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Lessons From the Frontlines: Strategies for Supporting Informed Consumer Decision-Making in the Health Insurance Marketplace

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Editor’s Note: As marketplaces prepare for the third open enrollment period, consumers are increasingly invested in selecting plans that meet their healthcare needs and align with their financial realities. Therefore, there is a growing demand for information and tools to help consumers easily and accurately evaluate plan options. In a new report prepared for the National Partnership of Women and Families—based on interviews with Navigators (entities certified to help consumers choose and apply for coverage) and national experts—Manatt Health shares a frontline perspective on how to improve consumers’ plan comparison and selection experience.

Building on our earlier analysis—“Supporting Informed Decision-Making in the Health Insurance Marketplace: A Progress Report”—our new paper assesses the tools consumers are using to compare and choose plans, identifies three pathways for supporting informed decision-making in the marketplace, and offers recommendations for improvement. Highlights are provided in the following summary. Click here to download a free PDF of the full report.

Roughly 16.4 million people have gained health coverage in the five years since passage of the Affordable Care Act (ACA), and more than 11 million people signed up for marketplace plans during the second open enrollment period alone.1 2 As consumers gain familiarity with their healthcare coverage, they are increasingly looking for plans that match both their healthcare needs and their economic circumstances. They recognize that their choice of plans can directly affect their access to providers, ability to afford prescription drugs and level of out-of-pocket spending. In response, policymakers and marketplace officials are seeking to enhance consumer access to information on health plan features, particularly concerning provider participation in plan networks, cost-sharing charges and prescription drug coverage.

In light of growing interest in how best to support consumer decision-making in the marketplace, Manatt Health interviewed national consumer assistance experts and Navigators in California, Colorado, Florida and Illinois. The insights they shared—based on their extensive experience

helping consumers select health plans during the last two enrollment periods—provide a frontline view of ways to improve plan comparison and selection for consumers. Drawing on Navigators’ experiences, we were able to identify three key pathways for supporting informed consumer decision-making in the marketplace:

- Improving consumer health literacy,
- Developing and applying tools that simplify and streamline plan comparison and selection, and
- Ensuring health plan information is accurate and reliable.

Summary of Key Findings and Recommendations

Consumers—particularly those who already have experience with marketplace plans—are eager for more help selecting health coverage. They want to be able to identify the plans that cover their preferred providers and prescription drugs and that protect them from excessive out-of-pocket costs. Interviews with Navigators and national experts suggest that the following will help consumers identify the marketplace plans that best meet their healthcare needs and align with their financial circumstances:


Continue to develop and share creative materials to improve consumer health literacy and integrate these tools into the plan comparison and selection process. Health literacy materials should include a list of factors to consider when selecting a plan, including definitions of key terms, guidance on how to use a provider directory and review a prescription drug formulary, differences among plan products and provider network models, and direction on how to use healthcare coverage. Policymakers and marketplace officials should work with advocacy organizations, Navigators and others to determine the best ways to deliver this information and integrate it into the plan selection process.

Provide consumers with a checklist of information they should have on hand prior to shopping for a plan. This information should include income and citizenship information, names and addresses of current providers, and a list of healthcare services and prescription medications they need.

2. Develop and Apply Tools That Simplify and Streamline Plan Comparison and Selection.

Continue to improve and develop tools that allow consumers to compare plans across key dimensions. These tools should be easily accessible and integrated into the plan shopping experience. The four fundamental tools for supporting informed consumer decision-making are:

- **Summary of Benefits Coverage Template**, enabling consumers to compare plans across standardized elements, such as benefit design and cost-sharing structuring.
- **Integrated Provider Directory**, enabling consumers to enter the names of their providers and see which plans include those preferred providers in network.
- **Integrated Prescription Drug Directory**, enabling consumers to enter the names and dosage levels of their prescription drugs and see which plans cover those medications.
- **Out-of-Pocket Cost Calculator**, enabling consumers to estimate their annual out-of-pocket costs under different plans, based on anticipated healthcare usage.

3. Ensure That Health Plan Information Is Accurate and Reliable.

Take specific steps to ensure plan information is complete, correct and up to date. At minimum, marketplaces should conduct occasional spot checks to assess the accuracy of plan information and establish procedures that consumers and Navigators can use to flag any inaccuracies or issues with plan data. Marketplaces should notify consumers that plan information is updated continuously and provide guidance on how consumers can access updated information. Policymakers and marketplaces must hold Qualified
Looking Ahead

As the third enrollment period approaches, marketplaces are well-positioned to strengthen and improve the tools and resources offered to consumers to support informed decision-making about plan selection. A key support system for consumers comparing and selecting marketplace plans, Navigators provide valuable insights into the tools consumers are currently using, how those tools could be improved and what additional tools are needed.

States, Healthcare.gov, Navigator organizations and public and private entities have taken important steps to synthesize information and provide tools that simplify and streamline plan comparison and selection. Even so, enrollment remains a time-consuming, complex and hugely challenging process for many consumers.

