

Background

The Patient Protection and Affordable Care Act contained a number of provisions to enhance access to quality medical care for American citizens. The Act created a list of services that every health plan offered in the individual and small group market must offer defined as essential health benefits.

Under the Essential Health Benefits (EHB) ruling, all plans must include items and services within various categories including prescription drugs.

The services offered within each of these categories must be equal in scope to benefits and services offered by a "typical employer plan." Each state is able to define this based on a state-specific benchmark plan that states could choose from several options.

The EHB proposed ruling was issued by Department of Health and Human Services (HHS) in November 2012 with a 60 day comment period for stakeholders to evaluate the services. A final ruling was released in February 2013.

Objective

Analyze key trends in public comments submitted on the essential health benefit (EHB) proposed ruling relating to prescription drug benefits from healthcare reform stakeholders and determine impact of public comments on EHB final ruling

Methods

Public comments submitted to HHS on EHB proposed ruling (CMS-9980-P) were downloaded from www.regulations.gov. Comments submitted by healthcare reform stakeholders (drug/device manufactures, managed care organizations, patient policy/advocacy groups, and professional/medical organizations) were analyzed to determine their opinions and recommendations on prescription drug benefits

Public comments were excluded from analysis if they met the following:

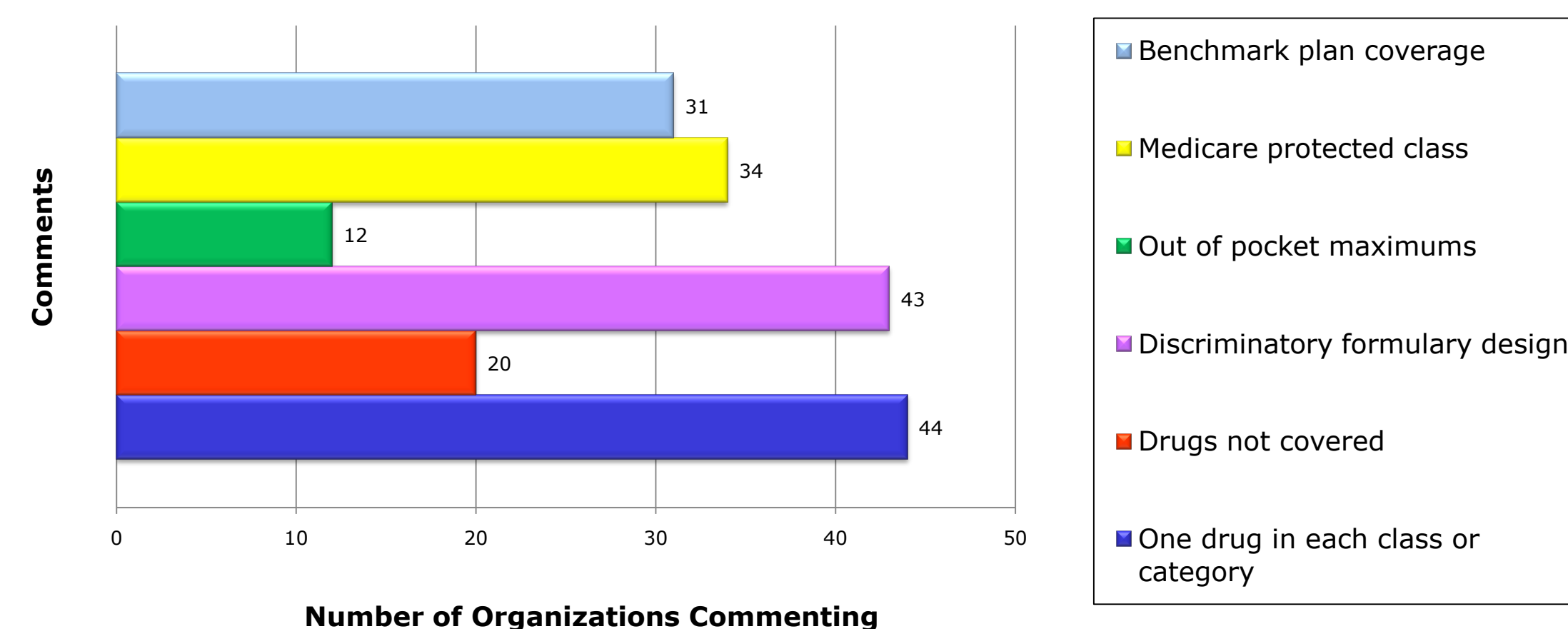
- Represented views from an individual
- Were submitted on behalf of an organization that was not a stakeholder
- Did not directly represent a group of national healthcare reform stakeholders (ie: state organization)
- Did not comment about prescription drug benefits

