHB benchmark plan. As we have previously stated in guidance, EHB-benchmark plans may not reflect all requirements effective for plan years starting on or after January 1, 2014. Therefore, when designing plans that are substantially equal to the EHB-benchmark plan, issuers should design plan benefits, including coverage and limitations, to comply with requirements and limitations that apply to plans beginning in 2014.[53]

In the proposed rule, we discussed three examples of potentially discriminatory practices: (1) Attempts to circumvent coverage of medically necessary benefits by labeling the benefit as a ''pediatric service,'' thereby excluding adults; (2) refusal to cover a single-tablet drug regimen or extended-release product that is customarily prescribed and is just as effective as a multi-tablet regimen, absent an appropriate reason for such refusal; and (3) placing most or all drugs that treat a specific condition on the highest cost tiers.

In this final rule, CMS adopts the same approach as described in the proposed rule. As we indicated in the proposed rule and the 2014 Letter to Issuers, we will notify an issuer when we see an indication of a reduction in the generosity of a benefit in some

[53] Guide to Reviewing EHB Benchmark Plans—*http://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.html#review* benchmarks.

manner for subsets of individuals that is not based on clinically indicated, reasonable medical management practices.[54] We conduct this examination whenever a plan subject to the EHB requirement reduces benefits for a particular group. Issuers are expected to impose limitations and exclusions based on clinical guidelines and medical evidence, and are expected to use reasonable medical management. Issuers may be asked to submit justification with supporting documentation to HHS or the State explaining how the plan design is not discriminatory.

We note that other nondiscrimination and civil rights laws may apply, including the Americans with Disabilities Act, section 1557 of the Affordable Care Act, Title VI of the Civil Rights Act of 1964, the Age Discrimination Act of 1975, section 504 of the Rehabilitation Act of 1973 and State law. Compliance with § 156.125 is not determinative of compliance with any other applicable requirements, and § 156.125 does not apply to the Medicaid and CHIP programs, but a parallel provision applies to EHBs furnished by Medicaid Alternative Benefit Plans.

*Comment:* Many commenters requested that we clarify that the examples provided are only examples and not *per se* discriminatory. Other commenters requested that we codify the examples and suggested additional examples of discriminatory practices that should be codified as well.

*Response:* We are not prohibiting certain practices in regulatory text at this time. Several factors must be taken into consideration during benefit design, and a discrimination determination is often dependent on the specific facts and circumstances. However, the examples identified in the proposed rule contain indications that they are discriminatory, and therefore further investigation by the enforcing entity may be required. We strongly caution issuers that the examples cited appear discriminatory in their application when looking at the totality of the circumstances, and may therefore be prohibited.

Additionally, as described later in this preamble, section 1302(b) of the Affordable Care requires that the definition of EHB be based on the scope of benefits provided under a typical employer plan, subject to requirements under the joint interpretive jurisdiction of the Departments of HHS, Labor, and the Treasury.[55] Because the nondiscrimination provisions are related to many other such requirements, HHS will consult with relevant Federal agencies, such as the Departments of Labor and the Treasury, as necessary, in developing new guidance related to discriminatory benefit designs.

*Comment:* Some commenters asked whether discrimination would be identified during certification or approval and therefore a finding of discrimination would be prospective only.

*Response:* As provided under § 156.125(a), an issuer does not provide EHB if the implementation of a benefit design discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. Some discriminatory practices might not be discovered until an enrollee files a complaint with the appropriate body. Once a discriminatory practice is identified, the issuer may be asked to submit a justification with supporting documentation to HHS or the State explaining why the practice is not discriminatory.

*Comment:* Some commenters expressed concern regarding the example of placing most or all drugs for a certain condition on a high cost tier. They noted that drug tiering reflects current realities of the drug market and is based on costs. The commenters asked CMS to clarify that having a specialty tier is not discriminatory.

*Response:* The examples provided in the proposed rule are potentially discriminatory if there is no appropriate non-discriminatory reason for the noted practice. Having a specialty tier is not on its face discriminatory; however, placing most or all drugs for a certain condition on a high cost tier without regard to the actual cost the issuer pays for the drug may often be discriminatory in application when looking at the totality of the circumstances, and therefore prohibited. When CMS or the State requests a justification for such a practice, issuers should be able to identify an appropriate non-discriminatory reason that supports their benefit design, including their formulary design.

*Comment:* Several commenters requested more detailed information regarding how CMS and States monitor and enforce discrimination.

*Response:* Enforcement of the requirement to cover EHB is governed by section 2723 of the PHS Act, which looks first to States for enforcement, then to the Secretary where a State informs CMS that it is not enforcing the requirement, or CMS finds that the State has failed to substantially enforce. Therefore the State, or CMS in States that are not substantially enforcing market-wide standards, is responsible for enforcing EHB standards, including the non-discrimination standard. In an FFE, CMS notifies an FFE issuer when we see an indication of a reduction in the generosity of a benefit for a subset of individuals and it is not apparent that the reduction is based on a clinical indication or reasonable medical management practices.[56] We conduct this examination whenever a plan on an FFE reduces benefits for a particular group. Limitations and exclusions are expected to be based on clinical guidelines and medical evidence, and medical management standards are expected to be reasonable. Issuers may be asked to submit a justification with supporting documentation to CMS or the State explaining how the plan design is not discriminatory.

HHS's Office for Civil Rights (OCR) has independent authority to enforce section 1557 of the Affordable Care Act (42 U.S.C. 18116), which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in any health program or activity, any part of which receives Federal financial assistance. OCR also enforces Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d, *et seq.*), section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), and the Age Discrimination Act of 1975 (42 U.S.C. 6101, *et seq.*) and their respective implementing regulations, which prohibit discrimination on the basis of race, color, national origin, disability, or age in health programs and activities that receive Federal financial assistance.

f. Cost-Sharing Requirements (§ 156.130)

We proposed to amend § 156.130 to clarify how the annual limitation on

[54] Letter to Issuers on Federally-facilitated and State Partnership Exchanges, April 5, 2013, page 15 and 2015 Letter to Issuers in the Federally facilitated Marketplaces, March 14, 2014, page 29.

[55] To inform the determination as to the scope of a typical employer plan, section 1302(b)(2)(A) of the Affordable Care act requires the Secretary of Labor to conduct a survey of employer-sponsored coverage to determine *the benefits typically covered by employers,* and to provide a report to the Secretary of HHS. These provisions suggest that, while detailed requirements for EHB in the individual and small group health insurance markets were deemed necessary, the benefits covered by typical employer plans providing primary coverage at the time the Affordable Care Act was enacted were seen as sufficient to satisfy the Act's objectives for the breadth of benefits needed for health plan coverage and, in fact, to serve as the basis for determining EHB.

[56] Letter to Issuers on Federally-facilitated and State Partnership Exchanges, April 5, 2013, page 15 and 2015 Letter to Issuers in the Federally-facilitated Marketplaces, March 14, 2014, page 29.

increases subject to review, the issuer will enter justifications in Part II of the URR rate filing justification in the rate review module of HIOS.

CMS plans to continue review for rate outliers in order to identify possible market disruptions, as described in Section 4 of the 2015 Letter to Issuers. CMS recognizes that the identification of a QHP rate as an outlier does not necessarily indicate inappropriate rate development. CMS will notify the appropriate State entity of the results of its outlier identification process and will consider the State's assessment of the plan's rates when determining whether, based on its rates, certifying the QHP to be offered on the FFMs would be in the interest of consumers.

## Section 9. Discriminatory Benefit Design

This section addresses how CMS will review health plans applying to be QHPs or SADPs in the FFMs for compliance with nondiscrimination standards. States performing plan management functions may use a similar approach.

As previously stated in guidance, EHB-benchmark plans may not reflect all requirements effective for plan years starting on or after January 1, 2014. Therefore, when designing plans that are substantially equal to the EHB-benchmark plan, issuers should design plan benefits, including coverage and limitations, to comply with requirements and limitations that apply to plans beginning in 2014. We also remind issuers that individuals under age 65 with end stage renal disease (ESRD) are not required to sign up for or enroll in Medicare. Further, individuals who do not have Medicare Part A or Part B are eligible to enroll in individual market coverage, including a QHP, if the individual meets the eligibility requirements for enrollment (i.e., criteria related to citizenship, lawful presence, incarceration, and residency).[32]

### *i. EHB Discriminatory Benefit Design*

Non-discrimination in benefit design with respect to EHB is a market-wide consumer protection that applies inside and outside of Marketplaces. As stated in 45 CFR 156.125(a), an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.

In the 2016 Payment Notice Final Rule, CMS addressed 45 CFR §156.125, which implements a prohibition on discrimination by issuers providing EHB. Also in the 2016 Payment notice Final Rule, CMS discussed three examples of potentially discriminatory practices. CMS cautions both

[32] For more information, see Frequently Asked Questions Regarding Medicare and the Marketplace, August 1, 2014, available at: http://www.cms.gov/Medicare/Eligibility-and-Enrollment/Medicare-and-the-Marketplace/Downloads/Medicare-Marketplace_Master_FAQ_8-28-14_v2.pdf.

issuers and States that age limits may potentially be discriminatory when applied to services that have been found clinically effective at all ages. For example, it might be arbitrary to limit a hearing aid to enrollees who are 6 years of age and younger since there may be some older enrollees for whom a hearing aid is medically necessary. Although CMS does not enumerate which benefits fall into each statutory EHB category, issuers should not attempt to circumvent coverage of medically necessary benefits by labeling the benefit as a "pediatric service," thereby excluding adults. CMS also cautions issuers to avoid discouraging enrollment of individuals with chronic health needs. For example, if an issuer refuses to cover a single-tablet drug regimen or extended-release product that is customarily prescribed and is just as effective as a multi-tablet regimen, absent an appropriate reason for such refusal, such a plan design might effectively discriminate against, or discourage enrollment by, individuals who would benefit from such innovative therapeutic options. As another example, if an issuer places most or all drugs that treat a specific condition on the highest cost tiers, that plan design might effectively discriminate against, or discourages enrollment by, individuals who have those chronic conditions.

