State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D)

Alternate Payment Model Brief

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Executive Summary

This Phase I SMART-D report provides an overview of how Alternative Payment Models (APMs) currently help private- and public-sector payers manage drug utilization and costs in the United States and Europe. Delving into health outcome-based and financial-based models, the issue brief considers potential benefits and barriers for state Medicaid agencies that might be interested in creating these programs. Phase II of the project will offer more detailed analyses of how states can develop and execute APMs.

As health care costs rise and put pressure on state budgets, state Medicaid programs struggle to ensure that their clients have access to all of the medications—including high-cost ones—necessary for quality care. The Medicaid Drug Rebate Program (MDRP), enacted in 1990, creates opportunities for state Medicaid programs to receive mandatory drug manufacturer rebates and supplemental rebates (Social Security Act, Section 1927). The program has been successful in lowering state costs. For instance, a recent study indicates that manufacturer rebates reduced Medicaid outpatient drug spending from $42 billion to $22 billion in 2014 (MACPAC, 2016). But MDRP has a serious drawback: the program requires states to provide coverage to all medications from drug manufacturers with federal rebate agreements. Although this requirement is intended to provide state Medicaid programs with lower prices than private payers, it also interferes with each state's ability to prioritize coverage of clinically superior drugs, those with the best clinical value, and those that are most cost-effective. As a result, Medicaid stakeholders have limited tools to manage drug utilization, especially the newer, high-cost treatments for conditions such as hepatitis C and HIV.

To address increasing drug costs, state Medicaid officials are focusing greater attention on alternative payment models (APMs). APMs are generally based on financial or health outcomes. Financial-based APMs, designed at either the patient or population level, rely on financial caps or discounts to provide predictability and limit the risk of uncontrolled spending. In health outcome-based APMs, payments for drugs are tied to predetermined clinical outcomes or measurements, or else coverage is conditional while data is being collected. Financial-based APMs, which focus on lowering costs and expanding patient access, tend to be easier to administer. APMs related to health outcomes require additional planning and data collection, but have the potential to increase the quality, value, and efficiency of treatments.

APMs are less common in the U.S. compared to other developed countries because purchasing power is distributed among a large number of stakeholders rather than being centralized, as it is in most developed countries. The extent to which APMs are used in the U.S. is not well-known

because most programs involve confidential contracts between pharmaceutical manufacturers and managed care organizations or their pharmacy benefit managers. However, there are some indications that the number of APMs could be growing.

APMs have been used in numerous European Union countries for many years; in some, such as the United Kingdom and Italy, they have become relatively commonplace. For many EU countries, APMs have become a valuable tool for financial management, quality improvement, and successful negotiations with drug manufacturers. The types of APMs utilized in the EU vary across markets. In the UK, the majority of APMs currently in effect are financial-based, while in Italy outcomes-based agreements are more frequent. Different APM forms can be employed to fulfill particular goals. In the UK, the purpose of an APM is to take a drug that is deemed not cost-effective and make it cost-effective. The easiest way to accomplish this is to reduce the price of the drug; hence, APMs utilized in the UK today are simple discounts. In other markets such as Italy's, where cost-effectiveness is not the primary decision criterion, health outcome-based APMs can be more appropriate. These APMs allow the Italian healthcare system to achieve goals such as facilitating faster access to drugs when the clinical benefit is certain and ensuring that patients do not continue on ineffective treatments.

The fragmented nature of the U.S. healthcare system limits Medicaid administrators' ability to utilize options that are available in other countries, such as being able to negotiate drug prices with manufacturers. In addition, state Medicaid programs have less leverage over manufacturers than private U.S. payers because they cannot restrict access to most drugs. Medicaid programs also encounter significant regulatory and technical challenges in the implementation of APMs. Still, SMART-D interviews with Medicaid officials in a range of positions showed a distinct interest in APMs, especially those related to health outcomes.

Phase II will deliver a more detailed analysis of how Medicaid program administrators can assess their level of readiness and develop and implement APMs. The Center for Evidence-based Policy has identified three areas of focus for its work with state Medicaid leaders to begin planning for potential APMs:

- Determine the scope and potential design of APMs within state Medicaid programs. Assess technological readiness to identify, manage, and track APM-related health, drug, and cost outcomes and ensure appropriate patient confidentiality.
- Establish a professional relationship between the state Medicaid program and one or more drug manufacturers to enable good-faith discussions about APM opportunities.
- Identify legal pathways that pair with the targeted APM and state Medicaid program design.

Research Methods

This report is based on a review of publicly available reports and policy literature, discussions with industry and academic experts, and interviews with state Medicaid pharmacy directors and

managers. The Center selected states to represent a range of program sizes and structures (fee-for-service and managed care). For definitions of the numerous acronyms and terms used throughout this report, see Appendix A.

Background

State Medicaid Program Officials' Interest in Alternative Payment Models

State Medicaid programs are experiencing a substantial increase in the cost and utilization of prescription drugs. Some estimates place overall Medicaid prescription drug spending growth at more than 24% per year. The rise in expenditures on specialty drugs is particularly pronounced: In 2014, high-cost drugs (defined as over $1,000 per claim) accounted for 32% of total Medicaid drug spending but only 0.9% of claims (MACPAC, 2016).

Compared to private payers, state Medicaid programs encounter additional challenges when addressing prescription drug costs. Unlike commercial insurance companies, state programs cannot increase budgets with premium hikes or patient cost sharing. Moreover, as detailed in the *Legal Brief: State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D),* the MDRP requires states to provide coverage to all drug manufacturers with federal rebate agreements. In addition, in most states, legislative or regulatory limitations exclude certain drug classes from preferred drug lists. Excluded drugs are not subject to a review process or negotiation of supplemental rebates for preferred drug list placement. State Medicaid administrators are limited in their ability to manage these drugs, which are often in therapy areas with expensive options (e.g., hemophilia). A detailed analysis of utilization management tools used by various state Medicaid programs is provided in the *Medicaid and Specialty Drugs: Current Policy Options* policy brief.

> *"Generally, putting high-cost products on non-preferred status and applying a prior authorization requirement on them seems to be the extent of what we can do to manage costs." —Medicaid program official*

State policymakers are paying more attention to APMs as a potential solution to rising drug costs. In March 2016, the National Association of Medicaid Directors (NAMD) released a letter to the U.S. Senate Finance Committee expressing concerns about limitations posed by current Medicaid drug policies. NAMD stated that although the MDRP has historically reduced drug costs for Medicaid programs, experiences with newer hepatitis C treatments underscored how its coverage requirements hinder states' ability to negotiate on price and expand patient access. In addition, prescription drugs have been excluded from value-based payment models developed for other health care services; NAMD emphasized the need for federal flexibility to allow states to move toward value-based models for medications (NAMD, 2016).

"Our primary goal is to make sure that the individuals who are enrolled in our program have access to the best possible health care and the best possible outcomes, and at the same time that we're getting the best possible value for our taxpayers and funders." — Medicaid program official

Most state Medicaid officials interviewed for this project expressed interest in potentially adopting APMs. Their reasons included the possibility of achieving better value for tax dollars spent, improvements in health outcomes, increased quality of care, reduced waste, greater cost and spending predictability, and lower overall spending.

To date, only a few state Medicaid programs have been approached by manufacturers to engage in these types of agreements. For most of these states, discussions have not progressed beyond the initial exploratory stage. One state Medicaid program official involved in SMART-D described significant progress with a manufacturer for a pay-for-performance type APM, potentially opening the door to future arrangements.

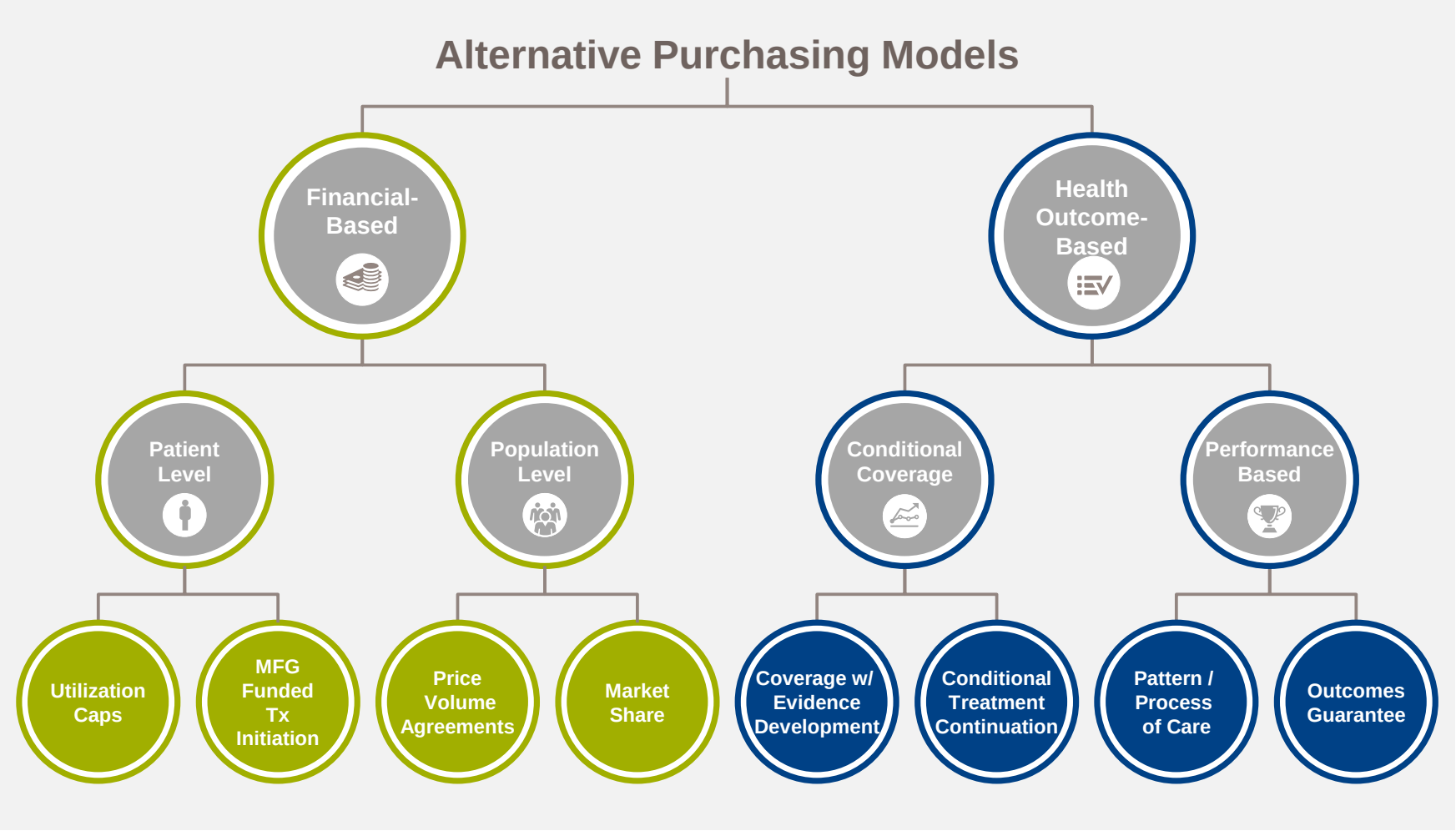
An Introduction to Alternative Payment Models

APMs are contracts that tie payment for a drug to agreed-upon measures. The manufacturer and payer share the risk that a drug might not be efficacious or that it could become overused, rather than the payer solely bearing the risk. These agreements differ in a variety of aspects but can generally be grouped into two major types, financial-based and health outcome-based (Figure 1).