While great progress has been made over the first two open enrollment periods, advocates and policymakers must continue collaborating to develop and refine tools that will help consumers make informed decisions about health plans that best meet their healthcare needs and financial circumstances. Only then can the promise of the healthcare marketplace be fully realized.


of the other three hospital systems—Allegiance, ProMedica and Branch, which are its closest competitors—to limit marketing of competing healthcare services. It also alleges that senior executives of the four hospitals developed and enforced a series of bilateral agreements.

The complaint describes in detail the agreements between Hillsdale and each of the other three hospitals and provides examples of hospital conduct consistent with the agreements. For example, the complaint alleges that the Hillsdale and Allegiance agreement, which was in effect since at least 2009, prevented Allegiance from conducting marketing activities for competing services in Hillsdale County, so that Allegiance allegedly excluded Hillsdale County from its marketing campaigns for oncology, cardiovascular and orthopedic services in 2013 and 2014. In addition, around 2012, Hillsdale prevented Allegiance from conducting free vascular screenings in Hillsdale County, where Hillsdale periodically charges for such services. The complaint also alleges that, in 2014, Allegiance discouraged one of its newly employed physicians from offering a seminar in Hillsdale County regarding services for which it competed with Hillsdale.

The Hillsdale/ProMedica and Hillsdale/Branch agreements allegedly also prevented the hospitals from marketing oncology and other services in each other's counties. In one instance cited in the complaint, a senior ProMedica hospital executive supposedly assured Hillsdale's CEO that he would look into taking down a ProMedica billboard located across from a physician's office in Hillsdale County after Hillsdale's CEO complained. The complaint also cites deposition testimony from Branch's CEO regarding the parties' "gentleman's agreement" not to market anything but new services in the other hospital's county. Branch allegedly educated its employees about a "gentlemen's agreement" to market only new services in the other hospital's county. Branch allegedly prohibited ProMedica from conducting free vascular screenings in Hillsdale County, where Hillsdale periodically charges for such services. The complaint also alleges that, in 2014, Allegiance discouraged one of its newly employed physicians from offering a seminar in Hillsdale County regarding services for which it competed with Hillsdale.

The DOJ and Michigan AG alleged that these agreements are per se illegal allocation agreements that deprived patients, physicians and employers of information to make important healthcare decisions, and in particular deprived patients of Hillsdale County's free medical services, including health screenings and physician seminars. The regulators further assert that Allegiance's agreement with Hillsdale denied Hillsdale's employers the opportunity to receive information and develop relationships that could have allowed them to improve the quality of medical care for their employees.

The Settlements

Although the proposed settlement does not require Hillsdale, ProMedica or Branch to pay monetary fines (apart from $5,000 each to the Michigan AG toward the costs of the investigation), the terms will restrict their conduct going forward. The proposed settlements prevent each hospital from agreeing with any healthcare provider to prohibit or limit marketing or to allocate geographic markets or territories. The settlement also would prohibit each hospital from having any communications with any of the other defendants about marketing in its or the other defendant's county, with limited exceptions.

In addition, the proposed settlements include several provisions to ensure compliance with the agreement, which will impose considerable administrative costs. Each hospital is required to appoint an Antitrust Compliance Officer, who must obtain certification from each officer, director, and marketing manager at the level of director and above that he or she has read and will abide by the terms of the settlement. The Antitrust Compliance Officer also is required to train such individuals annually on the meaning and requirements of the settlement and antitrust laws, and for a period of five years following the date the settlement is approved by the Court, the hospitals must annually certify that they have complied with its terms.

The settlement provides for government oversight and monitoring of compliance. Each hospital is required to grant access, upon reasonable notice, to records and documents relating to the settlement; must make employees available for deposition; and must provide other written information and reports relating to the settlement, upon request. Finally, the settlement also requires the settling hospitals to assist the government in the ongoing case against Allegiance.

Takeaways

The Michigan case reinforces that antitrust regulators will vigorously
prosecute agreements not to compete, even if they do not rise to the level of criminal price-fixing activities. The case demonstrates that antitrust regulators will closely scrutinize business agreements between competitors—even those that are relatively informal "gentlemen's agreements"—and serves as a reminder that all participants in the healthcare market must be careful of all interactions with competitors, including, in particular, agreements relating to marketing activities.

Failure to heed this reminder can get expensive quickly. In addition to the costs of defending through an investigation and litigation, the wrong sort of cooperation with competitors carries the risk that a hospital's conduct will remain in the regulatory spotlight going forward. The compliance and monitoring provisions increase administrative costs, as well as legal costs in any ongoing litigation against nonsettling parties.

Any government action carries a potential risk of follow-on private lawsuits, although in this case the anticompetitive impact from the conduct may be more difficult to establish, and the affected markets may be too small to attract plaintiff attorneys.

**Reforming Medicaid's Long-Term Care (LTC) System: Bridging the Gap Between Aspirations and Reality**

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Editor's Note: Medicaid is the single largest payer for healthcare services in every state. With nearly 10 million people enrolling in 2014 alone, total enrollment now tops 68 million. But Medicaid is not just undergoing soaring growth. It's also experiencing unprecedented change, fueled by its expanding ranks of participants, as well as new federal dollars available to encourage innovation.