The enforcement of this standard is largely conducted by States. CMS encourages States that are enforcing the Affordable Care Act to consider a number of strategies for assessing compliance with this standard including, but not limited, to analysis of information entered in the "explanations" and "exclusions" sections of the QHP Plans and Benefits Template.

Section 1302(b) of the Affordable Care requires that the definition of EHB be based on the scope of benefits provided under a typical employer plan, subject to requirements under the joint interpretive jurisdiction of the Departments of HHS, Labor, and the Treasury.[33] Because the nondiscrimination provisions are related to many other such requirements, HHS will consult with relevant Federal agencies, such as the Departments of Labor and the Treasury, as necessary in developing new guidance related to discriminatory benefit designs.

*ii. QHP Discriminatory Benefit Design*

For purposes of QHP certification, CMS will assess compliance with this standard by collecting an attestation that issuers' QHPs will not discriminate against individuals on the basis of health status, race, color, national origin, disability, age, sex, gender identity or sexual orientation,

[33] To inform the determination as to the scope of a typical employer plan, section 1302(b)(2)(A) of the Affordable Care act requires the Secretary of Labor to conduct a survey of employer sponsored coverage to determine the benefits typically covered by employers, and to provide a report to the Secretary of HHS These provisions suggest that, while detailed requirements for EHB in the individual and small group health insurance markets were deemed necessary, the benefits covered by typical employer plans providing primary coverage at the time the Affordable Care Act was enacted were seen as sufficient to satisfy the Act's objectives for the breadth of benefits needed for health plan coverage and, in fact, to serve as the basis for determining EHB.

consistent with 45 C.F.R. 156.200(e). CMS will continue to assess compliance through issuer monitoring and compliance reviews, including analysis of appeals and complaints.

In addition to complying with EHB non-discrimination standards identified above, QHPs must not employ market practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs pursuant to 45 C.F.R. 156.225. As in prior QHP certification review cycles, CMS will perform an outlier analysis on QHP cost sharing (e.g., co-payments and co-insurance). CMS's outlier analysis will compare benefit packages with comparable cost-sharing structures to identify cost-sharing outliers with respect to specific benefits.

Additionally, CMS is considering conducting a review of each QHP to identify outliers based upon estimated out-of-pocket costs associated with standard treatment protocols for specific medical conditions using nationally-recognized clinical guidelines. The conditions under consideration include: bipolar disorder, diabetes, HIV, rheumatoid arthritis, and schizophrenia.

Also in reviewing a plan's cost-sharing structure, CMS will analyze information contained in the Plans and Benefits Template, including, but not limited to the "explanations" and "exclusions" sections, with the objective of identifying discriminatory features or wording. Discriminatory cost sharing language would typically involve reduction in the generosity of a benefit in some manner for subsets of individuals for reasons not clearly based on common medical management practices.

CMS will notify an issuer when it sees an indication of a reduction in the generosity of a benefit in some manner for subsets of individuals that is not based on clinically indicated, reasonable medical management practices. CMS conducts this examination whenever a plan required to cover EHB reduces those benefits for a particular group. Issuers are expected to impose limitations and exclusions, if any, based on clinical guidelines and medical evidence, and are expected to use reasonable medical management. Issuers may be asked to submit justification with supporting documents to CMS explaining how the plan design is not discriminatory.

Section 10. Prescription Drugs

CMS seeks to ensure that all Marketplace consumers, regardless of medical condition, have appropriate access to prescription drugs. CMS will not review SADPs for adherence to prescription drug standards as part of the QHP certification process.

In 2015 for the FFM, CMS applied standards described in the 2015 Letter to Issuers to the formulary drug list URL that it collected as part of the QHP Application. Similar to 2015, CMS will collect QHPs' formulary drug list URLs as part of the QHP Application and will make formulary drug list links provided by issuers available to consumers on HealthCare.gov. This formulary drug list URL link should be the same direct formulary drug list link for obtaining

information on prescription drug coverage in the Summary of Benefits and Coverage, in accordance with 45 C.F.R. 147.200(a)(2)(i)(K).

In the 2016 Payment Notice Final Rule, CMS finalized a number of changes to the EHB prescription drug benefit. While some of these changes are not applicable until 2017, some of these changes apply starting with the 2016 plan year. These changes include a requirement that issuers' formulary drug lists be up-to-date, accurate, and include a complete list of all covered drugs. The formulary drug list must include any tiering structure that the plan has adopted and any restrictions on the manner in which a drug can be obtained. The Final Rule clarifies that for the purpose of 45 C.F.R. 156.122(d), for a formulary drug list to be considered complete, the formulary drug list must list all drugs that are EHB, and list all drug names that are currently covered by the plan at that time. The formulary drug list does not have to list every covered formulation for each covered drug, but the issuer should be prepared to provide information on the specific formulations upon request. Issuers must also include accurate information on any restrictions on the manner in which an enrollee can obtain the drug, including prior authorization, step therapy, quantity limits, and any access restrictions related to obtaining the drug from a brick and mortar retail pharmacy. The formulary drug list must be up-to-date, which means that the formulary drug list must accurately list all of the health plan's covered drugs at that time.

The formulary drug list must be published in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Marketplace, HHS, OPM, and the general public. A formulary drug list is easily accessible when it can be viewed on the plan's public web site through a clearly identifiable link or tab without requiring an individual to create or access an account or enter a policy number; and if an issuer offers more than one plan, when an individual can easily discern which formulary drug list applies to which plan. CMS is also requiring issuers to make this information publicly available on their websites in a machine-readable file and format specified by HHS, to allow the creation of user-friendly aggregated information sources. The purpose of establishing machine-readable files with this data is to provide the opportunity for third parties to create resources that aggregate information on different plans. We believe this will increase transparency by allowing software developers to access this information and create innovative and informative tools to help enrollees better understand the drug coverage in a specific plan. CMS established these requirements to enhance the transparency of QHP formulary drug lists and to help consumers make more informed decisions about their health care coverage.

The 2016 Payment Notice Final Rule also includes new requirements for the prescription drug exception process, under which an enrollee can request and gain access to a drug not on the plan's formulary. These provisions include a requirement that starting with the 2016 plan year, an issuer must notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage decision no more than 72 hours following the receipt of a standard exception request, as well as a requirement that the issuer must have a process for the enrollee or the enrollee's designee or the prescribing physician (or other

prescriber) to request that the denied exception request be reviewed by an independent review organization. As part of these requirements, we also finalized in the 2016 Payment Notice Final Rule that in the event that an exception request is granted, the plan must treat the excepted drug(s) as an EHB, including by counting any cost-sharing towards the plan's annual limitation on cost-sharing under 45 C.F.R. 156.130, and that a health plan that grants a standard exception request must provide coverage of the excepted non-formulary drug for the duration of the prescription, including refills (or in the case of an expedited request, a health plan that grants an exception must provide coverage of the excepted non-formulary drug for the duration of the exigency). Issuers must update their policies and procedures to reflect the new requirements for plan years beginning in 2016. In addition to the above standards, CMS continues to encourage issuers to temporarily cover non-formulary drugs, as well as drugs that are on an issuer's formulary but require prior authorization or step therapy, as if they were on formulary or without imposing prior authorization or step therapy requirements, during the first 30 days of coverage when an enrollee is transitioning to a new plan.

Finally, as discussed in the 2016 Payment Notice Final Rule, CMS is concerned about issuers making mid-year formulary changes, and especially changes that negatively affect enrollees. In particular, for QHPs, we have concerns about these changes to the plan design when the plan design was certified under the assumption that it was going to cover specific benefits. For these reasons, we are monitoring this issue and whether further standards are needed on the updating of formulary drug lists. We note that under guaranteed renewability requirements and the definitions of "product" and "plan," issuers generally may not make plan design changes, including changes to drug formularies, other than at the time of plan renewal. However, we recognize that certain mid-year changes to drug formularies related to the availability of drugs in the market may be necessary and appropriate. Such changes generally would not affect a QHP's certification.

To help ensure that QHPs are in compliance with applicable regulations, CMS will conduct the following reviews as part of the 2016 QHP certification process. If CMS identifies a QHP for follow-up based on this review, CMS will offer the issuer the opportunity to resolve the identified issue as part of the certification process. CMS anticipates that it will offer the issuer the opportunity to submit a justification with supporting documentation explaining how the plan is not discriminatory or to make a change to its application to address the concern.

*i. Formulary Outlier Review*

Consistent with 45 C.F.R. 156.225 and 45 C.F.R. 156.125, CMS will review each QHP's formulary drug list to ensure non-discrimination in QHP prescription benefit design. CMS will perform an outlier analysis to identify QHPs that are outliers based on an unusually large number of drugs subject to prior authorization and/or step therapy requirements in a particular USP category and class. CMS encourages States performing plan management functions in the FFMs to implement this type of review.