Financial-based APMs are structured to mitigate the risks associated with assumptions of real-world overutilization or volume for a given drug. These agreements can be structured at either the population or patient level. An example of a population-level APM is a price-volume agreement, often used in markets such as France's. In these agreements, financial expenditures for a medication are controlled by setting an agreed-upon budget ceiling. If the total amount spent for a drug exceeds this threshold, the manufacturer is responsible for the additional cost, often through a rebate paid back to the payer (INSEAD, 2014).

Alternatively, patient-level APMs tie financial benchmarks to individual patient drug utilization. These types of agreements can be in the form of a price cap in which drugs are provided free of cost after patients reach a fixed financial utilization limit. Another form is a dosage cap, in which the manufacturer and payer agree on a predetermined level of consumption, and the manufacturer pays for anything beyond this agreed limit. A recent example is an agreement between AstraZeneca and UK health authorities for Lynparza (olaparib), a novel ovarian cancer therapy, in which the manufacturer is responsible for the cost of the drug for patients who remain on treatment after 15 months (Levy, 2015).

Figure 1. ***Alternative Payment Models Taxonomy***



Full descriptions available in Appendix C

Adapted from Garrison, 2014; INSEAD, 2014

Health Outcome-based APMs

In health outcome-based APMs, drug payments are tied to clinical outcomes. Most of the Medicaid representatives interviewed for the SMART-D project expressed interest in these kinds of contracts, which can shift some of the risk of real-world patient health outcomes back to the manufacturer, instead of the risk being borne by taxpayers and Medicaid programs. Health outcome-based APMs are typically used when the health benefits provided by the drug are uncertain or unclear. These APMs can also be used to reduce waste, for instance, when a large proportion of patients prescribed the drug discontinue it or do not remain in treatment.

Health outcome-based APMs have certain core features (Garrison et al., 2013), which include a program for data collection that begins during the time period following market approval of a drug. In addition, the price, reimbursement, and/or revenue of the program are linked explicitly or implicitly to data results. Data collection is intended to address uncertainty about one or more of the following:

- The efficacy or effectiveness of a new drug in the test population compared to the standard of care (i.e., how the drug compares to currently used therapies)
- The drug's efficacy or effectiveness in a broader, more heterogeneous population than the one used in trials pivotal for approval or in pre-license testing
- The drug's effects on long-term or more clinically significant endpoints than those included in registration trials (e.g., if the trial relied upon surrogate markers)
- Adverse effects or adherence issues among patients
- Whether health care providers' management of the patient will change the relative benefits and harms under conditions of usual care
- The size and value of other health care cost offsets (e.g., fewer hospital visits)
- The proportion of patients who respond positively to the medication
- Number and types of patients likely to be treated with the new therapy in real-world practice
- Whether the patients treated are the "correct" ones (i.e., have attributes matching patients who the payer is willing to fund on the basis of current evidence, including or excluding off-label use).

Health outcome-based agreements have two forms: conditional coverage and performance-based (Garrison & Carlson, 2014). Conditional coverage arrangements grant coverage while data is being collected to make future coverage decisions (as in coverage with evidence development schemes), or to determine whether a patient should continue on a treatment based on achieving certain health outcomes (Remuzat, Toumi & Falissard, 2013). In the U.S., the Center for Medicare and Medicaid Services (CMS) uses coverage with evidence development schemes to reimburse promising treatments for Medicare patients while data on their effectiveness is being compiled. The data help CMS make coverage decisions for drugs and other medical technologies under Medicare.

Conditional coverage agreements evaluate the effectiveness of the drug during a trial period. A decision is then made as to whether continued treatment will be covered (INSEAD, 2014). In Italy, for example, patients on an Alzheimer's drug are evaluated for effectiveness after three months of treatment. If outcomes are favorable, the public healthcare system provides reimbursement for the drug for a maximum of two years.

Performance-based agreements help payers manage drug utilization by tying reimbursement to a pre-specified health measure or clinical outcome in a real-world setting. If the drug cannot fulfill the measure, the manufacturer reimburses the payer, typically through a rebate. An early example includes a 1988 APM in which Merck agreed to compensate patients and payers for the prescription costs of Zocor (simvastatin) if the drug failed to lower LDL cholesterol to target concentrations. In 2007, a performance-based APM was implemented in the UK for the multiple myeloma treatment Velcade (bortezomib) (Spoor, 2012). Following an initial rejection from the National Institute of Health and Care Excellence (NICE), the National Health Service (NHS) agreed to pay for the drug based on tumor shrinkage. The manufacturer (Millennium, a subsidiary of Takeda) provided a rebate for patients who did not respond to the treatment. In 2015, private U.S. payers reached performance-based agreements with the manufacturers of Entresto for heart failure and the PCSK9 inhibitors Repatha and Praluent for high cholesterol. Although the details have not been made public, these agreements demonstrate a transition by U.S. payers in adopting value-based payment models, particularly when manufacturers are motivated to engage with payers. APMs in the U.S. generally occur when manufacturers seek a competitive advantage while they introduce high-cost drugs into a therapy area that already has multiple options (Reinke, 2016).

Payer and Manufacturer Alignment in Alternative Payment Models

> *"Part of the struggle is that it's rarely the manufacturer who feels any pain; it's often the patients and the taxpayers. They are the ones losing out... I don't have a clear view on how to incentivize or encourage manufacturers based on the tools we have available. If they participate in the rebate program, we have to cover the drug." — Medicaid program official*

For an APM contract to be successfully negotiated, both drug manufacturers and payers must be willing to engage and must believe that the provisions solve a problem or improve their situation. Some payers could choose to focus on reducing expenditures related to a specific drug, particularly if it treats a niche disease or specialty area. Other payers could try to reduce overall health expenditures, possibly by avoiding a costly procedure later in the patient's life. A good example would be the hepatitis C virus for which newer therapies might reduce the number of patients needing a liver transplant at a later point in their lives. For single-payer markets in which one payer is typically responsible for health care costs throughout a patient's life, an APM

based on lowering the number of liver transplants might be appealing. However, a state Medicaid program, in which budgets are determined annually, may have more motivation to reduce spending in the short term. Therefore, an APM that addresses long-term goals might not address the program's short-term needs.

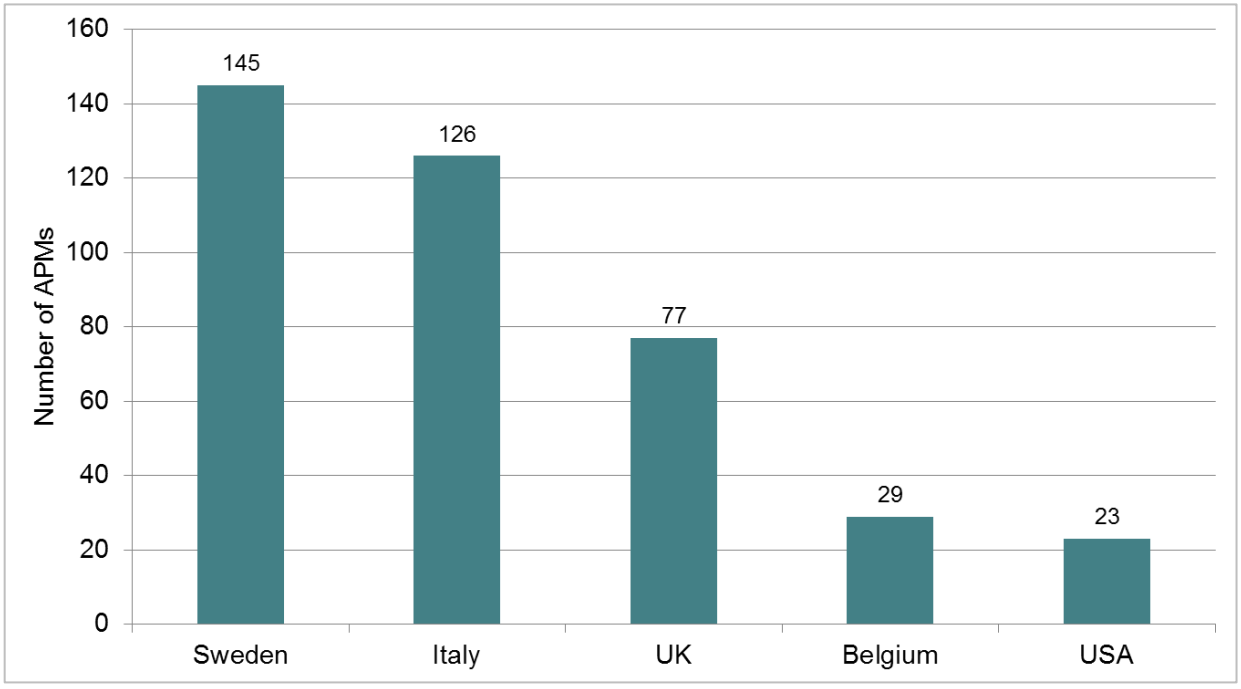
The challenges outlined above provide an immediate and clear rationale for state Medicaid officials to pursue new prescription drug payment models. But it is less obvious why manufacturers might want to make an APM agreement with a state Medicaid program. In the private sector, insurance companies are able to restrict access to and coverage for drugs, which enables the payers to pressure manufacturers to consider an APM that ensures access to their medication. In single-payer markets, such as those throughout Europe, payers can often exert tremendous pressure on manufacturers to enter into APMs because access and coverage are not guaranteed. Considering that MDRP provisions prevent state Medicaid programs from limiting coverage, drug manufacturers may be most likely to participate in APMs when they want to gain a competitive advantage. If market dynamics—such as an increase in competition—change, manufacturers' willingness to engage in an APM could change.

Findings

Alternative Payment Models in Europe

Use of APMs is fairly prevalent in many EU markets, including the UK, Italy, and Sweden (Figure 2). Experiences using APMs have been mixed, with some markets having more success than others. In certain countries, past experience has shaped the approach to these agreements. An examination of these APMs offers valuable insight into success factors, as well as potential challenges and pitfalls, for a state Medicaid program considering the implementation of an APM.

Figure 2. ***Publicly available APMs by country (2010–2016)***



Source: EMINET, 2013; AIFA, 2016; NICE, 2016; Mohr, 2010; Loftus, 2016; Pollack, 2015

A variety of APMs are utilized in the EU (Table 1). The most common is price-volume agreements (39.2% of total APMs), followed by requirements for data collection (29.2%), limited access to eligible patients (13.0%), conditional coverage (5.6%), results-based (5.4%), simple discounts (4.6%), price or dosage cap (2.2%), and price match (0.8%) (Ferrario & Kanavos, 2013).