In a recent two-part webinar series, "Medicaid Trends to Watch: Driving Transformation in 2015 and Beyond," Manatt Health revealed the top trends shaping Medicaid's reinvention, how they are contributing to achieving health reform's goals, and what to expect into the future. Part 1 of the series, summarized below, focuses on how states are thinking about LTC reform, adopting new models for LTC populations, and linking Medicaid payments for those populations to performance outcomes and cost containment. If you missed the webinar or want to view it again, click here to access it free on demand. To download a free PDF of the program, click here. (Watch for your next issue of "Manatt Health Update" for Part 2 of the series, "Medicaid Growth and Marketplace Convergence: Surging and Merging to Optimize the Coverage Continuum."

**How Do Long-Term Services and Supports (LTSS) Differ from Post-Acute Care?**

LTSS include a broad range of services that individuals require on an ongoing basis to meet their personal care and daily routine needs, such as bathing, dressing and preparing meals. They help people with disabilities or chronic conditions across the life span—from children to adults to seniors—to live independently and participate in community life. LTSS are mostly nonmedical but can include medical services, such as skilled nursing care and home healthcare. Medicaid is the primary payer of LTSS, although informal caregivers, such as family members and friends, provide the bulk of services.

LTSS differ from post-acute care, which typically includes short-term use of nursing facility, rehab and home care services upon discharge from an acute in-patient setting. Post-acute care services support an individual's continued recovery from illness or management of a chronic disease. Medicare, versus Medicaid, is the primary payer for post-acute care services, although Medicaid and commercial plans cover these services as well.

**LTSS Are a Vital Part of the Care Continuum**

LTSS are provided in both facility-based and community-based settings across the care continuum. People who use LTSS regularly receive care in each of these settings—and often in multiple settings during a single episode of care.

Social support services—such as affordable and accessible housing, transportation assistance, and employment support—are critical for people with LTSS needs. The efforts under way in many states to
integrate the care continuum through Medicaid accountable care organizations, integrated delivery networks, and other population health-focused care and payment models must incorporate LTSS to manage both patient care and overall costs effectively.

LTSS Are Distinct from Other Parts of the Care Continuum

Although LTSS are a critical part of the care continuum, they are quite different from medical care. Populations using LTSS services are unique. They tend to have higher rates of disabilities, chronic conditions, diseases and co-morbidities than people who do not use LTSS.

The goals of LTSS typically are not focused on medical recovery but optimal and independent functioning. LTSS populations' use of services is often longer and more intense than other groups—and therefore can be quite costly. Adding to the challenge is the fact that Medicaid eligibility, benefit coverage, and financing rules for both institutional and community-based LTSS are complex and difficult to navigate.

Who Uses LTSS?

People of all ages use LTSS. About half of the 12 million LTSS users are younger than 65, including more than half a million children. The diversity in the populations using LTSS is enormous with respect to types of disabilities or chronic conditions, service needs, service utilization, and spending. LTSS populations include individuals with physical disabilities; developmental disabilities or mental illness; progressive diseases, such as multiple sclerosis or Alzheimer's; or end-of-life needs, requiring palliative or hospice care. All of these services generate vastly different service use and costs.

Trend #1: LTC Is in Flux: Demand Is Increasing and Utilization Is Changing

The demand for LTSS has been growing and is expected to continue to grow based on changing demographic trends. The population is aging, and people with chronic diseases and disabilities are living longer. According to the Congressional Budget Office, by 2050, 20% of the population will be 65 or older, up from 12% in 2000—and 4% will be 85 or older, up from 1.5% in 2000.

Medicaid programs, which pay for the majority of LTSS costs, are starting to make some changes in how they deliver and purchase LTSS. Across the country, LTSS make up over a third of state Medicaid spending. Historically, these populations and services have remained in the unmanaged fee-for-service part of the Medicaid program in most states. Improving quality of care and managing costs for Medicaid beneficiaries who use LTSS is one of the last and most complex areas of focus for state policymakers.

Since the 1990s, we've seen a dramatic shift in LTSS utilization and spending from institutions to the community. About half of LTSS spending nationally is now on home and community-based services. This is particularly true for nonelderly LTSS users, about 80%-90% of whom receive services in the community.

Trend #2: Medicaid Is Footing (and Will Continue to Foot) the Bill

Medicaid now covers over half of all LTSS expenditures. Americans are uninsured for what is likely to be a costly eventuality in their lives. Even today, Americans are paying about 1 out of every 5 dollars that are spent on LTSS out of pocket. The total national spending on LTSS is now at $310 billion. Private insurance covers only 8% of expenditures.

It's important to recognize that Medicaid accounts for, on average, 23% of state budgets. A large part of those expenditures are attributable to LTSS. This high expense will continue to put tremendous pressure on state budgets.