Trends among all comments were identified and recorded into separated categories. Trends for managed care organization affiliated stakeholders were analyzed separately due to the variation in trends from the other stakeholder groups

Comments were analyzed to compare proposed regulations and final regulations to determine the impact of public comments by healthcare reform stakeholders.

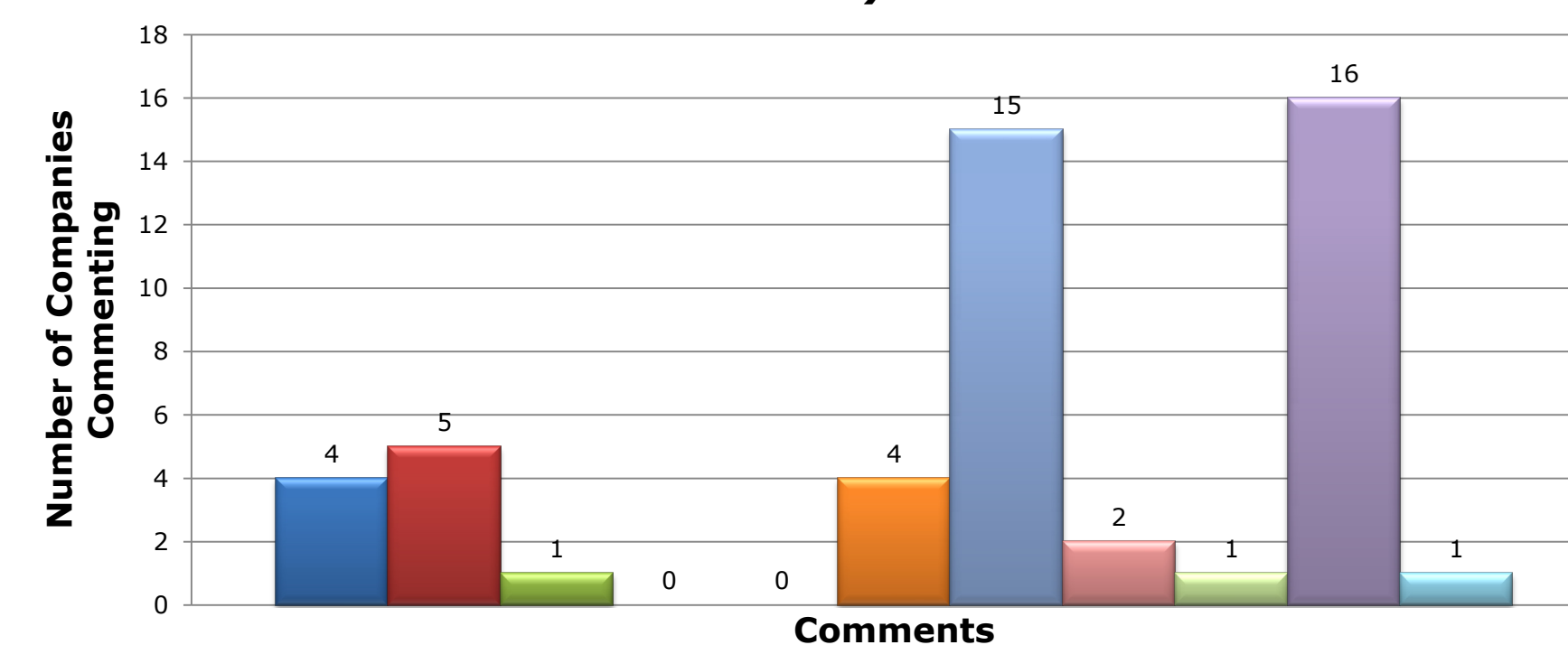
Results

Topics Consistent Across all Stakeholders