Table 1: *Types and Percentage of Total APMs in Europe*

Type	% of APMs	Description
Price-Volume	39.2%	The drug price is tied to the volume of utilization. Thresholds may exist in which the price would gradually decrease (e.g., $100 per patient for the first 10,000 patients and above that, $80 per patient).
Data Collection	29.2%	Additional data collection is required for coverage so that either (a) more thorough analysis of a health intervention can be conducted at a later time or (b) claimed cost savings can be validated in the real world.
Limited Access	13%	Access to a drug is more restrictive than the regulatory label. This covered group might include special populations perceived to receive the highest value from a treatment. Or certain health centers or specialists may be tasked with acting as gatekeepers for prudent use.
Conditional Coverage	5.6%	Coverage is provided under pre-specified conditions such as the conduct of additional clinical trials or publications of outcomes studies
Results-based	5.4%	Price corresponds to an economic, clinical, or humanistic outcome, for example, if the price is paid only for patients who achieve the agreed-upon outcome
Simple discounts	4.6%	A generally non-transparent price is provided to bring the affordability, cost-effectiveness, or value of a drug to an acceptable level. Typically used in markets that utilize cost-effectiveness-based coverage decisions, such as in the UK
Price or dosage cap	2.2%	The price may be capped per patient or dose. For instance, the payer would pay the same, singular, standard price for all patients, including those that remain on treatment for extremely long durations or that require significantly higher doses
Price match	0.8%	The price of a health technology is tied to a benchmark for any given setting. Typically done when products are widely available but large variations exist in price depending on the technology used

Source: Fessario, 2013

Countries have a tendency to use specific types of APMs. For example, most APMs in France are financial price-volume agreements. Health outcome-based APMs are more often employed in Italy, with many APMs structured as conditional coverage agreements. The average duration of known APMs in the EU ranges from one year in Belgium (renewable) to up to four years in the Netherlands or for an indefinite period of time subject to review (France and UK) (Ferrario & Kanavos, 2013).

In the UK, financial-based APMs have become more regularly used; 34 out of 35 of the most recent schemes are simple discounts (NICE, 2016). The switch occurred after disappointments with health outcome-based agreements in the UK, which can provide valuable lessons. An early example involves multiple sclerosis (MS) therapies (Spoor, 2012). NICE, the authoritative body tasked with evaluating the cost-effectiveness of drugs in the UK, initially did not recommend several beta-interferon MS therapies for reimbursement because of uncertainty about their long-term cost-effectiveness. As a result, the agreed-upon APM permitted coverage for the drugs while research was conducted to assess their long-term cost-effectiveness. If patients did not appear to benefit from the therapy, payments from the NHS were supposed to gradually cease. Clinical benefit was to be determined by the ability of the therapies to delay disease progression, specifically disability.

In implementing this APM for MS therapies, numerous issues were encountered from the beginning (Garrison et al., 2013). Recruitment of patients for the study took longer than expected and results were subsequently delayed, eventually being reported seven years after the agreement to create the scheme. Even though the results determined that the therapies were not effective in delaying disease progression, prices were never adjusted downward on the grounds that the evidence was inconclusive. Ultimately, the scheme was viewed by many as a failure and criticized for not providing value for the money to the NHS (Spoor, 2012).

The difficulties encountered in this scheme and a few others caused some British experts to question whether health outcome-based APMs were worth the effort, and these kinds of APMs became less prevalent. Still, valuable lessons can be learned from decades of experimentation and experience in the UK with health outcome-based APMs, including the importance of the following actions:

- Designing an APM that results in definitive conclusions and payment triggers
- Agreeing on an endpoint that can be clearly measured
- Maintaining or creating the capability to track and collect clinical data (e.g., an appropriate IT infrastructure is crucial)
- Engaging stakeholders—providers, pharmacists, managed care organizations (MCOs), purchasing pools—that are committed to the success of the APM

Health outcome-based APMs have been more successfully used in Italy. Known as managed entry agreements, these APMs have three configurations: cost sharing, in which a price reduction is required until patients show signs of responding; risk sharing, in which the manufacturer must

reimburse half the costs of treating patients who are not responding; and payment by results, in which the manufacturer reimburses payers the full cost of the drug for patients who are not responding. Cost sharing makes up the largest proportion of the schemes (50%), followed by payment by results (43%) and risk sharing (7%) (Garattini et al., 2015). The Italian health authorities have been able to implement these agreements because of the existence of infrastructure to collect the kind of data necessary for performance-based schemes. The national health authority, AIFA, or the Italian Medicines Agency, collects data for monitoring patient outcomes through online registries set up at the national level. These registries maintain records for each prescription given to patients using innovative or specialty drugs, particularly in oncology (Garrison et al., 2013). Yet, concerns have been raised about burdening physicians with entering additional patient data, and some Italian experts complain about the return on investment of these arrangements, which are associated with higher costs than financial-based schemes.

The divergent paths of the British and Italian health care systems make sense in light of their health authorities' differing aims. The goal of an APM in the UK is to take a drug that is deemed not cost-effective and make it cost-effective. The easiest way to accomplish this is to reduce the price of the drug; hence, APMs utilized in the UK today are simple discounts. In other markets such as Italy's, where cost-effectiveness is not the primary decision criterion, outcomes-based APMs can be more appropriate. These APMs allow the Italian healthcare system to achieve goals such as facilitating faster access to drugs when the clinical benefit is certain and ensuring that patients do not continue on ineffective treatments.

APMs can limit the growth in pharmaceutical expenditures, ensure that health gains are maximized within finite budgets, or both, including limiting off-label prescribing and prescribing outside identified subpopulations for which the value of the technology is greatest (Adamski et al., 2010). Several EU markets have reported the recognized revenue back to the health system from these APMs. In 2004, France reported total rebates that amounted to €670 million, around 3% of total pharmaceutical expenditure. In Hungary, the payback in 2006 was 22.5 billion HRF (approximately €90 million or 5.69% of the budget), and in Italy rebates amounted to €773 million in 2005.

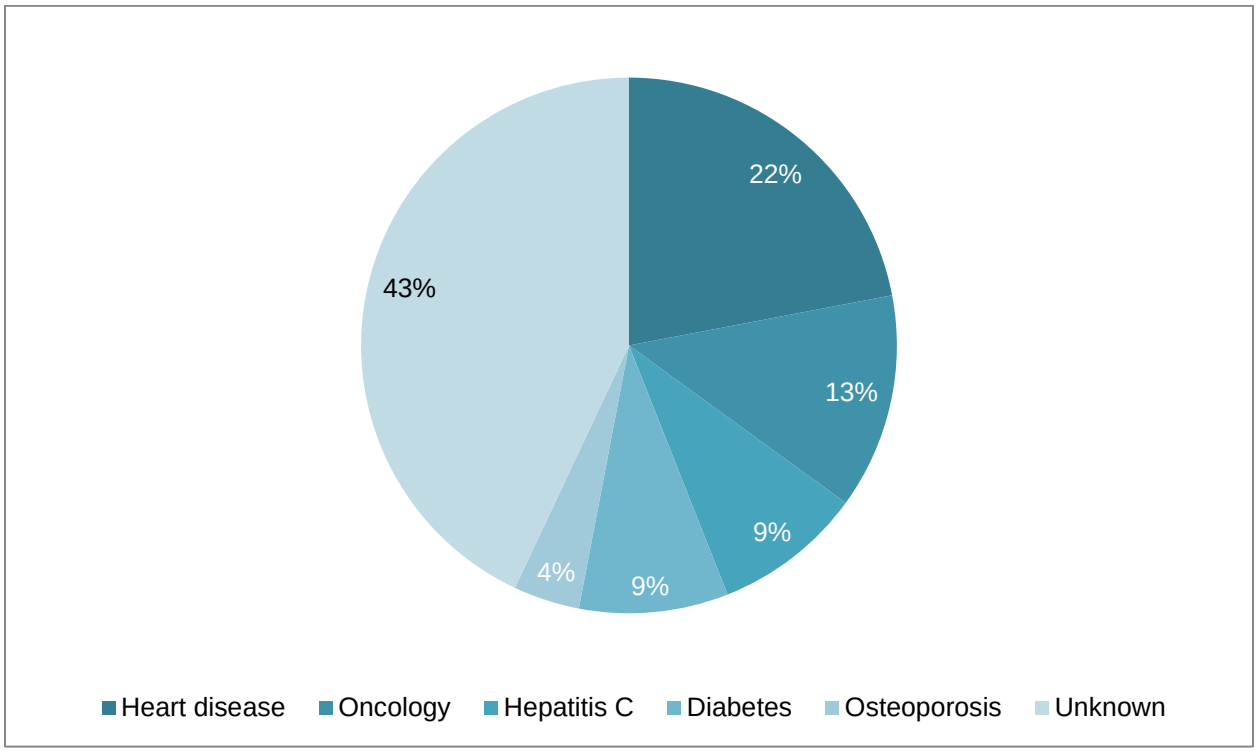
Despite the challenges encountered in past experiences, many EU markets continue to utilize and implement APMs because they are viewed as a valuable financial, quality improvement, and management mechanism, as well as a negotiation tool with drug manufacturers.

Alternative Payment Models in the U.S.

Compared to its EU counterparts, the U.S. has historically been slow to adopt APMs (Garrison et al., 2015). The exact count is unknown because many of these agreements, which so far involve private payers or Medicare, are confidential. An analysis conducted by the University of Washington Performance-Based Risk-Sharing Database shows that out of 148 risk-sharing agreements identified between the late 1990s and 2013, only 18 agreements were in the U.S.

(Garrison et al., 2015). Of these, 11 were in the public sector with Medicare (coverage with evidence development schemes), and the remaining seven were with private payers. A different analysis found at least 23 publicly acknowledged APMs across a variety of disease areas (Figure 3) (Mohr, 2010).

Figure 3. ***Distribution of APMs by Disease Type in the U.S.***



Source: Mohr, 2010; Loftus, 2016; Pollack, 2015

Despite the nontransparent manner under which these U.S. agreements have been executed, it is possible to examine several examples of U.S. APMs. The health outcome-based APM for Zocor (simvastatin) dates back to 1998 (Carlson et al., 2009). Roche-Genentech entered into a financial-based arrangement for Avastin (bevacizumab), a drug used for the treatment of multiple tumor types. Avastin received FDA approval for breast cancer in 2008 after initial resistance stemming from a low perceived benefit (improved median progression-free survival of only 0.9 months) for its estimated annual cost of more than $100,000 (Nature Medicine, 2010). The company reduced the cost of the drug to $55,000 annually for advanced breast cancer patients who met certain criteria.

Recently, several U.S. payers have announced APMs with manufacturers for newly launched therapies. For its new heart failure drug Entresto (sacubitril/valsartan), Novartis publicly proposed a pay-for-performance scheme with payers, in which insurers would initially pay a lower price, followed by another payment if the drug successfully kept patients out of the hospital and helped cut overall costs (Pollack, 2015). This proposal was initially met with some skepticism.

Citing the lack of infrastructure to collect the necessary data, the chief medical officer of Express Scripts, the largest pharmacy benefit manager in the U.S., publicly expressed doubts that a scheme like this could be successfully implemented (Helfand, 2015). However, two large private payers, Aetna and Cigna, announced agreements with Novartis for value-based pricing arrangements (Staton, 2016). Cigna's payments to Novartis will be linked to the rate of hospitalizations among patients taking the drug. Aetna stated that its deal with Novartis would be based on the drug delivering real-world results similar to those reported in the clinical trial (Humer, 2016).