### *ii. Review of Prescription Drugs*

CMS will review each QHP's prescription drug coverage to ensure that it meets applicable standards in 45 C.F.R. 156.225 and 45 C.F.R. 156.125. Based on data submitted by issuers in the prescription drug template, this review will analyze the availability of covered drugs recommended by nationally-recognized clinical guidelines used in the treatment of the following four medical conditions: bipolar disorder, diabetes, rheumatoid arthritis, and schizophrenia. The purpose of the analysis is to ensure that issuers are offering a sufficient number and type of drugs needed to effectively treat these conditions, and on some first line drugs, are not restricting access through lack of coverage and inappropriate use of utilization management techniques. Other conditions, including HIV, may be considered as part of future reviews.

## Section 11. Supporting Informed Consumer Choice/Meaningful Difference

The content of this section applies to QHP issuers in the FFM, including issuers participating in States that are performing plan management functions. This section does not apply to SADPs.

For 2016, CMS intends to use a similar approach as in previous years to assess whether all plans proposed to be offered by potential QHP issuers are meaningfully different from other plans the issuer has submitted for certification, in accordance with the requirements of 45 C.F.R.156.298.

CMS will organize an issuer's proposed QHPs from a given State into subgroups based on plan type, metal level, and overlapping counties/service areas. Second, CMS will review each subgroup to determine whether the potential QHPs in that subgroup differ from each other as detailed in the 2015 Letter to Issuers. If CMS finds that two or more plans within a subgroup do not differ based on at least one of the criteria, then those QHPs would be flagged for additional review and follow-up.

If CMS flags a potential QHP for follow-up, it anticipates that the issuer would be given the opportunity to amend its submission for one or more of the identified health plans. Alternatively, the issuer would be able to submit a justification to CMS explaining how the potential QHP is substantially different from others offered by the issuer for QHP certification and, thus, is in the interest of consumers to certify as a QHP.

CMS will not review SADPs for meaningful difference as part of the certification process.

## Section 12. Third Party Payment of Premiums and Cost-sharing

Issuers of individual market QHPs, including SADPs, are required under 45 C.F.R. 156.1250 to accept third party premium and cost-sharing payments made on behalf of enrollees by the Ryan

White HIV/AIDS Program; Indian tribes, tribal organizations, and urban Indian organizations; and other Federal and State government programs.[34]

HHS may impose civil money penalties against QHP issuers in the FFMs for violations of 45 C.F.R. 156.1250, as set forth in 45 C.F.R. 156.805(a)(1) and 156.805(a)(4). Under 45 C.F.R. 156.805(c), an issuer offering a QHP or SADP through the FFMs may be subject to a maximum penalty of $100 per day, per each individual who is adversely affected by the QHP or SADP issuer's non-compliance.

Section 13. Cost-Sharing Reductions

QHP issuers are required under 45 C.F.R. 156.420 to submit three plan variations for each silver level QHP an issuer offers through the Marketplace, as well as zero and limited cost-sharing plan variations for all QHPs an issuer offers through the Marketplace. This section does not apply to SADPs, as cost-sharing reductions do not apply to SADPs. In the 2016 certification cycle, CMS will continue to review QHP Applications for compliance with Part 156, subpart E.

The certification review will include a review of each submitted Plans and Benefits Template to ensure that silver plan variations:

- Meet 2016 AV requirements.
- Do not have an annual limitation on cost-sharing that exceeds the permissible threshold for the specified plan variation, as finalized in the 2016 Payment Notice Final Rule.
- Are designed such that the cost-sharing for enrollees under any silver plan variation for an EHB (or non-EHB, under the non-EHB out-of-pocket policy at 45 C.F.R. 156.420(d)[35]) does not exceed the corresponding cost-sharing in the standard silver plan or any other silver plan variation of the standard silver plan with a lower AV. For example, if an enrollee in a 87 percent plan variation pays a $40 co-pay for a specialist visit, the specialist visit co-payment for an enrollee in the associated 94 percent plan variation must be less than or equal to $40.

[34] This standard was effective on March 14, 2014; see Patient Protection and Affordable Care Act; Third Party Payment of Qualified Health Plan Premiums; Interim Final Rule; 79 Federal Register 15240 (March 19, 2014); codified at 45 C.F.R. part 156. The standard applies to all individual market QHPs and SADPs, regardless of whether they are offered through the FFM, an SBM, or outside of the Marketplace.

[35] To simplify benefit design, issuers may reduce out-of-pocket spending for non-EHB benefits for enrollees in plan variations, so that they no longer equal non-EHB out-of-pocket in the associated standard plan. However, such non-EHB cost-sharing reductions are not eligible for HHS reimbursement.

health insurance but more acceptable to discriminate for products such as life, disability, and long-term care insurance. In defending the right to such discriminatory underwriting, insurers have claimed that if applicants have relevant information that isn't available to insurers, such as robust genetic risk information, low-risk consumers will drop out of the mix and higher-risk consumers will disproportionately purchase coverage, forcing companies to raise prices and causing a "death spiral" of adverse selection.

This concern was largely theoretical until we showed that healthy people with higher-risk results on predictive genetic testing were more likely to use that information to make decisions about purchasing long-term care insurance.[5] If this finding is generalizable, then for insurance products that remain outside GINA's scope, the status quo is unlikely to last. As more people obtain their own genetic risk information, companies selling such products may feel forced to test customers genetically in order to stratify customer risk. Alternatively, we may eventually have to abandon risk-based underwriting and adopt a more unitary pricing system that pools risk.

The standard argument for regulating risk classification is that it's unfair for employers to discriminate or insurers to charge different rates because of immutable risks. GINA's exceptionalism may, in part, reflect a genetic determinism and therapeutic nihilism that were prevalent in 1995, when Congress first considered this issue, but that will be far less salient in the future. Although genetic determinism with regard to highly penetrant mendelian conditions may persist, it's now clear that everyone carries genetic variants that will influence, but in most cases not exclusively determine, one's health status. The science of genomic medicine is moving rapidly toward multiscale network and systems biology by elucidating the complex interactions of genomics, physiology, and environmental influences. In a future informed by this science, we may be able to personalize risk stratification and then tailor diet, exercise, and pharmaceuticals and even edit genes to promote wellness by preventing and minimizing illness. Eventually, the notion of immutable genetic risks may become obsolete, and it may be less important to grant genetic information special protection than to protect everyone from all forms of medical discrimination. As all medicine in a sense becomes genomic medicine, perhaps the genetic nondiscrimination secured by GINA will translate into nondiscrimination in all of medicine.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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# Using Drugs to Discriminate — Adverse Selection in the Insurance Marketplace

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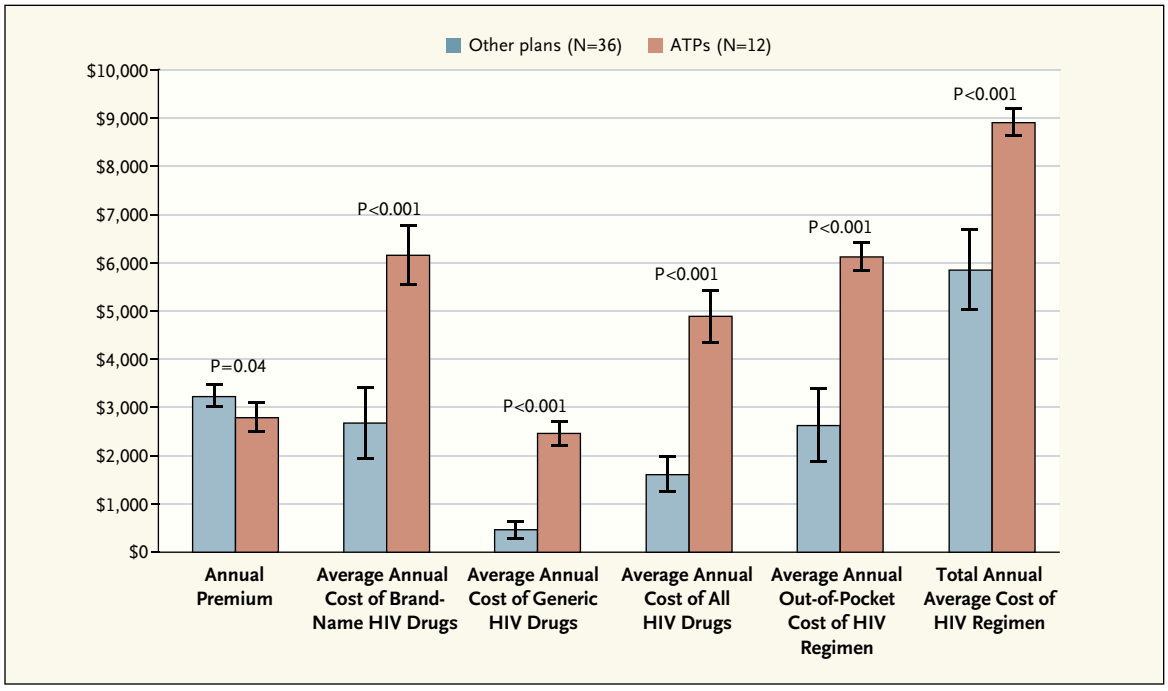
Eliminating discrimination on the basis of preexisting conditions is one of the central features of the Affordable Care Act (ACA). Before the legislation was passed, insurers in the nongroup market regularly charged high premiums to people with chronic conditions or denied them coverage entirely. To address these problems, the ACA instituted age-adjusted community rating for




**Average HIV-Related Costs for Adverse-Tiering Plans (ATPs) versus Other Plans.**

I bars represent 95% confidence intervals, and P values represent results of t-tests for significant differences between ATPs and other plans for each outcome. The "total annual average cost of HIV regimen" is the sum of the annual premium and the average annual out-of-pocket cost of HIV regimens. The HIV treatment regimen that was used for this calculation was emtricitabine, tenofovir, and efavirenz, a commonly prescribed single-pill regimen. Out-of-pocket spending was capped at each plan's out-of-pocket maximum under the Affordable Care Act, typically $6,350.

premiums and mandated that plans insure all comers. In combination with premium subsidies and the Medicaid expansion, these policies have resulted in insurance coverage for an estimated 10 million previously uninsured people in 2014.[1]

There is evidence, however, that insurers are resorting to other tactics to dissuade high-cost patients from enrolling. A formal complaint submitted to the Department of Health and Human Services (HHS) in May 2014 contended that Florida insurers offering plans through the new federal marketplace (exchange) had structured their drug formularies to discourage people with human immunodeficiency virus (HIV) infection from selecting their plans. These insurers categorized all HIV drugs, including generics, in the tier with the highest cost sharing.[2]

Insurers have historically used tiered formularies to encourage enrollees to select generic or preferred brand-name drugs instead of higher-cost alternatives. But if plans place all HIV drugs in the highest cost-sharing tier, enrollees with HIV will incur high costs regardless of which drugs they take. This effect suggests that the goal of this approach — which we call "adverse tiering" — is not to influence enrollees' drug utilization but rather to deter certain people from enrolling in the first place.