The average cost of a nursing home in the United States is over $87,000 annually. The cost of a home health aide is almost $46,000 a year. For a very significant number of seniors, these costs are unaffordable. Over half of individuals who spend down assets and qualify for Medicaid do so by paying for LTSS.

In spite of the expense, most Americans do not prepare for long-term care. By the time they become cognizant of the need for long-term care (LTC) insurance, the premiums tend to be high and benefits tend to be limited. The average premium for LTC is over $2,000 a year. Therefore, it's generally an affluent segment that is purchasing LTC insurance.
From the insurance carrier's point of view, LTC is not an attractive marketplace. The risk is hard to gauge, and there is always concern about adverse selection. There has been low interest in LTC insurance, resulting in income streams that are less than expected, leading to two developments. One is increased underwriting and reduced benefits, and the other is a substantial exit of carriers from the LTC marketplace.

There has been an effort to target lower-income groups in the LTC insurance marketplace. The Deficit Reduction Act of 2005 created LTC partnership programs, enabling states to partner with private LTC companies. As of 2014, 45 states had approved or were planning to approve partnership plans. The attraction is that people who buy a plan can automatically qualify for Medicaid after they exhaust their benefits no matter what their asset level—and can protect those assets from Medicaid estate recovery after death. Nonetheless, the premiums vary and can be quite costly. These programs have not made a dent in the acquisition of private LTC insurance.

It's important to note that LTC financing was largely untouched by the Affordable Care Act (ACA). The ACA originally did include the Community Living Assistance Services and Supports (CLASS) Act, which established a government-run LTC insurance program based on voluntary payroll deductions. In 2013, however, the CLASS Act was repealed due to concerns about whether the premiums would be affordable and the risk pool would be sufficiently large. The repeal also established the Bipartisan Commission on Long-Term Care.

The Commission came out with the recommendation that we need a hybrid public and private financing system that will simplify insurance offerings and change the LTC insurance benefit. For example, if the insurance is for home care only or if it has a time limit, premiums will be reduced substantially.

The Commission also concluded that our current LTSS system is fragmented, uncoordinated and difficult to navigate. Therefore, it recommended that each patient have a point person to go to when he or she has a question or problem. In addition, it recommended:

- Establishing a uniform assessment to ensure patients are receiving the right care at the right place.
- Leveraging and building on family caregiving.
- Investing in a well-trained workforce.
- Adopting innovative technology to integrate LTC into healthcare systems.

**Trend #3: States Are Leading the Way on Delivery System Reform. Is Payment Reform Next?**

States have stepped up their efforts over the last decade to address LTSS cost, quality and access issues. LTSS costs were bankrupting states and imposing a crushing fiscal burden on their Medicaid programs. At the same time, advocacy efforts at the state level were forcing states to come up with innovative and cost-effective ways to address LTSS.

The states have been very focused on shifting care to the community, both in response to cost pressures and to consumers' demand for services that are close to home. When we look at Medicaid spending on LTSS, three benefits dominate:

- Home health services, a mandatory Medicaid state plan service;
- Personal care services, an optional plan service; and
- 1915(c) home and community-based service waivers, designed to make it possible for people to receive services in noninstitutional settings.

Although the direction has been very much moving in the home and community-based services direction, Medicaid costs are still dominated, especially in some states, by institutional spending. In 2013, spending on home and community-based services accounted for 46% of the total spend, up from 32% in 2002.

To some extent the federal government has written the cookbook in terms of LTSS, and the states have gone about testing the recipes. While the ACA provided no real change in LTC financing, it wasn't silent on the subject. A host of initiatives to reshape the Medicaid and, to some extent, the Medicare programs to address the growing needs of the elderly either...
were given an additional boost in the ACA or were created by the ACA. Among the ACA’s programs providing new opportunities for improving access to community-based LTSS are:

The Money Follows the Person Program, a rebalancing initiative to try to move persons from institutions back into the community.

The Balancing Incentive Program, intending to rebalance the LTC system with a greater emphasis on community-based services.

The Health Homes Option, creating coordinated care for persons with chronic conditions and allowing a “whole person” approach to their physical and behavioral health, as well as their LTSS needs.

The Home and Community-Based Services Option, providing a range of new Medicaid services for persons who are looking for home and community-based options.

The 1915(k) Community First Choice Option, offering statewide home and community-based attendant services for individuals who would otherwise require an institutional level of care.

The Medically Frail Accessing LTSS through State Plan or Alternative Benefit Plan (ABP), providing for alternative benefit plan coverage for persons who are newly eligible for Medicaid.

The other major initiative driven by the crushing cost that states were bearing under the Medicaid program was to move in the direction of managed care approaches to LTSS. States with a greater penetration of already existent managed care and with larger LTSS expenditures have mostly led the way.

Many states also have been engaged in a very significant initiative as part of the ACA to try to bring the Medicare and Medicaid programs into greater alignment. The idea was to meld Medicare and Medicaid into a seamless benefit package for people eligible for both programs. The “dual eligible” demonstration programs are meant to end 50 years of battles between Medicare and Medicaid on eligibility and benefit design and to let people have all their care needs coordinated, whether paid for by Medicaid or Medicare.