Another recent example of APMs in the U.S. relates to a new class of high-cost therapies, PCSK9-inhibitors for the treatment of high cholesterol. Many payers were concerned about PCSK9-inhibitors well before their launch because of the high cost of the therapies for a potentially large patient population. The first two drugs in this class, Amgen's Repatha (evolocumab) and Sanofi-Regeneron's Praluent (alirocumab), launched in the U.S. within a couple of months of each other. Given that the two drugs have the same mechanism of action, very similar efficacy and safety profiles, and almost identical prices, competition to establish market share was fierce (Reinke, 2016). Announcements were made regarding which product was able to establish "preferred" status on which plans' formularies based on rebate contracting. One plan, Massachusetts-based Harvard Pilgrim Health Care, established a risk arrangement with Amgen for Repatha (Herman, 2015). The agreement required the product to reduce LDL cholesterol levels to those consistent with clinical trial results. Even with the agreement, Repatha is limited to its approved indication and is only available to patients after the failure of statins and ezetimibe (Zetia). Repatha is the only PCSK9-inhbitor on Harvard Pilgrim Health Care's formulary; the competitor Praluent is not on the formulary at this time.

Cigna's agreements with PCSK9-inhibitor manufacturers involved value-based arrangements for Repatha and Praluent (Loftus & Mathews, 2016). The outcomes in the agreements were similar to those of the Harvard Pilgrim Health Care agreement: payments were tied to the drugs' ability to reduce LDL cholesterol to levels at least as low as those demonstrated in clinical trials. These recently announced agreements with the manufacturers of Entresto and the two PCSK9 inhibitors seem to indicate a changing landscape, and could be a harbinger of an increasing number of APMs in the U.S.

Implications for State Medicaid Programs

Alternative Payment Models in State Medicaid Programs

As part of the Phase I SMART-D research, state Medicaid officials were presented with two hypothetical health outcome-based APMs. SMART-D researchers conducted interviews to gauge these officials' interest and ask them to discuss potential barriers to the execution of each arrangement. The first APM was a "money-back guarantee" that would provide a rebate for the cost of the drug for each patient who could not tolerate a given drug. The second APM tied financial arrangements to outcomes or performance of the drug.

Legal Constraints

Any APM would be contingent upon CMS approval, as all interviewees pointed out, which illustrates the importance of federal support to pursue new models. Several state Medicaid officials noted that relations with CMS can be complicated, and many interactions with different offices within CMS could be necessary to gain conceptual approval for a state plan amendment or other program modification. In addition, stakeholders noted that any agreement with a manufacturer, particularly those that might involve a rebate, could be subject to an audit from the Office of Inspector General. Several Medicaid officials said that the unwanted attention and potential scrutiny from the Office of Inspector General might be a possible deterrent to engaging in an APM.

> *"The state plan amendment part and working with CMS is a barrier to implementing an APM… We would need to get a state amendment through CMS and that process has become harder." — Medicaid program official*

As publicly funded government entities, state Medicaid programs are constrained by certain legal statutes and regulations at the federal and state level. An in-depth analysis of these legal constraints, including potential legal pathways to implement APMs, is provided in the *Medicaid and Specialty Drugs: Current Policy Options* policy brief.

Stakeholder Alignment

For any agreement to succeed, a certain degree of trust between the stakeholders involved has to be established. During interviews, the majority of Medicaid officials reported having a moderately amicable and open relationship with manufacturers. Manufacturers were cited as being a good resource for information, typically clinical and sometimes nonclinical. One Medicaid official relied on economic models provided by manufacturers when trying to predict the budget impact of a product. Some officials described situations in which their options were limited to nonexistent when dealing with manufacturers, particularly when an innovative, highly anticipated, high-cost therapy was launching for a disease with a potentially large patient population, such as hepatitis C.

Almost half of the interviewees identified hepatitis C as an area in which relations with manufacturers have been somewhat acrimonious. Patients, physicians, and payers highly anticipated the launch of Gilead's product Sovaldi (sofosbuvir) because of the clinical improvement it demonstrated in clinical trials and its more favorable safety profile compared to existing therapies. Prior to the introduction of Sovaldi, several state Medicaid program officials expressed concerns regarding the fiscal impact of the therapy, especially because the population of patients most in need of the product tends to come from Medicaid-eligible low-income households (Japsen, 2014). Some states were able to restrict access to Sovaldi through tools such as prior authorization; however, many states had limited ability to manage utilization of the drug.

The pressure of the likely major budget impact of this drug led some state Medicaid stakeholders to contact the manufacturer of Sovaldi to discuss drug cost management strategies, only to be rebuffed.

> *"The existing MCO contracts define the expectations regarding the products and services that are the responsibility of the MCO and their risk. It also identifies certain pharmacy products that are carved out of the contract. MCOs like to be able to manage their own products, and so we'll have to be very concrete and figure how it's advantageous for them to get involved. With all of their commercial experience, we wish they would take more active leadership in this area."*
> *—Medicaid program official*

For several states, MCOs are another key stakeholder in considering the pursuit of any APM with manufacturers (see Appendix E for a list of Medicaid MCOs by state). Many state Medicaid programs contract with MCOs to manage the pharmacy benefit for their enrollees. Medicaid agencies' approach to managed care contracting varies from state to state. Some have strict policies that must be followed, whereas others provide MCOs with more freedom to manage the pharmacy benefit. Even within a state, relationships between the state Medicaid administration and each MCO partner can differ. In several states, management of the pharmacy benefit is handled through both managed care and fee-for-service. Medicaid agency staff members from several states cited initiatives by state legislatures to increase the role of MCOs in the state's Medicaid program. As MCOs take more responsibility in managing the pharmacy benefit, their input in any potential APM becomes a larger consideration. For example, an agreement between a state Medicaid program and a manufacturer that establishes preferred access for a drug could clash with the utilization management efforts of MCOs (e.g., the MCO's preferred drug list), creating challenges for both the state and the MCOs in managing the pharmacy benefit.

States that participate in multistate purchasing pools must also consider whether engaging in an APM with a manufacturer would conflict with or support the efforts of the purchasing pool program. A consistently cited concern of state Medicaid officials was whether an APM would be able to accommodate the supplemental rebates negotiated through the purchasing pools or whether state officials would have to choose between receiving the supplemental rebate and engaging in an APM. In the latter case, many state Medicaid officials expressed reluctance to experiment with an APM because results might be questionable.

> *"For pharmacy dispensed drugs, we have a vendor, so we don't spend a lot of time in-house [managing it], we just keep an eye on it. One of the biggest pain points is continuing with volume-based purchasing compared to outcomes based purchasing… I think a [performance-based agreement] would be interesting."*
> *—Medicaid program official*

Another stakeholder group that would need to be persuaded about the benefits of an APM is healthcare providers. Several interviewees raised concerns about being able to engage providers in these agreements, especially if the arrangements require physicians to submit clinical data. In a health outcome-based agreement, in which rebates or payments from the manufacturer might be tied to a predefined outcome, physician involvement is most likely a necessity. Physicians might not be willing to collect and send data regarding patient outcomes unless an incentive were provided. Although state Medicaid officials reported being able to collect some results or data through existing prior authorization processes, this may not always be an available tool, particularly if the time in which the outcome is measured is post-treatment (e.g., sustained virus response in a 12-week treatment with Sovaldi). States already employ a variety of performance measures with physicians and in managed care contracts. For example, the standardized Healthcare Effectiveness Data and Information Set or HEDIS measures from National Committee for Quality Assurance, used by more than 90% of U.S. health plans, measure various health interventions and could be used to align health outcome measures in APMs with clinical or other performance measures already being collected (CMS, 2015).

Despite the potential challenges for stakeholder engagement and buy-in, several Medicaid administrators said APMs could be an innovative channel to facilitate open communication and collaboration among stakeholders, which many interviewees believed needed to be addressed in general. Because the U.S. healthcare system is fragmented at all levels, APMs could potentially catalyze a convergence in decision-making for high cost drugs.

Drug Approval Dilemmas

Some of the issues with Medicaid drug management start before medications are approved. In its drug approval process, the Food and Drug Administration (FDA) includes safety and efficacy (does the drug produce a therapeutic effect under ideal test circumstances?), but not effectiveness (does the drug help people in real-life situations?). States are curtailed by the criteria that are on drug labels (which would, for instance, not address off-label uses). By not addressing effectiveness in its drug approval process, the FDA blocks consideration of quality or comparative outcomes and prevents more holistic, productive discussions of value among Medicaid stakeholders and drug manufacturers. The Phase I SMART-D research has highlighted the need to include drug effectiveness within the FDA approval process.

Process and Execution Barriers

> *"There are challenges in the timeliness of demonstrating outcomes-based results, as well as the feasibility of operationalizing necessary IT system changes and stable eligibility populations." —Medicaid program official*

Medicaid officials had mixed opinions on whether health outcome-based APMs were feasible given their current capabilities and processes. The first challenge interviewees identified was the ability to plan and implement an agreement for drugs with FDA approval that would potentially

have a large effect on budgets. The majority of state Medicaid program officials described regularly conducting scans of pipeline products, but they were unsure how effective this would be in planning and managing future high-cost therapies. Available resources they cited included the Center's Drug Effectiveness Review Project (DERP) reports, pipeline reports, and resources from third-party vendors such as Magellan. Despite these resources, respondents reported having limited ability to forecast and effectively temper the impact of new products. Because scans and reports are commonly made available on a quarterly and/or biannual basis, there is insufficient time for planning how to manage the cost of a drug after it launches. Given federal MDRP requirements, respondents have minimal options to delay access to a new drug after it launches. State officials can attempt to limit access to high-cost drugs through prior authorizations; however, many times manufacturers can circumvent this process through appeals and in some cases legal issues arise. Given these challenges, coupled with the likely time needed to plan and implement an APM, several Medicaid officials questioned whether these agreements would be a viable option to manage spending on newly launched drugs.

In contrast to EU countries with centralized registries, several state Medicaid programs have a limited ability to track and analyze patient outcomes, making administration of health outcome-based APMs even more challenging. In addition to possible deficiencies in collecting data, other issues could be encountered, including disconnects between various data systems, limited data analysis capabilities, and potential legal hurdles to storing and sharing data.

There were some stark differences in IT infrastructure in the state Medicaid programs that were part of this study. Several states were in the midst of implementing new IT systems, some of which were several years away from being operational. According to interviewees, states with the greatest IT deficiencies use the Medicaid Management Information Systems claims systems implemented more than 30 years ago. In these older systems, several challenges exist in the usability of the data for analysis. Many of the systems are unable to support data exchange with newer technologies such as electronic medical records because much of the data received is not digital. Additionally, data are often received in inconsistent formats, making collection and refinement an additional administrative burden. Interviewees described significant delays in receiving data such as diagnosis codes, medical data, and billing, delays that lasted upwards of three months. For a few states, resource constraints have postponed plans for updating the current infrastructure by several years.