To explore the implications of this practice, we analyzed adverse tiering in 12 states using the federal marketplace: 6 states with insurers mentioned in the HHS complaint (Delaware, Florida, Louisiana, Michigan, South Carolina, and Utah) and the 6 most populous states without any of those insurers (Illinois, New Jersey, Ohio, Pennsylvania, Texas, and Virginia; for details, see the Supplementary Appendix, available with the full text of this article at NEJM.org). We examined the plans with the lowest, second-lowest, median, and highest premiums on the "silver" level in each state, analyzing formularies and benefit summaries to assess cost sharing for nucleoside reverse-transcriptase inhibitors (NRTIs), one of the most commonly prescribed classes of

HIV medications. We chose this example because HIV is associated with high insurance costs, requires lifelong treatment, and is treated with an expensive and disease-specific class of medications. We defined adverse tiering as placement of all NRTIs in tiers with a coinsurance or copayment level of at least 30%. In estimating enrollees' average annual medication costs, we used the negotiated drug price paid by Humana, which makes its prices available online.

We found evidence of adverse tiering in 12 of the 48 plans — 7 of the 24 plans in the states with insurers listed in the HHS complaint and 5 of the 24 plans in the other six states (see the Supplementary Appendix for sample formularies). The differences in out-of-pocket HIV drug costs between adverse-tiering plans (ATPs) and other plans were stark (see graph). ATP enrollees had an average annual cost per drug of more than triple that of enrollees in non-ATPs ($4,892 vs. $1,615), with a nearly $2,000 difference even for generic drugs. Fifty percent of ATPs had a drug-specific deductible, as compared with only 19% of other plans. Even after factoring in the lower premiums in ATPs and the ACA's cap on out-of-pocket spending, we estimate that a person with HIV would pay more than $3,000 for treatment annually in an ATP than in another plan.

Our findings suggest that many insurers may be using benefit design to dissuade sicker people from choosing their plans. A recent analysis of insurance coverage for several other high-cost chronic conditions such as mental illness, cancer, diabetes, and rheumatoid arthritis showed similar evidence of adverse tiering, with 52% of marketplace plans requiring at least 30% coinsurance for all covered drugs in at least one class.[3] Thus, this phenomenon is apparently not limited to just a few plans or conditions.

Adverse tiering is problematic for two reasons. First, it puts substantial and potentially unexpected financial strain on people with chronic conditions. These enrollees may select an ATP for its lower premium, only to end up paying extremely high out-of-pocket drug costs. These costs may be difficult to anticipate, since calculating them would require knowing an insurer's negotiated drug prices — information that is not publicly available for most plans.

***Adverse tiering will most likely lead to adverse selection over time, with sicker people clustering in plans that don't use adverse tiering for their medical conditions.***

Second, these tiering practices will most likely lead to adverse selection over time, with sicker people clustering in plans that don't use adverse tiering for their medical conditions. After enrollees with chronic conditions realize they're incurring higher-than-expected costs in an ATP, some will switch to different plans during the next enrollment period. Over time, thanks to word-of-mouth or clinicians' advice, plans offering generous prescription-drug benefits may see a large influx of sick enrollees, which would reduce their profits and could lead to a race to the bottom in drug-plan design. Although the ACA's risk-adjustment, reinsurance, and risk-corridor programs provide some financial protection to insurers whose enrollees are sicker than average, the existence of adverse tiering in 2014 suggests that selection opportunities remain. Furthermore, the reinsurance and risk-corridor programs will be phased out after 2016, which will only increase insurers' incentives to avoid sick enrollees.

Several policies could reduce the harms associated with adverse tiering. One approach to addressing unexpectedly high out-of-pocket costs for people with chronic conditions is price transparency. Insurers could be required to list on their formulary each drug's "estimated price to enrollee," based on the negotiated price and the copayment or coinsurance. However, if adopted in isolation, price transparency would probably accelerate the adverse-selection process.

Additional policies are needed to combat selection and end adverse tiering altogether. One potential approach with a policy precedent would be establishing protected conditions in drug formularies. Medicare Part D has designated several "protected classes" of drugs, including those used for HIV, seizures, and cancer, in order to maintain patients'

access to them. A similar approach in the marketplaces could set an upper limit on cost sharing for medications for protected conditions. Such a policy would reduce financial exposure for people with these conditions, even if they chose suboptimal plans — which, to judge from studies of consumers' plan selection, is likely to remain a common occurrence.[4] Other safeguards for protected conditions, such as limits on prior-authorization requirements, could also be implemented.

An important additional step would be to require marketplace plans to offer drug benefits that meet a given actuarial value — meaning that the percentage of drug costs paid by the plan (rather than the consumer) would have to exceed a particular threshold. This level could be set at the overall actuarial value for a given plan (i.e., 70% for silver plans) or above it. Under this approach, in order to significantly increase cost sharing for one drug, an insurer would have to reduce cost sharing for another drug. This step is crucial because it encompasses treatment of all health conditions — not just protected conditions — and addresses nonformulary-based methods of passing costs on to consumers (e.g., drug-specific deductibles) that may induce adverse selection.

Stopping adverse drug tiering will not completely eliminate discrimination in the insurance marketplace. Some insurers will invariably think of new ways to dissuade sick enrollees from joining their plans. Eliminating premium discrimination on the basis of health status was one of the ACA's chief accomplishments in the nongroup insurance market and one of the law's most popular features.[5] Preventing other forms of financial discrimination on the basis of health status — with the attendant risks of adverse selection in the marketplace — will require ongoing oversight. The ACA has already made major inroads in designing a more equitable health care system for people with chronic conditions, but the struggle is far from over.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From the Department of Health Policy and Management, Harvard School of Public Health, Boston.

**1.** Sommers BD, Musco T, Finegold K, Gunja MZ, Burke A, McDowell AM. Health reform and changes in health insurance coverage in 2014. N Engl J Med 2014;371:867-74.
**2.** The AIDS Institute and the National Health Law Program. Administrative complaint re: discriminatory pharmacy benefits design in select qualified health plans in Florida (http://www.healthlaw.org/component/jsfsubmit/showAttachment?tmpl=raw&id=00Pd000000B9TMYEA3).
**3.** Pharmaceutical Research and Manufacturers of America. An analysis of exchange plan benefits for certain medicines. Avalere, June 2014 (http://www.phrma.org/affordable-care-act/coverage-without-access-an-analysis-of-exchange-plan-benefits-for-certain-medicines).
**4.** Abaluck J, Gruber J. Choice inconsistencies among the elderly: evidence from plan choice in the Medicare Part D program. Am Econ Rev 2011;101:1180-210.
**5.** Zengerle P. Most Americans oppose health law but like provisions. Reuters. June 24, 2012 (http://www.reuters.com/article/2012/06/25/us-usa-campaign-healthcare-idUSBRE85N01M20120625).

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# Death Takes a Weekend

Perri Klass, M.D.

I wanted my mother to write this essay. My mother was a writer all her life — novels, memoirs, essays, even blog entries — and in recent years she'd written some articles about aging and illness, about the indignities of becoming less independent.[1,2] So when she got sick, I decided that when she was better, I would urge her to write a piece about being in the hospital — about pain and fear and comfort and cure, but also about unexpected revelations of hospital routine and custom, as seen from the patient's perspective. I even kept a list of topics for her, and the first one was the hospital weekend. Not too charged, I thought, not too personal — a good way to broach the subject of being a patient and to write about a practical problem while touching on the fear and pain underneath. She would write it when she was better, when she was home, when she was cured. But there was no comfort and no cure, so here I am.