The “duals demonstration” has had a rocky beginning. Among the 26 states that applied to participate, 10 have dropped out or opted for different customized plans, and several others have delayed their start dates. The latest numbers show that of 1.7 million people eligible to participate in the 11 states that are still part of the program, only 26%, or 450,000, have signed up so far.

In New York the level of disenrollment and lack of interest by enrollees has driven the state to contemplate whether the program is going to continue. As far as the state has publicly stated, the program is alive and well, but there has been a very high rate of disenrollment.

We’ll continue looking at New York as an example, because its Medicaid program—the largest on a per capita basis—spends close to 38% of its dollars on LTSS. In fact, LTSS are regarded as a major budgetary issue, and a major concern to federal regulators.

For decades New York has embraced managed care as an important element in addressing the issue of its high LTSS spend. In the 1980s and even more aggressively in the 1990s and the early 2000s, New York embraced a mandatory managed care enrollment program for the non-long-term population. More recently, it has required individuals who need more than 120 days of LTSS to enroll in a managed care plan.

Managed LTC began in the late 1990s as a voluntary program. It had relatively small enrollment until the last several years when the movement toward mandatory enrollment in managed LTC was fully implemented. The program went from just over 10,000 enrollees in around 2010 to 130,000 today.

In New York, and in many other states, efforts continue to revamp the payment program and contain costs. Among the current initiatives are the following:

New York’s Delivery System Reform Incentive Payment (DSRIP) program incorporates LTSS providers in new safety net hospital-led integrated delivery systems (IDS). IDS ultimately will contract with health plans through value-based purchasing agreements.

Massachusetts is developing a comprehensive Medicaid payment
Other Key LTSS Trends

There are a few other key LTSS trends worth noting. The first has to do with quality. There has been considerable attention given to the Star system that is used to rate nursing homes. There are concerns that two of the three indicators underpinning the Star system are self-reported by nursing homes, and there have been reports in the media that some of the self-reports produce artificially high quality ratings. In addition, there is continued attention to the fact that more than 40% of nursing homes in 11 states in particular receive low quality ratings. This attention is likely to continue, as the effort to develop meaningful quality measures across the states is in its infancy. The issues are compounded by the fact that there are multiple provider types with different ways of being paid and different requirements for Medicare and Medicaid. In addition, there are multiple assessment tools that capture similar information. But the key challenge is that clinical measures are often imported when what's really needed is to concentrate on nonclinical measures, such as patient goals and the patient and family experience.

We're also grappling with what the standardized metrics should be across different LTSS settings and where variation should be allowed. In addition, we're only in an early stage of connecting our efforts to the efforts around hospital admissions and readmissions.

Lastly, no matter what is achieved on the measurement front, there is still a need to determine how to increase organizations' ability to improve their quality performance.

The second trend to address is the continued existence of IT challenges. Unfortunately, the Hi-TECH program in which the federal government invested to encourage electronic medical record (EMR) adoption in the healthcare system did not include LTC providers. Many of them struggle with being able to produce the capital needed to make IT investments. As a result, interoperability is still only an aspiration.

The third trend to keep in mind is the number of large national companies paying increased attention to more targeted chronic care management programs. They are trying to figure out better ways to coordinate and integrate care, to continue the care outside the LTC system, and to build partnerships with health plans and accountable care organizations.

Finally, a major trend in the LTSS arena is the pressure on the workforce. Though the formal workforce includes nurses, physical therapists, and occupational therapists, direct care workers perform 70% to 80% of the work. Turnover among these workers continues to be high, with almost half employed at more than one job in a two-year period.

All of the economic data indicates that personal care aides and home health aides are the second- and third-fastest-growing occupations in our nation. Over the next decade, it's estimated we will need more than 1 million new workers in this field. Yet, on average, a personal care aide in the United States earns about $9.50 an hour and often turns to Medicaid because of a lack of benefits.

The informal workforce really carries the LTSS system on its shoulders. On any given day there are 42 million Americans providing care, and over 75% of adults who need help in the long-term care arena turn to their family or friends.

Conclusion

Key takeaways to consider as we seek to bridge the gap between aspirations and reality in the LTSS field are:

The number of Americans needing LTSS will continue to increase, and care will continue to shift to community settings.

Medicaid, by default, is the primary payer for LTSS. It was neither built for nor intended to serve this purpose and doing so threatens the
Biosimilars Coding and Reimbursement Significance Under Medicare Part B

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Editor's Note: On April 5, 2015, the Centers for Medicare and Medicaid Services (CMS) issued a preliminary recommendation for a Healthcare Common Procedure Coding Systems (HCPCS) code for Zarxio, the first biosimilar product ever to be approved by the Food and Drug Administration (FDA). CMS's recommendation provides the first indication of how the agency will establish HCPCS codes for biosimilars that are not interchangeable with the reference products they are based on, and also has significant implications for how such biosimilars will be reimbursed under Medicare Part B. In a new issue brief, summarized below, Manatt Health provides background information on biosimilars, reviews coding for Medicare Part B reimbursement of drugs and biologics, and discusses reimbursement incentives. Click here to download a free PDF of the full brief.