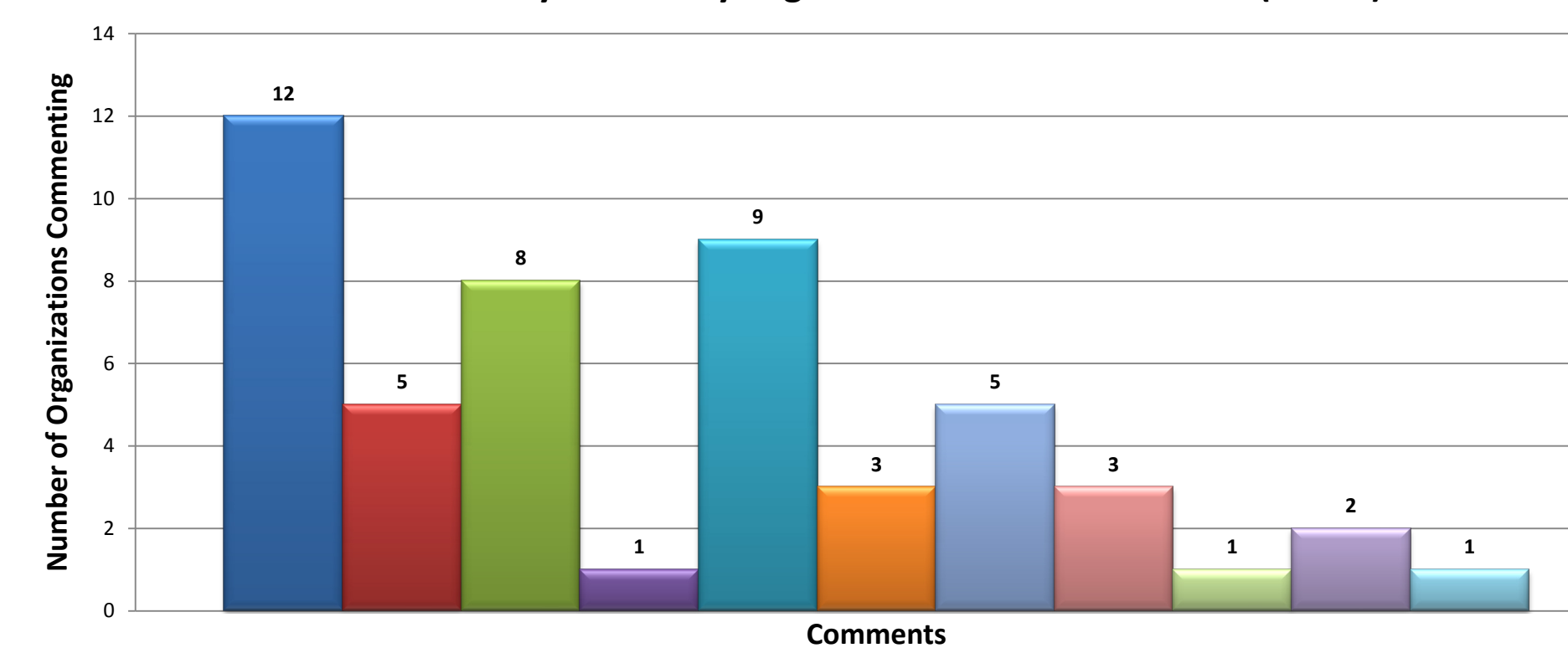


These results display the topics that were consistent among all four groups. Managed care organizations often held opposing positions to the other three groups although they were commenting on the same topics. They supported the exclusion of protected classes of medications similar to those in Medicare Part D. Some managed care organizations also supported the out of pocket maximum being set 15 months prior to the benefit year and the use of utilization management techniques.