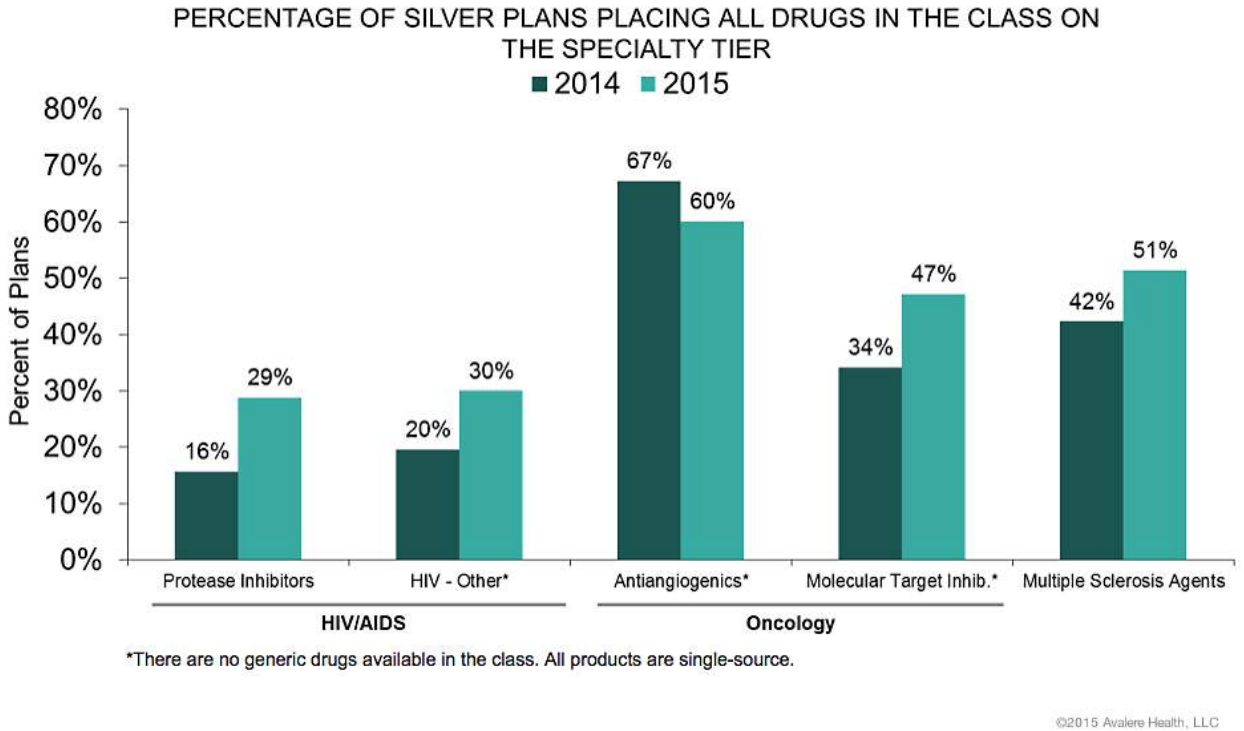
From the physician's perspective, weekends in the hospital are all about coverage. I remember, during residency, feeling that the attendings brought in doughnuts for weekend rounds because the

**Exchange Benefit Designs Increasingly**
**Place All Medications for Some Conditions on Specialty Drug Tier**

New analysis from Avalere Health finds that some exchange plans place all drugs used to treat complex diseases – such as HIV, cancer, and multiple sclerosis – on the highest drug formulary cost-sharing tier.

"Plans continue to innovate on benefit design in the exchange markets," said Dan Mendelson, CEO of Avalere. "These designs are calibrated to optimize enrollment by delivering low and stable premiums – the primary metric that consumers use to select a plan."

Specifically, in five of the 20 classes of drugs analyzed, plans placed all drugs in a class on the specialty tier. Specifically, in the Protease Inhibitor and Multiple Sclerosis Agents classes, 29 and 51 percent of plans respectively place all drugs, including available generics, on the highest tier. There are no generics in the other three classes of drugs listed below.



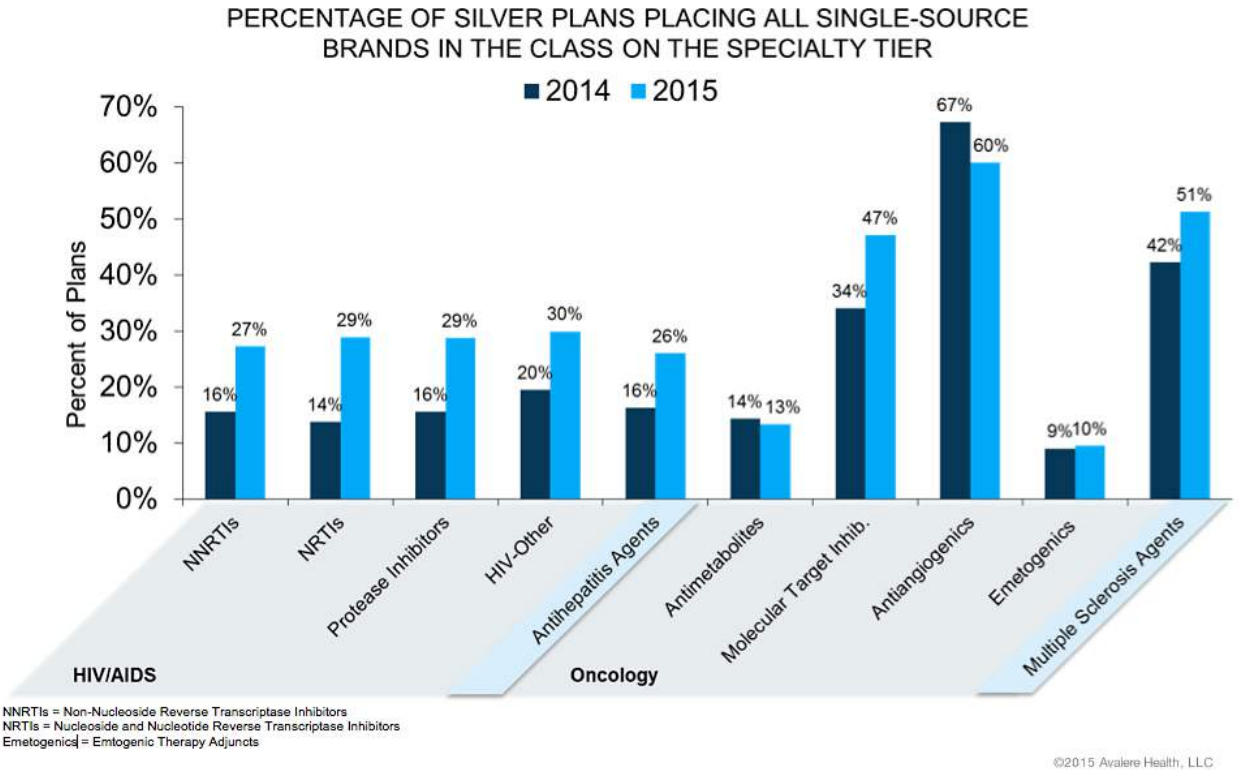



Moreover, a subset of plans in each of 10 drug classes[1] placed all single-source branded drugs in a class on a specialty tier. Specifically, in 8 of the 10 classes, 2015 exchange plans were

[1] Avalere analyzed 20 classes, including a mix of specialty and primary care drugs. Of those 20 classes, a subset of plans in 10 classes placed all drugs on the specialty tier.

more likely than 2014 plans to assign all single-source branded drugs to the highest cost sharing tier. A single-source branded medication is a brand name drug without a generic equivalent.

The practice was most common for some cancer drugs and drugs used to treat multiple sclerosis. Roughly 30 percent of plans also place all single-source drugs for HIV/AIDS on the specialty tier.




Seven of the 10 classes listed above include at least one lower cost generic product, which could be a lower cost alternative for some consumers.[2]

“Enrolling in a plan that places all medications for a particular disease on the specialty tier can mean significant out-of-pocket costs for consumers, particularly if they do not qualify for cost sharing reductions,” said Caroline Pearson, Vice President at Avalere. “Plans that place some drugs in a class on lower tiers may allow consumers to find lower cost alternatives.”

Avalere noted that the total cost impact to a customer will vary based on a variety of factors, including subsidies, out-of-pocket limits, and overall plan benefit design. In 2015, more than 8 in 10 individuals who selected a plan in the exchange received a premium tax credit, which lowers their monthly premium cost by an average of 72 percent.[3]

[2] There are no generics in the HIV-Other; Molecular Target Inhibitors; or Antiangiogenics classes.
[3] ASPE Research Brief, February 9. 2015 , http://aspe.hhs.gov/health/reports/2015/MarketPlaceEnrollment/APTC/ib_APTC.pdf.

Avalere conducted additional analysis on the tier placement and cost sharing associated with 20 classes of medications. The full report is available here.

## Methods

Analysis using Avalere PlanScape®, a proprietary analysis of exchange plan features, updated February 2015. This analysis isbased on data collected by Managed Markets Insight & Technology, LLC. The sample includes silver plans in six states (FL, GA, IL, NC, PA, and TX) relying on HealthCare.gov, and CA and NY. Coverage is weighted according to unique plan-state combinations. Avalere analyzed brand and generic drug coverage in a total of 20 classes, including a mix of specialty and primary care drugs.

*Avalere Health is a strategic advisory company whose core purpose is to create innovative solutions to complex healthcare problems. Based in Washington, D.C., the firm delivers actionable insights, business intelligence tools and custom analytics for leaders in healthcare business and policy. Avalere's experts span 230 staff drawn from Fortune 500 healthcare companies, the federal government (e.g., CMS, OMB, CBO and the Congress), top consultancies and nonprofits. The firm offers deep substance on the full range of healthcare business issues affecting the Fortune 500 healthcare companies. Avalere's focus on strategy is supported by a rigorous, in-house analytic research group that uses public and private data to generate quantitative insight. Through events, publications and interactive programs, Avalere insights are accessible to a broad range of customers. For more information, visit avalere.com, or follow us on Twitter @avalerehealth.*

# ADMINISTRATIVE COMPLAINT

Office of Civil Rights, U.S. Department of Health and Human Services
200 Independence Avenue, S.W., Room 509F
Washington, D.C. 20201

Timothy Noonan, Regional Manager, Region IV
Office for Civil Rights, U.S. Department of Health and Human Services
Sam Nunn Atlanta Federal Center, Suite 16T70
61 Forsyth Street, S.W.
Atlanta, GA 30303-8909

**RE: DISCRIMINATORY PHARMACY BENEFITS DESIGN IN SELECT QUALIFIED HEALTH PLANS OFFERED IN FLORIDA**

**COMPLAINANTS**

The AIDS Institute
17 Davis Boulevard, Suite 403
Tampa, FL 33606

The National Health Law Program
1444 I Street NW Suite 1105
Washington, DC 20005

The AIDS Institute (TAI) is a national nonprofit AIDS agency focusing on public policy, research, advocacy, and education. It began as a grass roots community mobilization effort in the mid1980s and was incorporated in 1992. TAI has offices in Tampa, Florida and Washington, DC, and has been a leading voice both in Florida and nationally in ensuring people with HIV and other chronic diseases, such as hepatitis, have access to quality and affordable health care.