Background on Biosimilars

A similar biologic medicinal product, commonly referred to as a biosimilar, is a copy of an approved original biologic medicine whose data protection has expired. A biosimilar, as its name implies, is similar to but not an exact copy of the original product. Because biologics are derived from living cells or organisms and consist of relatively large and often highly complex molecules, the biosimilar cannot be entirely identical to the original biologic, also referred to as the reference product.

The FDA approved the first biosimilar, Zarxio, on March 6, 2015. Zarxio is a biosimilar of the biologic reference product Neupogen, active ingredient filgrastim. As part of the approval, FDA also gave Zarxio a temporary name, filgrastim-sndz, composed of the name of the biologic and a modifier identifying the manufacturer, Novartis (Sandoz).

When physician-administered biologics are provided in freestanding physician clinics and hospital outpatient departments, Medicare Part B payment amounts for drugs and biologics are tied to the HCPCS codes assigned to them. In April 2015, as part of its annual review of HCPCS code applications, CMS announced its preliminary recommendation that Zarxio (filgrastim-sndz) be assigned HCPCS code Q5101 [Injection, Filgrastim (G-CSF), Biosimilar, 1 microgram]. This preliminary code descriptor reveals CMS's approach to biosimilar coding, and its acknowledgement that this approach is subject to change. Below, we explain the main concepts of HCPCS coding, how it relates to Medicare Part B payment, and some implications.

Coding for Medicare Part B Reimbursement of Drugs and Biologics

The HCPCS is divided into two principal subsystems. Level I of the HCPCS is comprised of CPT (Current Procedural Terminology), a numeric coding system maintained by the American Medical Association (AMA). It is a uniform coding system consisting of descriptive terms and identifying codes that are used primarily to identify medical services and procedures furnished by physicians and other healthcare professionals. Level II of the HCPCS is a standardized coding system that is used primarily to identify products, supplies and services not included in the CPT codes, including drugs and biologics.

For drugs and biologics, one of three types of HCPCS codes may be assigned. Most drugs and biologics eventually receive a permanent "J
code.” Initially, but not always, CMS may assign a temporary but specific “Q” code for the particular biologic,\(^3\) as in the case of Zarxio. In these cases, CMS may lack the information it needs to assign a permanent code. If a manufacturer has not yet applied for a HCPCS code or CMS has not yet assigned a specific HCPCS code for the particular drug or biologic, providers would report the drug or biologic using a “J” code designated for unclassified biologics or unclassified drugs.

There are several interesting observations about CMS's preliminary recommendation to assign Zarxio (filgrastim-sndz) the HCPCS code Q5101 [Injection, Filgrastim (G-CSF), Biosimilar, 1 microgram].\(^4\)

First, CMS assigned Zarxio (filgrastim-sndz) its own unique code and not the code of the reference product Neupogen, which is reported with J1442 [Injection, Filgrastim (G-CSF), 1 microgram]. Generally, a brand-name drug and therapeutically equivalent generic versions of the drug would have the same HCPCS code.\(^5\) CMS's assignment of a unique HCPCS code for Zarxio suggests that CMS does not consider biosimilars with the Purple Book designation of “B” (biosimilar to the reference product) as therapeutically equivalent.

Second, CMS chose not to use the FDA's temporary naming convention, filgrastim-sndz, but rather to include the name of the active ingredient only, filgrastim. Traditionally, CMS has established HCPCS code descriptors that are neutral to manufacturers.

Third, CMS chose to use the term "biosimilar" in the code descriptor. This is unique to biologics.

Fourth, by assigning a “Q” code, which is a temporary code assignment, CMS indicates that this initial coding assignment and descriptor are subject to change.

Finally, as with most HCPCS code descriptors, the unit of measure follows CMS's preference for billing units tied to the ingredient, rather than the standard billing units established by the National Council for Prescription Drug Programs, Inc. (NCPDP).

**Reimbursement Incentives**

For drugs and biologics, a single HCPCS code may apply to multiple National Drug Codes (NDCs) where each NDC captures different labelers, strengths, dosages, and packaging. For example, the HCPCS code for the biologic epoetin alfa is J0885 [Epoetin Alfa (for non-esrd use),1000 units] and it applies to Amgen's Epogen (represented by six NDCs) and Janssen's Procrit (represented by eight NDCs).\(^6\) Regardless of the NDC, the billing units for the HCPCS code is the same, namely 1000 units of the ingredient, as indicated in the HCPCS code descriptor.