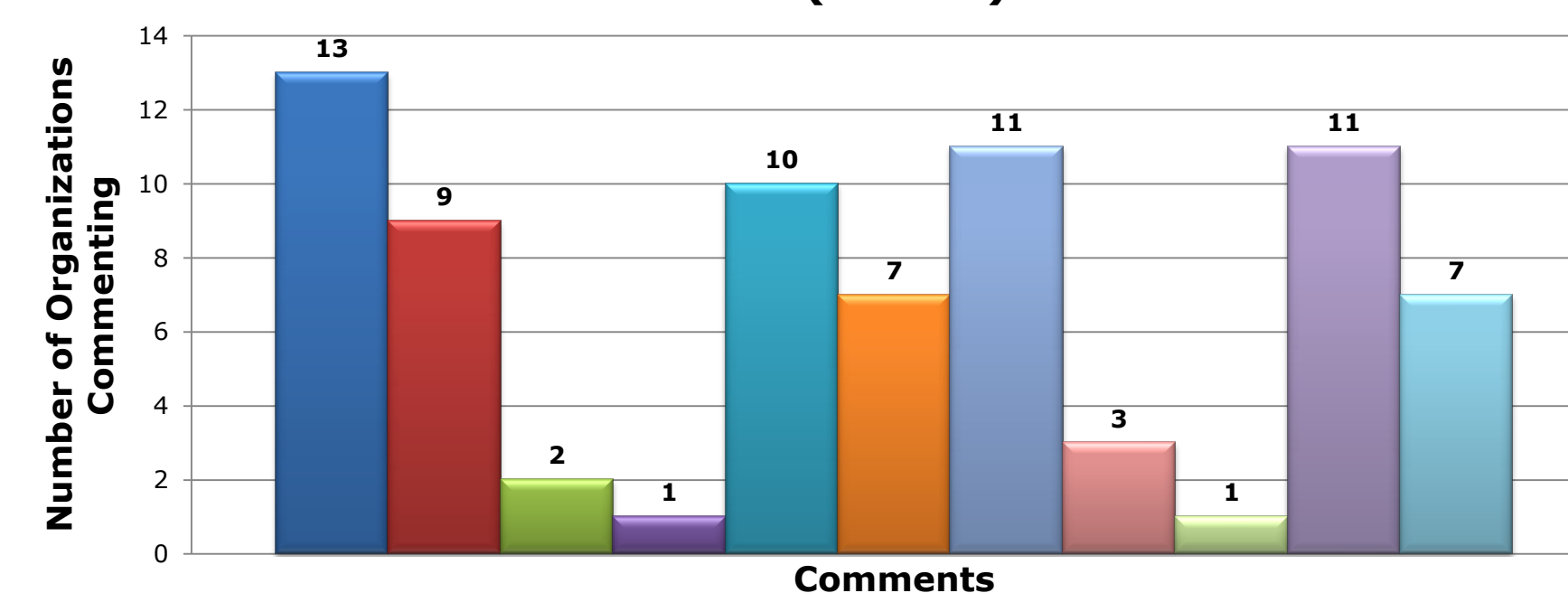
Pharmaceutical Manufacturers Comment Trends (n = 19)



Patient Advocacy and Policy Organization Comment Trends (n = 15)



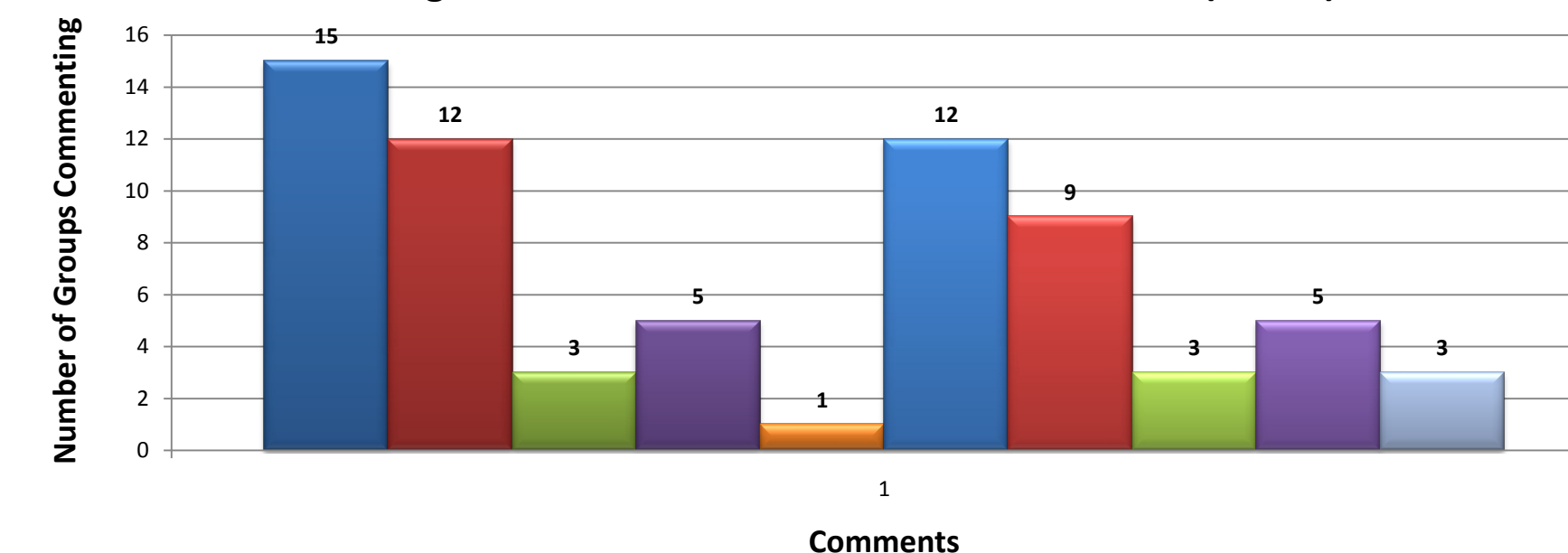
Healthcare Professional Organization Comment Trends (n = 17)