In addition to the shortcomings of current IT infrastructure, there are potential challenges involved in linking data from multiple sources. For some state Medicaid programs, different types of data are collected through various systems, and often the ability to access data across those systems is limited or nonexistent. In some situations, access to specific medical claims data (e.g., chart notes, laboratory values, health resources, and utilization) might be limited or unavailable. Because independent systems can be used for data collection, administrators might encounter significant delays in gathering, aggregating, and analyzing the data.

While several states are dealing with the challenges of outdated IT infrastructure, others have been making strides in implementing new systems. However, questions still remain as to whether the new systems will enable APM implementation or present new challenges. The majority of technology improvements will likely result in a greater ability to implement an APM, however, state Medicaid administrators would likely benefit from technical assistance on how to make the most out of their investments. Tremendous opportunity exists for states in the early stages of planning their IT upgrades to ensure that they have the necessary tools to effectively manage their pharmacy spending. To carry out complex and sophisticated APMs, specific requirements should be met, such as providing access to multiple data sources, developing the ability to collect and track data to a certain level of detail, and allowing providers to enter patient information that can be recalled digitally.

Although there is a possibility that capabilities for collecting and tracking patient data can be improved through upgraded IT infrastructure, the ability to analyze, store, and share data within the confines of regulatory requirements remains a concern. Some interviewees reported having the necessary analytics teams in place, whereas others relied on third-party vendors. Still others anticipated encountering issues securing the appropriate resources for rigorous data analysis. In addition, any sharing of patient data would have to be HIPAA-compliant. The sensitivity of the data means that additional resources could be necessary, along with audits or reviews to ensure that patient confidentiality is not being compromised.

A final concern of state Medicaid officials revolved around their ability to execute an APM while accommodating rebates. In addition to rebates from the MDRP, many states participate in supplemental rebate programs. Medicaid officials questioned whether an APM could be executed while taking into account these refunds. (After these interviews were conducted, CMS issued a program notice in July 2016 expressly encouraging use of value-based arrangements as part of supplemental rebate agreements between Medicaid and drug manufacturers. (CMS, 2016b) One concern identified was how rebates from both the MDRP and supplemental rebate programs would be handled if the manufacturer also provided a refund for a drug that did not meet defined measures. The need to account for the various rebate programs could result in a significant accounting burden and increased risk of misplaced or unaccounted-for revenue. This situation would be further complicated if agreed-upon outcomes were measured months (or even years) after the patient begins treatment. Medicaid officials believed that there could be more room to work around supplemental rebates that are less restrictive than statutory MDRP rebates.

The necessity of using APMs, and the desire to do so, will ultimately depend on the goals and needs of each state's Medicaid administration. Given the fragmented nature of the U.S. health care system, options that are available in other countries, such as the ability to negotiate drug prices with manufacturers, are not readily available to state Medicaid administrators. Consequently, alternative solutions must be considered. APMs could offer a viable avenue to help address the fiscal pressures resulting from new high-cost specialty medications, particularly when limited options exist.

Avenues to APMs

Health-outcome and financial-based purchasing arrangements, which potentially benefit both states and manufacturers, are difficult to achieve within the MDRP. But there are opportunities—within and outside of the MDRP—that are listed below and detailed in the *Legal Brief: State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D):*

- Supplemental Rebate Arrangements
- MCO Contracting
- Physician-Administered Drugs That Fall Outside The Definition of "Covered Outpatient Drug"
- MCO/340B Covered Entity Partnerships
- Hospital-Dispensed Covered Outpatient Drugs
- Section 1115 Waivers
- Section 1937 Alternative Benefits Plans

To implement an APM using one of these legal pathways, some further clarification or approval could be required from CMS. In other cases, collaboration with key stakeholders such as managed care partners, purchasing pool administrators, providers, and pharmacies could be a critical aspect of a successful implementation.

APMs are an intriguing tool, but they are one of many levers that a state needs to effect changes in drug spending and patient outcomes. State Medicaid agencies can use these arrangements to support and reinforce existing strategies for value-based reimbursement. Creating the agreements will require time and labor to develop the capacity to negotiate agreements, track outcomes, and identify high-yield opportunities. Because of these costs, in their early stages, APMs might not save money for state Medicaid agencies. The success of APMs might best be judged according to the Triple Aim: States could first see improvements in patient outcomes and the health of Medicaid populations, followed by reductions to the per capita cost of health care over time. Most importantly, APMs can provide states with a way to take control of often out-of-control drug costs.

Next Steps

State Medicaid officials interviewed for this project are interested in exploring new alternative payment options for drugs that provide better value. With spending reaching unsustainable levels, all stakeholders must act to shape the environment to identify alternative models that reward innovation and improve patient health outcomes, quality, and efficiency.

Phase II of SMART-D will deliver a detailed analysis of how state Medicaid officials can assess their level of readiness, then develop and implement APMs. The Center for Evidence-based Policy has identified four areas of focus for its work with state Medicaid leaders:

- Develop Potential APM Designs

    - Create a basic plan to determine the scope and potential design of APMs.
    - Outline a list of disease areas, associated drugs, and challenges related to value or efficiency of spending and outcomes.
    - Identify opportunities to link an APM to other state payment reform efforts (e.g., an accountable care organization or bundled payment model).
- Improve Information Technology and Data Capabilities
    - Assess technological readiness to identify, manage, and track APM-related health, drug, or cost outcomes and ensure appropriate patient confidentiality.
    - Identify simple, available tools to administer APMs. This includes the use of prior authorizations and reauthorization or certification to gather data needed for health outcome measurement.
    - Seek potential third-party collaborations (e.g., registries and health information exchanges) when data capabilities need to be supplemented.
- Engage Key Stakeholders
    - Establish a professional relationship between the state and the drug manufacturer to enable good-faith discussion of possible APM opportunities.
    - Discuss options regarding APMs with managed care and purchasing pool partners to open a dialog on a path forward.
    - Consider hospital or care centers of excellence for early discussions on potential roles in APMs; engage pharmacists and providers in planning.
- Identify Legal Pathways
    - Identify legal pathways that pair with the targeted APM and state Medicaid program design.
    - Begin scoping state plan amendments or waiver applications to receive approval from CMS, when appropriate and required.

Appendix A: Glossary

Actual Acquisition Cost (AAC): Actual cost to pharmacy for obtaining the ingredients of a drug.

Alternative Payment Model (APM): Contracts that tie payment for the drug to an agreed-upon measure.

Centers for Medicare & Medicaid Services (CMS): An agency within the U.S. Department of Health & Human Services responsible for administration of several key federal health care programs

Coverage with Evidence Development (CED): Coverage is granted while data is being collected to make future coverage decisions

Drug Effectiveness Review Project (DERP): A collaborative of state Medicaid and public pharmacy programs dedicated to producing comparative, evidence-based research products that assist policymakers and other decision-makers grappling with difficult drug coverage decisions. DERP focuses on specialty and other high-impact drugs—particularly those that have potential to change clinical practice. DERP reports evaluate the efficacy, effectiveness, and safety of drugs to ultimately help improve patient safety and quality of care while helping government programs contain increasing costs for new therapies.

Electronic Medical Records (EMRs): A digital version of the traditional paper-based medical record for an individual. The EMR represents a medical record within a single facility, such as a doctor's office or a clinic.

Fee-for-Service (FFS): A payment model in which services are unbundled and paid for separately. In health care, the model provides an incentive for physicians to provide more treatments because payment is dependent on the quantity of care, rather than quality of care.

Food and Drug Administration (FDA): A federal agency of the United States Department of Health and Human Services. The FDA is responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices, cosmetics, animal foods and feed, and veterinary products.

Hepatitis C Virus (HCV): Hepatitis C is an infectious disease caused by the hepatitis C virus (HCV) that primarily affects the liver.

Health Insurance Portability and Accountability Act of 1996 (HIPAA): The primary goal of this law is to make it easier for people to keep health insurance, protect the confidentiality and security of healthcare information, and help the healthcare industry control administrative costs.

Italian Medicines Agency (AIFA): The national authority responsible for drug regulation in Italy. It is a public body operating autonomously, transparently, and according to cost-effectiveness

criteria, under the direction of the Ministry of Health and the vigilance of the Ministry of Health and the Ministry of Economy.

Managed Care Organizations (MCOs): A term used in the U.S. to describe organizations that use a variety of techniques intended to reduce the cost of providing health benefits and improve the quality of care.

Managed Entry Agreements (MEAs): Examples include cost-sharing in which a price reduction is required until patients show signs of responding; risk-sharing, in which the manufacturer is required to reimburse half the costs of treating patients who are not responding; and payment by results, in which the manufacturer reimburses payers the full cost of the drug for patients who are not responding.

Medicaid Drug Rebate Program (MDRP): A program that includes CMS, state Medicaid agencies, and participating drug manufacturers that helps to offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients. Approximately 600 drug manufacturers currently participate in this program. The program requires a drug manufacturer to enter into, and have in effect, a national rebate agreement with the Secretary of the Department of Health and Human Services in exchange for state Medicaid coverage of most of the manufacturer's drugs.

Medicaid Management Information Systems (MMIS): A mechanized claims processing and information retrieval system for Medicaid the federal government requires.

Medicare Part D: Also called the Medicare prescription drug benefit, this is a federal government program to subsidize the costs of prescription drugs and prescription drug insurance premiums for Medicare beneficiaries.

Multistate purchasing pool: Purchasing pools generally involve agencies across multiple states that contract jointly with a pharmacy benefit manager to negotiate manufacturer rebates and to manage benefits.

National Association of Medical Directors (NAMD): NAMD members are state Medicaid directors from all 50 states, the District of Columbia, and U.S. territories

National Health Expenditure Accounts (NHEA): The official estimates of total health care spending in the United States.

National Medicaid Pooling Initiative (NMPI): NMPI is a multistate Medicaid pharmaceutical purchasing pool administered by Magellan Medicaid Administration, Inc./Provider Synergies.

National Institute for Health and Care Excellence (NICE): The authoritative body tasked with evaluating the cost-effectiveness of drugs in the UK.

Office of Inspector General (OIG): Office of Inspector General for the U.S. Department of Health and Human Services (HHS) identifies and combats waste, fraud, and abuse in the HHS's more than 300 programs, including Medicare and programs conducted by agencies within HHS, such as the Food and Drug Administration, Centers for Disease Control and Prevention, and National Institutes of Health.

Pharmacy Benefit Manager (PBM): An organization that provides programs and services designed to help maximize drug effectiveness and contain drug expenditures by appropriately influencing the behaviors of prescribing physicians, pharmacists, and members.

Preferred drugs lists (PDLs): A formal published list of specific prescription drug products by brand and generic name, usually divided into two separate categories: preferred and non-preferred.

Prior Authorization (PA): A requirement that a physician obtain approval from patients' health insurance plan to prescribe a specific medication for them. PA is a technique for minimizing costs, wherein benefits are paid only if the medical care has been preapproved by the insurance company.

Quantity Limit (QL): A limit on how much of a particular drug can be obtained at the time of dispensing and for a specific time period.

Sustained Viral Response (SVR): Undetectable viral load after treatment ended.

The Optimal PDL $olution (TOP$): The multistate Medicaid pharmaceutical purchasing pool administered by Provider Synergies, LLC.

340B: The 340B Drug Discount Program is a U.S. federal government program created in 1992 that requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices.