Founded in 1969, the National Health Law Program ("NHeLP") protects and advances the health rights of low-income and underserved individuals. It is the oldest non-profit of its kind. NHeLP advocates, educates, and litigates at the federal and state levels to further its mission.

## DEFENDANTS

Coventry Health Care, Inc., which offers Qualified Health Plans (QHPs) in Florida under the name CoventryOne, is wholly owned by Aetna, which reported over $47 billion in revenue for 2013.[1]

Cigna is headquartered in Bloomfield, Connecticut, reporting $32 billion in revenue for 2013.[2]

Humana is headquartered in Louisville, Kentucky, reporting over $41 billion in revenue for 2013.[3]

Preferred Medical is headquartered in Coral Gables, Florida. Its 2013 annual report is not available.

## JURISDICTION

This complaint is filed pursuant to Section 1557 of the Patient Protection and Affordable Care Act (ACA), codified at 42 U.S.C. § 18116. Section 1557 prohibits federal health programs, activities, and contracts of insurance sold through the health insurance Marketplaces from discriminating against individuals living with disabilities, including HIV and AIDS. The HHS Office of Civil Rights (OCR) has primary responsibility for ensuring compliance with Section 1557 through investigations and enforcement action. Although the HHS OCR has primary oversight over Section 1557, the Department of Justice (DOJ) has coordinating responsibility pursuant to Executive Order 12250.[4]

## PRELIMINARY STATEMENT

Under the ACA, health insurers may no longer discriminate on the basis of disability. Section 1557 and other ACA provisions prohibit discriminatory health insurance practices, including plan benefit designs which discourage enrollment of persons with significant health needs, including people living with HIV and AIDS.

The AIDS Institute conducted an analysis (available here; hard copy attached) of the prescription drug formularies and cost structure for all silver-level Qualified Health Plans (QHPs) operating in Florida. The analysis found that, of the 36 plans reviewed, the QHPs offered by CoventryOne, Cigna, Humana, and Preferred Medical charge

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[1] *See* Aetna 2013 Financial Highlights, accessed April 30, 2013, http://www.aetnastory.com/financial-highlights.php. For a list of Florida counties in which each of these QHPs operate, see the Florida Office of Insurance Regulation, Health Insurance Companies Offering Plans in the Individual and Small Group Markets By Count (Sept. 6, 2013) http://www.floir.com/siteDocuments/HealthInsCoOfferingPlansIndivSmGrpMktsCounty.pdf.

[2] 2013 Cigna Annual Report (Feb. 27, 2014) at 2, http://www.cigna.com/assets/docs/annual-reports-and-proxy-statements/cigna-2013-interactive-annual-report.pdf.

[3] Humana, Inc. 2013 Annual Report (Feb. 19, 2014) at 2, http://phx.corporate-ir.net/phoenix.zhtml?c=92913&p=irol-reportsannual.

[4] Exec. Order No. 12,250, 3 C.F.R. 298 (1980).

inordinately high co-payments and co-insurance for medications used in the treatment of HIV and AIDS.[5] Other plans available through the Marketplace offer HIV/AIDS medications in a range of tiers and cost sharing structures.

- **CoventryOne** places all HIV drugs on Tier 5, including generics (with a 40% co-insurance after a $1,000 Rx deductible) and most require prior authorization.
- **Cigna** places all HIV drugs on Tier 5, including generics (in some plans with a 40% co-insurance after deductible ranging from $0 to $2,750).
- **Humana** places all HIV drugs on Tier 5, including generics (with a 50% co-insurance after a $1,500 Rx deductible).
- **Preferred Medical** places all HIV drugs on a Specialty Tier, including generics, and requires 40% co-insurance. It is unclear which require prior authorization.

The QHP drug benefits offered by CoventryOne, Cigna, Humana, and Preferred Medical impose overly restrictive utilization management which unduly limits access to commonly used HIV/AIDS medications. Moreover, by placing all HIV/AIDS medications, including generics, on the highest cost-sharing tier, CoventryOne, Cigna, Humana, and Preferred Medical discourage people living with HIV and AIDS from enrolling in those health plans – a practice which unlawfully discriminates on the basis of disability.

## DISCUSSION

### I. ACA anti-discrimination protections

Prior to the ACA, health insurance companies routinely discriminated against people living with HIV and AIDS. Plans denied coverage to individuals with pre-existing conditions including HIV and could exclude from their coverage treatment for those conditions. Additionally, insurance companies imposed annual and lifetime caps on benefits, which disproportionately affected people living with HIV and AIDS. The ACA intends to put an end to these discriminatory practices. The ACA requires guaranteed issue of coverage in the individual and small group health insurance markets so that no one can be denied health insurance due to a preexisting condition.[6] Health insurers may no longer exclude coverage of a preexisting condition.[7] The ACA further prohibits discrimination against individual participants and beneficiaries based on health status or medical condition,[8] and it prevents insurers from imposing annual or lifetime limits on benefits.[9]

The ACA contains additional provisions barring discriminatory plan benefit design, establishing that a Qualified Health Plan may "not employ marketing practices or benefit

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[5] The QHPs also do not cover all HIV/AIDS medications available. For a list of medications used in HIV/AIDS treatment, see National Institutes of Health, *HIV Treatment - FDA-Approved HIV Medicines* (Last updated 9/30/2013). Accessed March 25, 2014, *available at* http://aidsinfo.nih.gov/education-materials/fact-sheets/21/58/fda-approved-hiv-medicines#.

[6] 42 U.S.C. § 300gg-1.

[7] *Id.*

[8] 42 U.S.C. § 300gg–4.

[9] 42 U.S.C. § 300gg-11.

designs that ***have the effect of discouraging the enrollment in such plan by individuals with significant health needs***."[10] ACA regulations prohibit discrimination on the basis of on race, color, national origin, disability, age, sex, gender identity, or sexual orientation.[11]

The ACA requires all QHPs to provide prescription drug coverage as an essential health benefit (EHB).[12] Under HHS regulations, health plans that provide EHBs "must cover at least the greater of (1) one drug in every United States Pharmacopeial Convention (USP) category and class or (2) the same number of prescription drugs in each USP category and class as the state's EHB -benchmark plan."[13] A QHP fails to meet the essential health benefits standard and can be decertified if the insurer employs a discriminatory benefits design.[14]

**A. Section 1557 protections**

Most significantly, the ACA applies several existing federal anti-discrimination and civil rights statutes, including the Rehabilitation Act, to the QHPs offered through the health insurance Marketplaces. Prior to the ACA, private health insurance plans were not subject to the Rehabilitation Act, which prohibits discrimination in federal programs against persons living with disabilities, including HIV and AIDS. Under the ACA's Section 1557, the Rehabilitation Act now expressly applies to the "contracts of insurance" available in the Marketplaces:

> An individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 794 of title 29 [the Rehabilitation Act], be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments).[15]

Section 1557 expressly identifies "credits, subsidies, [and] contracts of insurance" as federal financial assistance to make clear that each trigger its application. Unlike Section 1557, Title VI, Title IX, and the Rehabilitation Act either explicitly exclude or have been interpreted in some circumstances to exclude contracts of insurance as a form of federal financial assistance.[16] A contract of insurance that is federal financial

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[10] 42 U.S.C. § 18031(c)(1)(a)(emphasis added); *see also* 45 C.F.R. §156.225(b).
[11] 45 C.F.R. § 156.200(e).
[12] 42 U.S.C. § 18022.
[13] 45 C.F.R. § 156.122.
[14] 45 C.F.R. § 156.125(a).
[15] 42 U.S.C. § 18116.
[16] Because "contracts of insurance" are not excluded in the statutory text of Section 504 [of the Rehabilitation Act] but in its regulations, there have been conflicting decisions about whether the

assistance is any contract of insurance that is funded, entered into, administered, or guaranteed by the federal government. Thus, an insurance company in a Marketplace that receives federally-subsidized payments such as through premium tax credits is covered by Section 1557.

Section 1557 specifically references the enforcement mechanisms "provided for" and "available under" Title VI, Title IX, Section 504, and the Age Discrimination Act ("the Age Act"). Disparate impact claims are allowed under the civil rights statutes referenced by Section 1557.[17] Because Section 1557 incorporates the enforcement mechanisms in those statutes, it too must be interpreted to provide for complaints brought on behalf of an individual, a class, or by a third party.

**B. The Rehabilitation Act**

The Rehabilitation Act prohibits programs and services which receive federal funds from discriminating against persons with disabilities.