Key for Manufacturers, Advocacy Organizations, and Professional Societies Comment Trends

- Oppose one drug per class
- Support Medicare protected drug classes
- Define appeals process for drugs not covered
- Oppose discriminatory formulary management
- Clarification around combination therapies
- Support out of pocket maximum
- Oppose greater of one drug or state benchmark
- Support access to diagnostic tests
- Defining process to include "new drugs"
- Support process for off-label or unclassified drugs
- Support Medicare Part D drug classifications (2 or more per class)

Managed Care and Health Plan Comment Trends (n = 23)



Key for Managed Care and Prescription Benefit Managers Comment Trends

- Oppose one drug in each class and category
- Oppose coverage of the same # of Rx drugs in each category and class of benchmark
- Support Rx drug coverage consistent with state benchmark plan
- Support lack of protected Class
- Define appeals process to request clinically appropriate drugs not covered
- Use of age related utilization management techniques (request to clarify anti-discrimination language)
- Support formulary decisions made by P&T / flexibility in choice
- Change "clinically appropriate" to "medically appropriate"
- Drug Class/Use (Off-label, USP classes, Unclassified drugs)
- Out of pocket maximum set 15 months prior to benefit year

Discussion

Most organizations disagreed with the proposed ruling's one drug per USP class coverage of prescription drugs, noting that many diseases are complex and patients respond differently based on their specific needs. In the final ruling, the one drug per class standard from the earlier guidance has been replaced with "at least the greater of one drug in every United States Pharmacopeia (USP) category and class; or the same number of prescription drugs in each category and class as the EHB-benchmark plan.

Another prominent comment seen throughout most public comments was the need for EHB to clearly define how patients could access clinically appropriate drugs not covered. In the final ruling, plans are required to establish procedures to ensure that enrollees have access to clinically appropriate drugs not covered by the health plan, consistent with private plan practice today.

In the final ruling, HHS has also recognized that due to the variation in coverage across states and benchmark plans, patients will have a wide difference in the number of drugs they can access. EHB plans would have discretion to select the specific covered drugs subject to meeting the minimum number per category and class and also subject to meeting the requirement that drugs listed must be chemically distinct. HHS is relying on states for assistance in ensuring patients have access to drugs they need.

Plans that use structures and cost tiers that are discriminatory in nature are in violation of the Act. States are encouraged to monitor, identify and test for such discriminatory prescription drug benefit designs.

Notably absent from the final ruling is any language to enact the "protected class" requirement for EHB that many organizations and patient advocates suggested be considered to protect vulnerable patient populations.

Limitations

Due to the volume of comments received on EHB, not all letters were analyzed. Comments that were analyzed were restricted to only organizations with national scope, commented specifically on prescription drug benefits, and represented a minimum number of lives within certain categories of groups.

Conclusions

Some of the major trends in comments (one drug per class, appeals process for drugs not on formulary) were incorporated into the final ruling for EHB, however, HHS did not include language that broadened coverage too greatly (e.g. implementing the protected class requirement).

Disclosures

All the authors are affiliated with the Rutgers Institute for Pharmaceutical Industry Fellowships and are completing their Fellowship at Bristol-Myers Squibb.