Appendix B: Authoritative Health Bodies

Country	Authoritative Body	Description (from website)
Belgium	Federal Agency for Medicines and Health Products (FAMHP)	The FAMHP is the competent authority responsible for the quality, safety, and efficacy of medicines and health products. We work with health professionals and other competent authorities at the national and international level to ensure the population the optimal use of the medicines and health products they need. (http://www.fagg-afmps.be/en)
France	Haute Autorité de Santé (French National Authority, HAS)	The French National Authority for Health (HAS) is an independent public scientific authority with an overall mission of contributing to the regulation of the health care system by improving health quality and efficiency. (http://www.has-sante.fr/portail/)
Italy	Agenzia Italiana del Farmaco (Italian Medicines Agency, AIFA)	The Italian Medicines Agency (AIFA) is the national authority responsible for drug regulation in Italy. It is a public body operating autonomously, transparently, and according to cost-effectiveness criteria, under the direction of the Ministry of Health and the vigilance of the Ministry of Health and the Ministry of Economy. It cooperates with regional authorities, the National Institute of Health, research institutes, patients' associations, health professionals, scientific associations, the pharmaceutical industry, and distributors. (http://www.agenziafarmaco.com/en)
Netherlands	Nederlandse Zorgautoriteit (Dutch Healthcare Authority, NZa)	The Dutch Healthcare Authority (NZa) is an autonomous administrative authority, falling under the Dutch Ministry of Health, Welfare, and Sport (VWS). The duties and tasks of the NZa have been laid down in the Healthcare Market Regulation Act. (https://www.nza.nl/organisatie/sitewide/english/)

Country	Authoritative Body	Description (from website)
Sweden	Läkemedelsverket (Medical Products Agency, MPA)	The Medical Products Agency (MPA) is the Swedish national authority responsible for regulation and surveillance of the development, manufacturing, and marketing of drugs and other medicinal products. Its task is to ensure that both the individual patient and healthcare professionals have access to safe and effective medicinal products and that these are used in a rational and cost-effective manner. (https://lakemedelsverket.se/english/)
United Kingdom	National Institute of Health and Care Excellence (NICE)	The National Institute for Health and Care Excellence (NICE) provides national guidance and advice to improve health and social care. (https://www.nice.org.uk/)
United States	Centers of Medicare & Medicaid Services (CMS)	CMS is a federal agency within the U.S. Department of Health and Human Services (HHS) that administers the Medicare program and works in partnership with state governments to administer Medicaid, the State Children's Health Insurance Program (SCHIP), and health insurance portability standards. (https://www.cms.gov/)

Appendix C: Alternative Payment Model Types

Adapted from Garrison, 2014; INSEAD, 2014; Ferrario, 2013

Risk Type	Scheme Type	Example	Description
Financial	Patient-level	Utilization caps	Manufacturers and payers agree on a predetermined level of utilization, either by expenditure (price) or consumption (dose or time), in which the cost of using the drug beyond this limit would be the manufacturer's responsibility.
Financial	Patient-level	Manufacturer-funded treatment initiation	The manufacturer covers the cost of the drug during an initial trial period. Patients who do not respond would discontinue treatment and responders would continue treatment with the payer paying for the drug at its full price.
Financial	Population-level	Price-volume agreements	Payers specify the level of expenditure for the drug. Any utilization above this level is funded by the manufacturer, typically through a rebate back to the payer.
Financial	Population-level	Market share	Agreement between manufacturer and payer that ties financials to an agreed-upon market share allocation.
Health-outcome	Performance-based	Pattern or process of care	Payments are linked to the impact of the drug or technology on clinical decision-making or practice patterns.
Health-outcome	Performance-based	Outcomes guarantee	Arrangement between manufacturers and payers that ties financials to the drug's ability to achieve certain outcome. measures—failure to achieve agreed-upon outcome measures typically results in a rebate from the manufacturer.
Health-outcome	Conditional coverage	Coverage with evidence	Coverage for a drug is funded for eligible patients participating in a research study designed to generate

Risk Type	Scheme Type	Example	Description
		development	clinical evidence to determine future coverage decisions.
Health-outcome	Conditional coverage	Conditional treatment continuation	Coverage of the drug is initially granted, however, continued coverage is dependent on patients achieving certain agreed-upon goals, typically a clinical measure or outcome.

Appendix D: Publicly-available Alternate Payment Models

A. Alternate Payment Models in the United States		
Treatment	**Indication**	**Description**
Avastin (bevacizumab)	Breast Cancer	Roche-Genentech reduced the price of their breast cancer drug, Avastin, to $55,000 annually for patients who met certain criteria, such as annual income below $100,000 (Chase, 2008).
Oncotype Dx	Breast Cancer	At the time of its launch, there was not enough evidence to support that Oncotype Dx had clinical utility—that it could affect treatment decisions and thus patient outcomes. United Healthcare agreed to cover Oncotype Dx for 18 months, based on the assumption that it would reduce the use of chemotherapy in patients with negative test results. However, if a significant number of women were still receiving chemotherapy despite low scores, UHC would receive rebates on the test (Carlson, 2009).
Vectibix (panitumumab)	Colorectal cancer	Amgen placed a price cap on Vectibix, so that after a patient reached the cap (5% of their adjusted gross income), he or she would become eligible for the SAFETY NET(R) Foundation (Amgen, 2006).
Zocor (simvastatin)	Hypercholesterolemia	Rebate for nonperformance to refund up to six months of patients' and insurers' prescription costs if simvastatin plus diet did not help them lower low-density lipoprotein cholesterol to target levels (Neumann et al., 2011).
Repatha (evolocumab)	Hypercholesterolemia	Amgen and Harvard Pilgrim agreed on specific cholesterol targets for various patient groups, and if Repatha doesn't help patients reach their goals, the insurer can collect additional rebates. More rebates would be due if Harvard Pilgrim's spending on the drug surpasses an agreed-upon threshold. As a result, Repatha received exclusive coverage on the Harvard Pilgrim formulary in the PCSK9 category (Reinke, 2016).

A. Alternate Payment Models in the United States		
Treatment	**Indication**	**Description**
Entresto (sacubitril/valsartan)	Heart Failure	Cigna and Aetna have agreed on outcomes-based pricing deals with Novartis for its heart failure drug Entresto, which is claimed to reduce the rate of heart-failure and subsequently hospitalization due to heart failure. Initially, Entresto will be provided at a discounted rate to the health plan, and if it achieves the predetermined outcomes (not disclosed) that relate to improved patient outcomes, Novartis will receive additional reimbursement for the drug (Staton, 2016).
Januvia (sitaglyptin)/Janumet (sitagliptin+metformin)	Diabetes	Merck increases Cigna's rebate for Januvia and Janumet when there is an increase in the percentage of Cigna-insured patients who reach appropriate blood glucose levels taking any oral antidiabetic therapy. The company increases the rebate further if the percentage of patients who are adherent to Januvia or Janumet increases (Neumann, 2011).
Actonel (risendronate)	Osteoporosis	Procter & Gamble and Sanofi agreed to pay for the cost of treating fractures in patients with osteoporosis who continue to exhibit osteoporosis symptoms despite demonstrating adequate Actonel compliance (Neumann, 2011).
Sovaldi (sofosbuvir)/Harvoni (lediapsvir+sofosbuvir)	Hepatitis C	CVS Health and Anthem chose Gilead's drugs as their preferred treatment in exchange for a discount (Humer & Berkrot, 2015).
Viekira Pak (ombitasvir-paritaprevir-ritonavir+dasabuvir)	Hepatitis C	ExpressScripts covers Viekera Pak but dropped coverage of competitors Sovaldi/Harvoni in exchange for a discount from AbbVie (Humer & Berkrot, 2015).

B. Alternate Payment Models in the UK (NICE, 2016)		
Treatment	**Indication**	**Description**
Bortezomib (Velcade)	Multiple myeloma	Response scheme: NICE agreed to pay for Velcade on the condition that J&J, the manufacturer, would provide a rebate for non-responders. The Institute for Clinical and Economic Review threshold decided upon was £20,700/ quality-adjusted life-year.
Ranibizumab (Lucentis)	Macular degeneration (acute wet AMD)	Simple discount
Sunitinib (Sutent)	Renal cell carcinoma	Free stock: Pfizer agreed to provide Sutent (sunitinib) to the NHS for free during the first treatment cycle for renal cell carcinoma and gastrointestinal stromal tumor patients
Lenalidomide (Revlimid)	Multiple myeloma	Dosage cap
Cetuximab (Erbitux)	Metastatic colorectal cancer (first line)	Rebate
Sunitinib (Sutent)	Gastrointestinal stromal tumor	Free stock: Pfizer agreed to provide Sutent (sunitinib) to the NHS for free during the first treatment cycle for renal cell carcinoma and gastrointestinal stromal tumor patients
Ustekinumab (Stelera)	Moderate to severe psoriasis	Free stock
Trabectedin (Yondelis)	Advanced soft tissue sarcoma	Dosage cap
Certolizumab pegol (Cimzia)	Rheumatoid arthritis	Free initial stock: UCB agreed to provide free stock of Cimzia (Certolizumab pegol) to the NHS for the initial treatment of rheumatoid arthritis patients

B. Alternate Payment Models in the UK (NICE, 2016)		
Treatment	**Indication**	**Description**
Gefitinib (Iressa)	Non-small cell lung cancer	Single fixed price
Pazopanib (Votrient)	Advanced renal cell carcinoma	Dosage cap
Azacitidine (Vidaza)	Myelodysplastic syndromes, chronic myelomonocytic leukemia and acute myeloid leukemia	Simple discount
Golimumab (Simponi)	Psoriatic arthritis	Free stock
Romiplostim (Nplate)	Chronic idiopathic (immune) thrombocytopenic purpura	Simple discount
Golimumab (Simponi)	Rheumatoid arthritis	Free stock
Golimumab (Simponi)	Ankylosing spondylitis	Free stock
Mifamurtide (Mepact)	High-grade resectable non-metastatic osteosarcoma	Simple discount
Tocilizumab (RoActemra)	Systemic juvenile idiopathic arthritis	Simple discount

B. Alternate Payment Models in the UK (NICE, 2016)		
Treatment	**Indication**	**Description**
Nilotinib (Tasigna)	Imatinib-resistant chronic myeloid leukemia	Simple discount
Tocilizumab (RoActemra)	Rheumatoid arthritis	Simple discount
Nilotinib (Tasigna)	First-line treatment of chronic myeloid leukemia	Simple discount
Fingolimod (Gilenya)	Highly active relapsing-remitting multiple sclerosis	Simple discount
Erlotinib (Tarceva)	First-line treatment of locally advanced or metastatic EGFR-TK mutation-positive non-small-cell lung cancer	Simple discount
Abiraterone acetate (Zytiga)	Castration-resistant metastatic prostate cancer previously treated with a docetaxel containing regimen	Simple discount
Denosumab (Xgeva)	Skeletal related events in adults with bone metastases from solid tumors	Simple discount