> No otherwise qualified individual with a disability . . . shall, solely by reason of her or his disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance or under any program or activity conducted by any Executive agency or by the United States Postal Service.[18]

Under regulations implementing Section 504, programs subject to the Rehabilitation Act may not "provide benefits or services in a manner that limits or has the effect of limiting the participation of qualified persons with disabilities."[19]

Persons living with HIV fall within the definition of "disabled" under regulations implementing the Rehabilitation Act, where disability is defined as:

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regulations properly exclude it. Compare *Moore v. Sun Bank of North Florida*, 923 F.2d 1423, 1429-32 (11th Cir. 1991) (finding that because Section 504 did not expressly exclude contracts of insurance or guaranty, regulations containing the exclusion were invalid as inconsistent with congressional intent and that the contract at issue did in fact constitute federal financial assistance) with *Gallagher v. Croghan Colonial Bank*, 89 F.3d 275 (6th Cir. 1996) (holding that based on the Section 504 regulation's exclusion of contracts of insurance or guaranty as federal financial assistance, a bank's receipt of reimbursement for default loans was not federal financial assistance and thus the bank was not subject to the Rehabilitation Act).

[17] Dep't. of Justice, *Title VI Legal Manual* (2001), http://www.justice.gov/crt/about/cor/coord/vimanual.php#B (stating that Title VI regulations "may validly prohibit practices having a disparate impact on protected groups, even if the actions or practices are not intentionally discriminatory")(citing *Guardians Ass'n v. Civil Serv. Comm'n*, 463 U.S. 582, 582 (1983) and *Alexander v. Choate*, 469 U.S. 287, 293 (1985)); Dep't of Justice, *Title IX Legal Manual* (2001), http://www.justice.gov/crt/about/cor/coord/ixlegal.php#2 (citing cases and stating "[i]n furtherance of [Congress'] broad delegation of authority [to implement Title IX's prohibition of sex discrimination], federal agencies have uniformly implemented Title IX in a manner that incorporates and applies the disparate impact theory of discrimination.").

[18] 29 U.S.C. § 794(a).

[19] 45 C.F.R. § 84.52(a)(iv).

(i) A physical or mental impairment that substantially limits one or more of the major life activities of such individual;
(ii) A record of such an impairment; or
(iii) Being regarded as having such an impairment.[20]

Under long settled case law that even asymptomatic persons living with HIV are considered disabled and thus protected under federal anti-discrimination laws.[21]

**C. Applicability of the ADA safe harbor provision for insurers**

The Americans with Disabilities Act (ADA) offers protections to persons with disabilities, in employment and public accommodation.[22] The ADA is generally read in conjunction with the Rehabilitation Act.[23] While the Rehabilitation Act applies exclusively federal funded programs and services, the ADA applies to private entities in areas such as employment, public accommodations, commercial facilities, and transportation.[24]

The ADA's protections have previously been held by courts to apply to the sale, but not the content of private health insurance plans.[25] The ADA contains a safe harbor provision that protects insurers, stating that its protections do not prohibit, "an insurer, hospital or medical service company, health maintenance organization, or any agent, or entity that administers benefit plans, or similar organizations from underwriting risks, classifying risks, or administering such risks that are based on or not inconsistent with State law."[26]

However, the ADA's safe harbor provision is not a license for health insurers to discriminate. Insurers may not employ this safe harbor provision as "subterfuge" to circumvent anti-discrimination protections.[27] Courts have held that insurers do not have to provide actuarial data to justify coverage limits but those limits must be based upon actual or reasonably predictable risks.[28] Instead, "the issue is whether the classifications made in the plan are rational ones or merely a pretext to effectuate a form of discrimination."[29] In fact, "what is needed is a rational nexus, based on underwriting experience, between the formation of the plan and the classifications made."[30]

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[20] 45 C.F.R. § 84.52(j). *See also* 29 C.F.R. § 1630.2(g).
[21] E.g., *Bragdon v. Abbott*, 524 U.S. 624, 633 (1998).
[22] 42 U.S.C. §§ 12101-12213.
[23] *Helen L. v. DiDario*, 46 F.3d 325 (3d Cir. 1998).
[24] 42 U.S.C. §§ 12181-12189.
[25] See *Doe v. Mutual of Omaha Ins. Co.*, 179 F.3d 557 (7th Cir. 1999) (upholding lifetime and annual caps on health insurance, which disproportionately affect people living with HIV and AIDS, because under the ADA "the content of the goods or services offered by a place of public accommodation is not regulated.").
[26] 42 U.S.C. § 12201(c)(1).
[27] 42 U.S.C. § 12201(c)(3).
[28] See *Ford v. Schering-Plough Corp.*, 145 F.3d 601 (N.J. 1998), *Currie v. Group Ins. Com'n.*, 147 F.Supp.2d 30 (D.Mass. 2001).
[29] *Currie, 147 F.Supp.2d* at 37.
[30] *Id.*

In contrast to the ADA, the Rehabilitation Act contains no safe harbor provision for health insurance companies. And notably, Section 1557 applies the Rehabilitation Act, but not the ADA, to QHPs sold through the Marketplace.[31]

Section 1557 extends anti-discrimination protections not just to the sale of health insurance plans, but to their content as well. Even if the safe harbor provision did apply to QHPs, as explained below CoventryOne, Cigna, Humana, and Preferred Medical would not be protected because their prescription drug benefit designs exhibit no rational nexus to underwriting risks.

## II. Florida QHPs with a discriminatory prescription drug benefit design

Antiretroviral therapy (ART) is recommended for all persons with HIV infection and should be offered to those with early HIV infection.[32] Treatment adherence is particularly important for persons living with HIV and AIDS because "even short interruptions of care can threaten health and undermine prevention effects."[33] Notably, higher cost sharing, including copayment and coinsurance, can often result in missing doses or falling out of treatment, which can lead to the development of drug resistance.[34] Moreover, prior authorizations result in fewer prescriptions filled and increased non-adherence.[35]

Some Florida health insurers designate certain medications, including those used in the treatment of HIV/AIDS, as specialty drugs. There is no statutory or regulatory definition of "specialty drugs," nor is there a common industry standard definition.

Likewise, the practice of tiering medications is becoming increasingly common among health insurers. There is no statutory or regulatory definition for tiering drugs in QHPs, nor is there a common industry standard definition.[36] In the absence of guidelines or industry standards, the practice of tiering medications according to required

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[31] *Henrietta D. v. Bloomberg*, 331 F.3d 261, 272 (2d Cir. 2003) (claims under the ADA and Rehabilitation Act are treated identically unless one of the differences in the two statutes is pertinent to a claim).

[32] Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. http://aidsinfo.nih.gov/contentfiles/lvguidelines/aa_recommendations.pdf. Accessed March 25, 2014, page 6.

[33] Dana P. Goldman, et al., *The Prospect Of A Generation Free Of HIV May Be Within Reach If The Right Policy Decisions Are Made*, 33 *Health Affairs*, 430 (2014).

[34] Matthew L. Maciejewski, et al., *Copayment Reductions Generate Greater Medication Adherence In Targeted Patients*, *29 Health Affairs*, 2002 (2010); National Institutes of Health, HIV Medication Adherence (Sept. 2013), http://aidsinfo.nih.gov/education-materials/fact-sheets/print/21/54/0/0.

[35] Ridley D.B., Axelsen K.J., Impact of Medicaid preferred drug lists on therapeutic adherence. 24 *PharmacoEconomics* 65 (2006) http://www.ncbi.nlm.nih.gov/pubmed/17266389.

[36] The Medicare Part D program contemplates tiering, but requires CMS approval that the prescription drug coverage and any tiering system have an "actuarial bases provided and reasonably and equitably reflect the revenue requirements." 42 C.F.R. § 423.272(b)(1). Medicare Part D plans must provide an exceptions process to tiering. See 42 C.F.R, §§ 423.104(d)(2), 423.578.

copayments, prior authorization, and quantity limits can lead to abuses that harm medically vulnerable populations such as people with HIV and AIDS.[37]

### A. CoventryOne

CoventryOne offers two silver-level plans through the Federally Facilitated Marketplace (FFM) operating in Florida - Coventry One FL Silver $10 Copay HMO and Coventry One FL Silver $10 Copay HMO Carelink. The plans have the same formularies and pricing structure but feature different provider networks to correspond with the regions in which they are sold.

For most of its health plans offered outside the Marketplace, CoventryOne offers prescription drug coverage in three tiers, with generics in Tier 1 and brand name and some non-preferred drugs in Tier 3. Tier 3 is the highest tier with highest co-pays and deductibles.[38] By contrast, for silver-level plans available through the Marketplace, CoventryOne provides prescription drug coverage in six tiers.

Tier 1A: Lower Cost Preferred Generic Drugs
Tier 1: Preferred Generic Drugs
Tier 2: Preferred Brand Drugs
Tier 3: Non-preferred Brand/Generic Drugs
Tier 4: Preferred Specialty Drugs
Tier 5: Non-preferred Specialty Drugs[39]

CoventryOne designates all HIV drugs as "specialty" drugs.[40] CoventryOne places all its anti-retroviral therapies in Tier 5, including the generic versions of Combivir, Epivir, Ziagen, and Zerit, which are widely prescribed anti-retrovirals. Tier 5 drugs require prior authorization, 40% coinsurance, and quantity limits. The company provides no information on total out of pocket expenditures required for enrollees paying "coinsurance."[41]

### B. Cigna

Cigna offers five silver-level QHPs in Florida: myCigna Copay Assure Silver, myCigna Health Flex 1500, myCigna Health Flex 2750, myCigna Health Flex 5000, and myCigna

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[37] See attached chart by The AIDS Institute for a complete listing of the Florida QHP HIV/AIDS drug formulary and tiering structure. *See also* Katie Keith et al., *Nondiscrimination Under the Affordable Care Act*, The Center on Health Insurance Reforms, Georgetown University's Health Policy Institute 13 (July 2013) http://chir.georgetown.edu/pdfs/NondiscriminationUndertheACA_GeorgetownCHIR.pdf.
[38] 2014 CoventryOne Prescription Drug list http://chcflorida.coventryhealthcare.com/web/groups/public/@cvty_regional_chcfl/documents/document/c104396.pdf.
[39] *See* 2014 Individual Carelink Plans on the Health Insurance Marketplace, accessed April 29, 2014, http://www.coventryone.com/web/groups/public/@cvty_individual_c1/documents/document/hmochcfl.pdf.
[40] Specialty drugs, http://www.coventryone.com/web/groups/public/@cvty_regional/documents/document/c113361.pdf.
[41] QHPs are required to make the amount of enrollee cost sharing available. 45 C.F.R. § 156.220(d).