For physician-administered biosimilars such as Zarxio, statute sets the Medicare Part B reimbursement at average sales price (ASP) plus 6 percent of the reference biologic when provided in freestanding physician clinics.\(^7\) Statute does not, however, specify how physician-administered biosimilars are to be reimbursed when provided in hospital outpatient departments.\(^8\)

This ASP-based payment amount is the weighted average of the manufacturer's ASP for all NDCs assigned to the HCPCS code, the billing and payment code. More specifically, it is the manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions such as volume discounts, prompt pay discounts, and cash discounts; free goods contingent on purchase requirements; chargebacks; and rebates other than those obtained through the Medicaid drug rebate program.\(^9\) The Medicare database of ASPs is the basis for many private payers in setting drug reimbursement, although some private payers pay higher or lower percentages than Medicare's ASP plus 6 percent.\(^10\) Until information on the manufacturer's ASP is available for the biosimilar, CMS pays 106 percent of the wholesale acquisition cost (WAC) of the product.\(^11\)

At this time there is only one biosimilar assigned to the HCPCS code Q5101 [Injection, Filgrastim (G-CSF), Biosimilar, 1 microgram]. In recent guidance, CMS indicated it will create a separate code to distinguish the biosimilar from the reference biological, but is considering other policy options for coding of additional biosimilars.\(^12\)

If a biosimilar product does not have the same HCPCS billing code as the
reference biologic, then there is no change to the ASP-based payment of the reference biologic. Because the payment amount for the biosimilar as established under the ACA includes 6 percent of the reference product instead of the biosimilar, there is a modest incentive to use the biosimilar, because the payment amount for the reference product is unaffected.

If the biosimilar biologic product shares the same HCPCS billing code with the reference biologic, then the ASP-based payment creates more incentive to use the biosimilar and reduces the incentive to use the reference biologic. The presumably lower sales price of the biosimilar product will be factored into the weighted ASP paid by a physician for either product. This would increase the margin on the lower-priced biosimilar product for the physician and decrease the margin on the reference product for the physician. Assuming an increase in utilization, the payment incentive to use the biosimilar will attenuate over time as the biosimilar weighs more heavily in the ASP.

Conclusion

CMS’s preliminary recommendation for the HCPCS code assigned to Zarxio gives an indication of how it will set reimbursement for biosimilars that are not interchangeable. It would allow CMS to assign each subsequent biosimilar of the same reference product to the same HCPCS code and not necessarily create a unique HCPCS code for each biosimilar. However, by assigning a temporary "Q" code, CMS suggests that its approach is subject to change.

CMS has already taken important steps to make its HCPCS coding decisions more transparent. Continued transparency will be particularly important as CMS revisits its "HCPCS Decision Tree for External Requests to Add or Revise Codes" to address coding for biosimilars. The resulting implications for payment and coverage are significant. Depending on CMS’s approach, private payers may choose to use CMS’s assigned HCPCS codes or may choose to develop their own HCPCS codes, i.e., "S" codes are temporary national HCPCS codes established by private payers that are not recognized by Medicare.


7Social Security Act 1847A(b)(3), 1847A(c)(3), Biologics Price Competition Act

8Social Security Act 1833(b)(14).

9Social Security Act 1847A(c).


The FCC has established an exemption from the Telephone Consumer Protection Act (TCPA) consent requirements for healthcare messages that are regulated by the Health Insurance Portability and Accountability Act (HIPAA). On the surface, healthcare providers and others covered by HIPAA appear to have broad latitude in calling and texting patients. However, since HIPAA doesn't specifically define what a healthcare message is, there is substantial ambiguity that can translate into significant risks.

In a new, free webinar, Marc Roth and Christine Reilly, co-chairs of Manatt's TCPA Compliance and Class Action Defense Group, and Anne O. Karl, an attorney in Manatt's healthcare practice, help clarify the ambiguities at the intersection of HIPAA and TCPA. During this comprehensive session attendees will:

- Gain insights into the TCPA's healthcare message exemption.
- Understand what is—and isn't—defined as marketing under HIPAA.
- Discover the four key questions all HIPAA-covered entities and their business associates should consider before making automated calls to mobile devices or prerecorded calls to landlines.
- Examine case studies to help evaluate TCPA and HIPAA risks when promoting wellness programs, providing payment and appointment reminders, and performing market research.

The panelists will also share the latest news from the FCC and discuss the latest technological advances designed to help minimize TCPA-related risk.

Make sure you have the information you need to navigate the complexities of the TCPA and HIPAA. Even if you can't make our original airing on July 23, click here to register now, and we'll send you a link to view the program on demand.

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Manatt's Joel Ario, Managing Director, and Melinda Dutton, Partner, Healthcare Industry shared the answers at a new, free webinar, "What's Next for Marketplaces: Trends in a Post-King World." The program provides an in-depth look at what the decision means and how it impacts emerging trends in the healthcare landscape. If you or anyone on your team missed this important event, you can access it now on demand. Click here to view the webinar free. If you'd like a free copy of the webinar presentation for your continued reference, click here—or click here to read Manatt's full analysis of the decision and its implications.
California Courts Clarify Effect of Hospital Conditions of Admission Forms

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Hospitals typically require patients to sign Conditions of Admission (COA) forms, which constitute a contract between the hospital and the patient. COAs typically outline the patient's obligations with respect to the hospital services they receive, which may include the duty to pay for services rendered per the hospital's chargemaster (or to assign to the hospital rights that the patient may have under the patient's health insurance plan). In addition, COAs include provisions under which patients provide informed consent for treatment and may also require patients to confirm their understanding of various arrangements related to their treatments (e.g., that physicians staffing the hospital are independent contractors and not employees, representatives, or agents of the hospital). Though challenges have been made to the enforceability of various provisions of hospital COAs, California courts have recently clarified the effect of at least two common COA features.