B. Alternate Payment Models in the UK (NICE, 2016)		
Treatment	**Indication**	**Description**
Ipilimumab (Yervoy)	Advanced melanoma, second line	Simple discount
Vemurafenib (Zelboraf)	Metastatic mutation positive melanoma	Simple discount
Ranibizumab (Lucentis)	Diabetic macular edema	Simple discount
Colistimethate (Colobreathe)	Pseudomonas aeruginosa for adults and children over 6 with cystic fibrosis	Simple Discount
Tobramycin (TOBI Podhaler)	Pseudomonas aeruginosa for adults and children over 6 with cystic fibrosis	Simple Discount
Omalizumab (Xolair)	Severe persistent asthma	Simple Discount
Abatacept (Orencia)	Rheumatoid arthritis, polyarticular juvenile idiopathic arthritis	Simple Discount
Pirfenidone (Esbriet)	Mild to moderate idiopathic pulmonary fibrosis	Simple Discount
Ranibizumab (Lucentis)	Macular edema secondary to retinal vein occlusion	Simple Discount

B. Alternate Payment Models in the UK (NICE, 2016)		
Treatment	**Indication**	**Description**
Eltrombopag (Revolade)	Chronic immune (idiopathic) thrombocytopenic purpura	Simple Discount
Aflibercept (Eylea)	Wet age-related macular degeneration	Simple Discount
Ranibizumab (Lucentis)	Choroidal neovascularisation secondary to pathologic myopia	Simple Discount
Fluocinolone (Iluvien)	Diabetic macula edema	Simple Discount
Teriflunomide (Aubagio)	Active relapsing-remitting multiple sclerosis	Simple Discount
Aflibercept (Eylea)	Visual impairment caused by macular edema secondary to central retinal vein occlusion	Simple Discount
Pixantrone (Pixuvri)	Multiple relapsed or refractory aggressive non-Hodgkin's B-cell lymphoma	Simple Discount
Afatinib (Giotrif)	Locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR)	Simple Discount

B. Alternate Payment Models in the UK (NICE, 2016)		
Treatment	**Indication**	**Description**
Enzalutamide (Xtandi)	Metastatic hormone-relapsed prostate cancer in adults whose disease has progressed during or after docetaxel-containing chemotherapy	Simple Discount
Ipilimumab (Yervoy)	Adults with previously untreated advanced (unresectable or metastatic) melanoma	Simple Discount
Dimethyl fumarate (Tecfidera)	Adults with active relapsing-remitting multiple sclerosis	Simple Discount
Dabrafenib (Tafinlar)	Unresectable or metastatic melanoma with a BRAFV600 mutation	Simple Discount
Lenalidomide (Revlimid)	Myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality	Dosage cap
Golimumab (Simponi)	Moderately to severely active ulcerative colitis	Free stock

B. Alternate Payment Models in the UK (NICE, 2016)		
Treatment	**Indication**	**Description**
Axitinib (Inlyta)	Advanced renal cell carcinoma after failure of prior systemic treatment	Simple discount
Omalizumab (Xolair)	Previously treated chronic spontaneous urticaria	Simple discount
Ustekinumab (Stelara)	Active psoriatic arthritis	Free stock
Vedolizumab (Entyvio)	Moderately to severely active ulcerative colitis	Simple discount
Obinutuzumab (Gazyvaro)	Untreated chronic lymphocytic leukemia	Simple discount
Ofatumumab (Arzerra)	Untreated chronic lymphocytic leukemia	Simple discount
Aflibercept (Eylea)	Diabetic macular edema	Simple discount
Nintedanib (Vargatef)	Previously treated locally advanced, metastatic, or locally recurrent non-small-cell lung cancer	Simple discount
Secukinumab (Cosentyx)	Moderate to severe plaque psoriasis	Simple discount
Vedolizumab (Entyvio)	Moderately to severely active Crohn's disease after prior therapy	Simple discount

B. Alternate Payment Models in the UK (NICE, 2016)		
Treatment	**Indication**	**Description**
Pembrolizumab (Keytruda)	Advanced melanoma after disease progression with ipilimumab	Simple discount
Tolvaptan (Jinarc)	Autosomal dominant polycystic kidney disease	Simple discount
Pembrolizumab (Keytruda)	Advanced melanoma not previously treated with ipilimumab	Simple discount
Abatacept (Orencia)	Polyarticular juvenile idiopathic arthritis	Simple discount
Tocilizumab (RoActemra)	Polyarticular juvenile idiopathic arthritis	Simple discount
Erlotinib (Tarceva)	Non-small-cell lung cancer that has progressed after prior chemotherapy	Simple discount
Elosulfase alfa (Vimizim)	Mucopolysaccharidosis type IVa	Simple discount
Certolizumab pegol (Cimzia	For rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed	Free stock (operational scheme with new indication)

B. Alternate Payment Models in the UK (NICE, 2016)		
Treatment	**Indication**	**Description**
Abatacept (Orencia)	For rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed	Simple discount (operational scheme with new indication)
Tocilizumab (RoActemra)	For rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed	Simple discount (operational scheme with new indication)
Golimumab (Simponi)	For rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed	Free stock (operational scheme with new indication)
Radium-223 dichloride (Xofigo)	Hormone-relapsed prostate cancer with bone metastases	Simple discount (fixed price)
Enzalutamide (Xtandi)	Metastatic hormone-relapsed prostate cancer before chemotherapy is indicated	Simple discount (operational scheme with new indication)
Nintedanib (Ofev)	Idiopathic pulmonary fibrosis	Simple discount (fixed price) (operational scheme with new indication)

B. Alternate Payment Models in the UK (NICE, 2016)		
Treatment	**Indication**	**Description**
Panobinostat (Farydak)	Multiple myeloma after at least 2 previous treatments	Simple discount (fixed price)
Olaparib (Lynparza)	Maintenance treatment of relapsed, platinum-sensitive, BRCA mutation-positive ovarian, fallopian tube and peritoneal cancer after response to second-line or subsequent platinum-based chemotherapy	Time cap
Certolizumab pegol (Cimzia)	TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis	First 12 weeks free of charge, equivalent to 10 vials.
Golimumab (Simponi)	TNF-alpha inhibitors for ankylosing spondylitis.	Free stock (operational scheme with new indication)
Ruxolitinib (Jakavi)	Disease-related splenomegaly or symptoms in adults with myelofibrosis.	Simple discount
Cabazitaxel (Jevtana)	Hormone-relapsed metastatic prostate cancer treated with docetaxel.	Simple discount

C. Alternate Payment Models in Italy (Agenzia Italiana del Farmaco [AIFA], 2016)		
Treatment	**Indication**	**Description**
Vidaza	Acute myeloid leukemia	Financial-based agreement
Revlimid	Amyloidosis AL	Appropriateness control
Velcade	Amyloidosis AL	Appropriateness control
Eliquis	Arthroplasty Venous Thromboembolism	Appropriateness control
Pradaxa	Arthroplasty, Replacement Venous Thromboembolism	Appropriateness control
Eliquis	Arthroplasty, Replacement Venous Thromboembolism	Appropriateness control
Pradaxa	Arthroplasty, Replacement Venous Thromboembolism	Appropriateness control
Xarelto	Arthroplasty, Replacement Venous Thromboembolism	Appropriateness control
Xarelto	Arthroplasty, Replacement Venous Thromboembolism	Appropriateness control
Prolia	Bone Resorption Osteoporosis, Postmenopausal	Appropriateness control
Afinitor	Breast Neoplasms	Outcomes-based agreement
Avastin	Breast Neoplasms	Outcomes-based agreement

C. Alternate Payment Models in Italy (Agenzia Italiana del Farmaco [AIFA], 2016)		
Treatment	**Indication**	**Description**
Halaven	Breast Neoplasms	Outcomes-based agreement
Kadcyla	Breast Neoplasms	Outcomes-based agreement
Perjeta	Breast Neoplasms	Appropriateness control
Tyverb	Breast Neoplasms	Outcomes-based agreement
Tyverb	Breast Neoplasms	Outcomes-based agreement
Erivedge	Carcinoma, Basal Cell	Financial-based agreement
Nexavar	Carcinoma, Hepatocellular	Outcomes-based agreement
Alimta	Carcinoma, Non-Small-Cell Lung	Outcomes-based agreement
Avastin	Carcinoma, Non-Small-Cell Lung	Outcomes-based agreement
Giotrif	Carcinoma, Non-Small-Cell Lung	Outcomes-based agreement
Iressa	Carcinoma, Non-Small-Cell Lung	Outcomes-based agreement
Opdivo	Carcinoma, Non-Small-Cell Lung	Appropriateness control
Tarceva	Carcinoma, Non-Small-Cell Lung	Financial-based agreement
Tarceva	Carcinoma, Non-Small-Cell Lung	Financial-based agreement

C. Alternate Payment Models in Italy (Agenzia Italiana del Farmaco [AIFA], 2016)		
Treatment	**Indication**	**Description**
Xalkori	Carcinoma, Non-Small-Cell Lung	Outcomes-based agreement
Afinitor	Carcinoma, Renal Cell	Outcomes-based agreement
Avastin	Carcinoma, Renal Cell	Outcomes-based agreement
Inlyta	Carcinoma, Renal Cell	Outcomes-based agreement
Nexavar	Carcinoma, Renal Cell	Financial-based agreement
Sutent	Carcinoma, Renal Cell	Financial-based agreement
Torisel	Carcinoma, Renal Cell	Outcomes-based agreement
Votrient	Carcinoma, Renal Cell	Outcomes-based agreement
Javlor	Carcinoma, Transitional Cell Urologic Neoplasms	Outcomes-based agreement
Mnesis	Cardiomyopathy in Friedreich's ataxia	Appropriateness control
Toctino	Chronic eczema	Appropriateness control
Igvena	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)	Appropriateness control
Venital	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)	Appropriateness control

C. Alternate Payment Models in Italy (Agenzia Italiana del Farmaco [AIFA], 2016)		
Treatment	**Indication**	**Description**
Privigen	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) in children	Appropriateness control
Bosulif	Chronic myeloid leukemia Ph+	Outcomes-based agreement
Vidaza	Chronic myelomonocytic leukemia	Financial-based agreement
Humira	Colitis, Ulcerative	Outcomes-based agreement
Inflectra	Colitis, Ulcerative	Appropriateness control
Remicade	Colitis, Ulcerative	Appropriateness control
Simponi	Colitis, Ulcerative	Outcomes-based agreement
Avastin	Colorectal Neoplasms	Outcomes-based and financial agreement
Erbitux	Colorectal Neoplasms	Outcomes-based agreement
Vectibix	Colorectal Neoplasms	Outcomes-based agreement
Zaltrap	Colorectal Neoplasms	Financial-based agreement
Kalydeco	Cystic Fibrosis	Appropriateness control
Lucentis	Diabetes Complications Macular Edema	Outcomes-based agreement
Xiapex	Dupuytren Contracture	Outcomes-based agreement