Health Savings 3400. Cigna places prescription drugs on 5 Tiers, available through retail or mail order:

Tier 1 - Retail Preferred Generic
Tier 2 - Retail Non-Preferred Generic
Tier 3 - Retail Preferred Brand
Tier 4 - Retail Non-preferred Brand
Tier 5 - Retail Specialty[42]

The company places all HIV/AIDS drugs on Tier 5, including generic versions of Combivir, Retrovir, Trizivir, Viramune, Ziagen, and Zerit, which are widely prescribed anti-retrovirals. In most of its plans, Cigna charges 40-50% co-insurance for Tier 5 drugs after a deductible ranging from $0 to $2,750. Cigna requires prior authorization for these commonly used HIV/AIDS treatment regimens and limits enrollees to only a 30 day supply. The company provides no information on total out of-pocket expenditures required for enrollees paying "coinsurance."

**C. Humana**

Humana offers two silver-level QHPs through the Florida Marketplace: Humana Connect Silver 4600/6300 Plan and the Humana Direct Silver 4600/6300 Plan. Humana also has a five tier pricing structure for prescription drugs offered through its Florida QHPs.[43]

Humana places all HIV drugs on Tier 5, including generic versions of Combivir, Epivir, Retrovir, Videx, Viramune, Ziagen, and Zerit. Humana requires enrollees to pay 40-50% co-insurance after a $1,500 Rx deductible. The company requires prior authorization for these commonly used HIV/AIDS treatment regimens and limits enrollees to only a 30 day supply. Humana provides no information on total out of pocket expenditures required for enrollees paying "coinsurance."

**D. Preferred Medical**

Preferred Medical offers two QHPs through the Florida Marketplace: Preferred Medical Plan Silver Deluxe AX Dade and Preferred Medical Plan Silver Deluxe CX Dade. The company places all HIV drugs on a Specialty Tier, including generic versions of Combivir, Epivir, Retrovir, Ziagen, and Zerit. Preferred Medical requires enrollees pay 40% co-insurance. It is unclear whether all require prior authorization. Preferred Medical provides no information on total out of pocket expenditures required for enrollees paying "coinsurance."

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[42] Cigna Individual and Family Plan Comparison, at 15, http://www.cigna.com/assets/docs/individual-and-families/medical-plans/florida/863952-plan-comparison-medical-dental-florida.pdf.

[43] Humana does not directly post the Summary of Benefits and coverage on its website. These documents are available via www.healthcare.gov.

## III. How CoventryOne, Cigna, Humana, and Preferred Medical prescription drug benefit designs compare to other QHPs sold in Florida

The practice of placing all anti-retrovirals on the highest tier is not a market-norm or necessity. Other issuers vary tiering or place HIV drugs on more affordable tiers.[44] Below are examples of plans available in Florida with more balanced cost-sharing practices:

- **BlueCross** is the Florida Marketplace issuer with the largest share of plans in the silver market. Blue Cross places most HIV drugs on either Tier 1 or Tier 2, requiring a co-payment of between $10 and $25 for Tier 1 drugs (after a deductible in some cases) and a co-payment of between $40 and $70 for Tier 2 drugs (after a deductible in some cases). Only one drug is on Tier 3 without a generic or alternate form on a lower tier. Tier 3 co-payments range from $70-$100.
- **Ambetter** places most HIV drugs on Tier 1 and Tier 2 and two HIV drugs on Tier 4. Tier 1 co-payments range from $10 to $25 and Tier 2 co-payments range from $50 to $75 (sometimes after meeting a deductible). Tier 4 drug coinsurance ranges from 20% to 30% (after a deductible), with one plan benefit structure using a $250 (after deductible) co-payment.
- **Aetna** places generic versions of HIV drugs Combinvir, Epivir, Retrovir, Videx, Zerit, Ziagen, Viramune on Tier 1.
- **Florida Healthcare Plans (an independent licensee of Blue Cross)** places HIV drugs on Tier 2 and Tier 3, requiring a $10 co-payment for Tier 2 drugs and a $30 co-payment for Tier 3 drugs (after meeting a deductible).
- **Molina** places most drugs on Tiers 1 and 2, with one drug on Tier 3, and two drugs on Tier 4. Tier 1 requires a $20 co-payment and Tier 2 a $55 co-payment. Tiers 3 and 4 require a 30% co-insurance.

## IV. Compliance reviews and enforcement authority

While OCR has primary responsibility to monitor and enforce civil rights protections, other agencies and entities also have a role. The Centers for Medicare & Medicaid Services (CMS) conducts compliance reviews of QHPs as part of the certification process for QHP participation in the FFMs. CMS examines compliance with ACA standards, including ACA regulations prohibiting discrimination on the basis of on race, color, national origin, disability, age, sex, gender identity, or sexual orientation; not employing marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs.

In its 2015 Letter to Issuers, the Center for Consumer Information and Insurance Oversight (CCIIO) indicates it will perform an outlier analysis on QHP cost sharing (e.g.,

[44] See attached analysis by The AIDS Institute of Florida QHP drug formularies and tiering structures.

co-payments and co-insurance) as part of the QHP certification application process.[45] CCIIO further promises to "review plans that are outliers based on an unusually large number of drugs subject to prior authorization and/or step therapy requirements in a particular category and class."

The certification application process does not preclude or replace non-discrimination enforcement by the OCR.[46] Moreover, given that discrimination is often based on long-standing and pervasive benefit design customs in the insurance industry, looking for outliers will likely prove inadequate in detecting pervasive and endemic patterns of discrimination against persons with HIV/AIDS and others with significant health care needs.

**RELIEF REQUESTED**

The AIDS Institute and the National Health Law Program request that OCR:

1. Review drug plan tiering, cost sharing structures, prior authorization requirements, and supply limits for the HIV/AIDS prescription drug benefits in QHPs offered by CoventryOne, Cigna, Humana, and Preferred Medical;

2. Take all necessary steps to remedy the unlawful conduct of CoventryOne, Cigna, Humana, and Preferred Medical, including a corrective action plan and targeted outreach and enrollment of people living with HIV and AIDS;

3. Require CoventryOne, Cigna, Humana, and Preferred Medical to fund a study of other compensable damages for enrollees living with HIV and AIDS affected by the barriers to accessing prescription drugs. The study should examine issues including, but not limited to, the development of HIV treatment resistance in enrollees, adverse events including hospitalizations resulting from interruptions in treatment, the need for salvage therapy, and overcharges to enrollees living with HIV/AIDS;

4. Seek civil monetary penalties and decertification of the above-named Florida QHPs, for continued non-compliance with federal civil rights protections.

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[45] CMS, *2015 Letter to Issuers in the Federally-facilitated Marketplaces*, at 28 (March 14, 2014) http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2015-final-issuer-letter-3-14-2014.pdf.

[46] In a January 16, 2014 letter to the HIV Health Care Access Working Group (on file with The AIDS Institute and the National Health Law Program), CCIIO's then-director Gary Cohen acknowledged concerns raised by The AIDS Institute and other stakeholders regarding the discriminatory prescription drug benefit cost sharing structures of some QHPs. Cohen noted that consumer complaints regarding benefits and cost sharing could be directed to state departments of insurance or the Call Center for healthcare.gov. However, Cohen neither validates nor denies a discriminatory prescription drug plan benefit design, nor does his advice to advocates preclude OCR from its civil rights monitoring and enforcement responsibilities.

Barriers to care and treatment interruptions can lead to serious, adverse health consequences for people living with HIV/AIDS. The AIDS Institute and the National Health Law Program strongly urge OCR to investigate discriminatory HIV prescription drug benefit designs in Florida, and elsewhere, as expeditiously as possible. We are available to offer any assistance necessary to ensure that people living with HIV/AIDS get full access the health benefits provided under the ACA.

Respectfully submitted,

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May 29, 2014

OFFICE OF INSURANCE REGULATION

KEVIN M. MCCARTY
COMMISSIONER

IN THE MATTER OF:

Case No.: 162231-14-CO

COVENTRY HEALTH CARE OF FLORIDA, INC.
_____/

CONSENT ORDER

THIS CAUSE came on for consideration as the result of an agreement between COVENTRY HEALTH CARE OF FLORIDA, INC. (hereinafter referred to as "COVENTRY"), AETNA, INC. (hereinafter referred to as "AETNA"), and the OFFICE OF INSURANCE REGULATION (hereinafter referred to as the "OFFICE"), regarding an alleged violation of Section 641.3007, Florida Statutes. Following a complete review of the entire record, and upon consideration thereof, and being otherwise fully advised in the premises, the OFFICE hereby finds as follows:

1. The OFFICE has jurisdiction over the subject matter and parties to this proceeding.

2. COVENTRY is a Health Maintenance Organization (hereinafter referred to as an "HMO") that is licensed as an HMO provider in Florida and is subject to the jurisdiction and regulation of the OFFICE in accordance with the Florida Insurance Code.