1. Can a signed COA provide sufficient notice of unspecified future hospital charges?

Yes. In Nolte v. Cedars-Sinai Medical Center, 236 Cal. App. 4th 1401 (Cal. App. 2d Dist. 2015), the California Court of Appeal upheld the dismissal of a patient's lawsuit claiming that certain hospital charges were unfairly assessed because the charges were purportedly not specifically described to the patient in advance. In its holding, the Court of Appeal noted that the signed COA required the patient to pay charges and did not require the hospital to specifically disclose charges in advance and that the hospital met its notice duties under California law by publishing its chargemaster. After receiving services at an outpatient hospital facility, the patient was assessed a "facility fee" that the hospital charged to enroll new patients into the hospital billing system. The patient argued that because he was not specifically advised or otherwise given prior notice of the facility fee beforehand, the assessment of the fee was unfair and fraudulent under California's Unfair Competition Law, Business & Professions Code §17200. In dismissing the suit, the court noted that the patient signed the hospital's COA, stating that he understood that he was being admitted to a hospital facility for outpatient services, that the hospital and its independent physician contractors would bill him for their services separately, and that the patient agreed to pay for such services.

The Court of Appeal ruled that the patient's allegation that the hospital did not separately and specifically disclose and explain the facility fee to him was not unfair or fraudulent under the Unfair Competition Law because (1) the terms of the COA did not require the hospital to obtain the patient's consent to specific charges, (2) California law only requires hospitals to post their chargemasters online and to post notices of their online chargemasters in their facilities (see Health & Safety Code §1339.51), and (3) the chargemaster notices under California law were reasonable.

Overall, Nolte stands for the proposition that hospitals may enforce signed COAs in which (1) patients acknowledge that they are being admitted to a hospital facility and agree to pay separate charges for services rendered by the hospital and its independent contractor physicians and (2) hospitals do not agree to identify specific charges. When such a COA has been properly executed, hospitals need not disclose each specific charge that may be assessed as a result of the hospital visit where hospitals meet all legal requirements regarding disclosure of charges.

2. Can signage and COAs stating that physicians are independent contractors relieve a hospital of liability for physician malpractice?

No, but signage and COAs can be part of the factual analysis of whether a physician was an agent of a hospital. In Whitlow v. Rideout Memorial Hospital, 237 Cal. App. 4th 631 (Cal. App. 3d Dist. 2015), the Court of Appeal examined a grant of summary judgment striking down a patient's claims of malpractice against a hospital based on the purported malpractice of its emergency physicians. In reversing, the Court of Appeal noted that signed COAs and other indicia of the independent contractor nature of emergency physicians were not sufficient as a matter of law to defeat claims that a hospital is liable for the purported malpractice of its emergency physicians under an ostensible agency theory.

The trial court ruled that the emergency room physician who failed to diagnose and treat a decedent's brain hemorrhage was not an ostensible agent of the hospital as a matter of law. The Court of Appeal sided with
the patient's estate, which argued that despite the signed COA and signage stating the emergency room physicians are independent contractors, and despite the presence of insignia on the physician's clothing identifying the physician's medical group employer, triable issues of material fact existed as to whether the patient entrusted herself to the hospital; whether the hospital selected the physician; whether the patient reasonably believed the physician was an agent of the hospital; and whether the form, signage, and insignia could give meaningful notice of the employment status of the emergency room physician to a patient suffering an acute medical condition.

Whitlow stands for the proposition that COAs and other notices explaining that physicians are independent contractors rather than employees of hospitals are not sufficient, as a matter of law, to conclusively dispose of claims against the hospital for the physician's malpractice. Though this opinion's clearest implications relate to how hospitals formulate their physician credentialing and privileging standards and risk assessment processes, the decision also reminds hospitals that COAs do not exist in a vacuum, but are in some cases only one part of a larger factual analysis.

Conclusion

Although the courts have not consistently enforced COA provisions, hospitals should continue to use COAs to clearly describe patient responsibilities, obligations, and understandings with respect to the hospital services they receive. The importance of properly drafted and appropriately implemented COAs will continue to increase due to the increased scrutiny being applied to many of the items covered in COAs. As consumers continue to question hospital pricing policies, legislators continue to conduct inquiries regarding hospital billing practices, and as various government agencies continue to implement complicated new regulatory regimes delineating specific requirements relating to hospital billing and collections rules (e.g., Internal Revenue Code Section 501(r), California Hospital Fair Pricing Act), hospitals must take special care to properly draft and implement COAs to ensure that they will be effective.

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