C. Alternate Payment Models in Italy (Agenzia Italiana del Farmaco [AIFA], 2016)		
Treatment	**Indication**	**Description**
Eylea	Edema Diabetes Complications	Appropriateness control
Trobalt	Epilepsy	Appropriateness control
Xgeva	Fractures, Bone Neoplasm Metastasis	Appropriateness control
Erbitux	Head and Neck Neoplasms	Outcomes-based agreement
Mozobil	Hematopoietic Stem Cell Transplantation Lymphoma Multiple Myeloma	Outcomes-based agreement
Daklinza	Hepatitis C, Chronic	Financial-based agreement
Harvoni	Hepatitis C, Chronic	Financial-based agreement
Olysio	Hepatitis C, Chronic	Financial-based agreement
Sovaldi	Hepatitis C, Chronic	Financial-based agreement
Victrelis	Hepatitis C, Chronic	Appropriateness control
Viekirax Exviera	Hepatitis C, Chronic	Financial-based agreement
Adcetris	Hodgkin Disease	Financial-based agreement
Adempas	Hypertension, Pulmonary	Appropriateness control
Signifor	Hypopituitarism	Outcomes-based agreement
Esbriet	Idiopathic Pulmonary Fibrosis	Appropriateness control

C. Alternate Payment Models in Italy (Agenzia Italiana del Farmaco [AIFA], 2016)		
Treatment	**Indication**	**Description**
Samsca	Inappropriate ADH Syndrome	Appropriateness control
Arzerra	Leukemia, Lymphocytic, Chronic, B-Cell	Financial-based agreement
Iclusig	Leukemia, Lymphoid Leukemia, Myeloid	Outcomes-based agreement
Iclusig	Leukemia, Lymphoid Leukemia, Myeloid	Outcomes-based agreement
Revlimid	Leukemia, Myelogenous, Chronic	Appropriateness control
Revlimid	Leukemia, Myelogenous, Chronic	Appropriateness control
Tasigna	Leukemia, Myelogenous, Chronic, BCR-ABL Positive	Financial-based agreement
Tasigna	Leukemia, Myelogenous, Chronic, BCR-ABL Positive	Outcomes-based agreement
Sprycel	Leukemia, Myelogenous, Chronic, BCR-ABL Positive Precursor Cell Lymphoblastic Leukemia-Lymphoma	Financial-based agreement

C. Alternate Payment Models in Italy (Agenzia Italiana del Farmaco [AIFA], 2016)		
Treatment	**Indication**	**Description**
Sprycel	Leukemia, Myelogenous, Chronic, BCR-ABL Positive Precursor Cell Lymphoblastic Leukemia-Lymphoma	Financial-based agreement
Dacogen	Leukemia, Myeloid	Financial-based agreement
Benlysta	Lupus Erythematosus, Systemic	Appropriateness control
Zevalin	Lymphoma, Follicular	Appropriateness control
Torisel	Lymphoma, Mantle-Cell	Financial-based agreement
Adcetris	Lymphoma, Non-Hodgkin	Financial-based agreement
Mabthera	Lymphoma, Non-Hodgkin	Appropriateness control
Eylea	Macular Edema	Appropriateness control
Lucentis	Macular Edema	Outcomes-based agreement
Tafinlar	Melanoma	Outcomes-based agreement
Tafinlar	Melanoma	Outcomes-based agreement
Yervoy	Melanoma	Outcomes-based agreement
Zelboraf	Melanoma	Outcomes-based agreement
Zelboraf	Melanoma	Outcomes-based agreement
Elaprase	Mucopolysaccharidosis II	Appropriateness control

C. Alternate Payment Models in Italy (Agenzia Italiana del Farmaco [AIFA], 2016)		
Treatment	**Indication**	**Description**
Revlimid	Multiple Myeloma	Appropriateness control
Thalidomide	Multiple Myeloma	Appropriateness control
Thalidomide	Multiple Myeloma	Appropriateness control
Revlimid	Myelodysplastic Syndromes	Appropriateness control
Vidaza	Myelodysplastic Syndromes	Financial-based agreement
Jakavi	Myeloproliferative Disorders	Outcomes-based agreement
Lucentis	Myopia, Degenerative	Outcomes-based agreement
Mepact	Osteosarcoma	Appropriateness control
Avastin	Ovarian Neoplasms	Outcomes-based agreement
Avastin	Ovarian Neoplasms	Outcomes-based agreement
Yondelis	Ovarian Neoplasms	Outcomes-based agreement
Abraxane	Pancreatic Neoplasms	Outcomes-based agreement
Afinitor	Pancreatic Neoplasms	Outcomes-based agreement
Atriance	Precursor T-Cell Lymphoblastic Leukemia-Lymphoma	Appropriateness control

C. Alternate Payment Models in Italy (Agenzia Italiana del Farmaco [AIFA], 2016)		
Treatment	**Indication**	**Description**
Atriance	Precursor T-Cell Lymphoblastic Leukemia-Lymphoma	Appropriateness control
Jevtana	Prostatic Neoplasms	Appropriateness control
Xtandi	Prostatic Neoplasms	Financial-based agreement
Zytiga	Prostatic Neoplasms	Outcomes-based agreement
Zytiga	Prostatic Neoplasms	Financial-based agreement
Daxas	Pulmonary Disease, Chronic Obstructive	Appropriateness control
Nplate	Purpura, Thrombocytopenic, Idiopathic	Appropriateness control
Revolade	Purpura, Thrombocytopenic, Idiopathic	Appropriateness control
Votrient	Sarcoma	Financial-based agreement
Yondelis	Sarcoma	Outcomes-based agreement

C. Alternate Payment Models in Italy (Agenzia Italiana del Farmaco [AIFA], 2016)		
Treatment	**Indication**	**Description**
Sativex	Spasticity in multiple sclerosis	Outcomes-based agreement
Humira	Spondylitis, Ankylosing	Outcomes-based agreement
Herceptin	Stomach Neoplasms	Outcomes-based agreement
Caprelsa	Thyroid Neoplasms	Financial-based agreement
Sirturo	Tuberculosis, Multidrug-Resistant	Financial-based agreement
Orfadin	Tyrosinemias	Appropriateness control
Avastin	Wet Macular Degeneration	Appropriateness control
Eylea	Wet Macular Degeneration	Appropriateness control
Lucentis	Wet Macular Degeneration	Outcomes-based agreement
Macugen	Wet Macular Degeneration	Outcomes-based agreement

Appendix E: Medicaid MCOs and their Parent Firms

Adapted from the Henry J. Kaiser Family Foundation State Health Facts project

State	Medicaid MCO	Parent Firm
Arizona	**13 Health Plans**	
	Care1st Arizona	Blue Shield of California
	Cenpatico Integrated Care	
	Children's Rehabilitative Services (CRS)	UnitedHealth Group
	Department of Economic Services (DES) Foster Care	
	Health Choice	IASIS Healthcare
	Health Choice Integrated Care	IASIS Healthcare
	Health Net Access	Centene
	Maricopa Health Plan	
	Mercy Care Plan	
	Mercy Maricopa Integrated Care	
	Phoenix Health Plan	
	UnitedHealthcare Community Plan	UnitedHealth Group
	University Family Care	
California	**22 Health Plans**	
	Alameda Alliance for Health	
	Anthem Blue Cross Partnership Plan	Anthem
	California Health & Wellness	Centene
	CalOptima*	
	CalViva Health	
	Care1st Partner Plan, LLC	Blue Shield of California
	CenCal Health*	
	Central California Alliance for Health*	
	Community Health Group Partnership Plan	
	Contra Costa Health Plan	
	Gold Coast Health Plan*	
	Health Net Community Solutions, Inc.	Centene

State	Medicaid MCO	Parent Firm
	Health Plan of San Joaquin	
	Health Plan of San Mateo*	
	Inland Empire Health Plan	
	Kaiser Permanente	Kaiser Permanente
	Kern Family Health Care	
	L.A. Care Health Plan	
	Molina Healthcare of California Partner Plan, Inc.	Molina
	Partnership Health Plan of California*	
	San Francisco Health Plan	
	Santa Clara Family Health Plan	
Colorado	**2 Health Plans**	
	Denver Health Medicaid Choice Plan	
	Rocky Mountain Health Plans	
Delaware	**2 Health Plans**	
	Highmark Health Options	
	UnitedHealthcare Community Plan of Delaware	UnitedHealth Group
District of Columbia	**4 Health Plans**	
	AmeriHealth Caritas	Independence Health Group
	Health Services for Children with Special Needs	
	MedStar Family Choice	MedStar Health
	Trusted Health Plan	
Florida	**17 Health Plans**	
	AHF / Positive Healthcare	
	Amerigroup Florida, Inc.	Anthem
	Better Health	Anthem
	Children's Medical Services Plan**	
	Coventry Health Care of Florida	Aetna
	Freedom Health, Inc.	
	Humana Medical Plan	Humana
	Magellan Complete Care, LLC	

State	Medicaid MCO	Parent Firm
	Molina Healthcare of Florida	Molina
	Prestige Health Choice	
	Simply DBA Clear Health Alliance	Anthem
	Simply Healthcare Plans, Inc.	Anthem
	South Florida Community Care Network (SFCCN)	
	Staywell Health Plan of Florida	WellCare
	Sunshine State Health Plan, Inc.	Centene
	Sunshine State Health Plan, Inc. (Foster Care)	Centene
	UnitedHealthcare of Florida	UnitedHealth Group
Georgia	**3 Health Plans**	
	Amerigroup Community Care	Anthem
	Peach State Health Plan	Centene
	WellCare	WellCare
Hawaii	**5 Health Plans**	
	AlohaCare	
	Hawaii Medical Service Association	
	Kaiser Foundation Health Plan	Kaiser Permanente
	Ohana Health Plan	WellCare
	UnitedHealthcare Community Plan	UnitedHealth Group
Illinois	**12 Health Plans**	
	Aetna Better Health	Aetna
	Blue Cross Community Plan	Health Care Service Corporation
	Cigna HealthSpring	Cigna
	Community Care Alliance of Illinois	
	CountyCare	
	Family Health Network	
	Harmony Health Plan	WellCare
	Health Alliance Medical Plan	
	Humana Health Plan	Humana
	IlliniCare Health	Centene

State	Medicaid MCO	Parent Firm
	Meridian Health Plan	Meridian Health Plan
	Molina Healthcare	Molina
Indiana	**3 Health Plans**	
	Anthem BlueCross BlueShield	Anthem
	Managed Health Services (MHS)	Centene
	MDWise Hoosier Alliance	Independence Health Group
Iowa	**3 Health Plans**	
	Amerigroup Iowa, Inc.	Anthem
	AmeriHealth Caritas Iowa, Inc.	Independence Health Group
	UnitedHealthcare Plan of the River Valley, Inc.	UnitedHealth Group
Kansas	**3 Health Plans**	
	Amerigroup Kansas, Inc.	Anthem
	Sunflower State Health Plan	Centene
	UnitedHealthcare Community Plan of Kansas	UnitedHealth Group
Kentucky	**5 Health Plans**	
	Aetna Better Health***	Aetna
	Anthem Kentucky	Anthem
	Humana CareSource	Humana
	Passport Health Plan	
	WellCare of Kentucky	WellCare
Louisiana	**5 Health Plans**	
	Aetna Better Health of Louisiana	Aetna
	Amerigroup Louisiana	Anthem
	AmeriHealth Caritas Louisiana	Independence Health Group
	Louisiana Healthcare Connections	Centene
	UnitedHealthcare Community Plan	UnitedHealth Group
Maryland	**8 Health Plans**	
	Amerigroup Community Care	Anthem
	Jai Medical Systems	
	Kaiser Permanente	Kaiser Permanente

State	Medicaid MCO	Parent Firm
	Maryland Physicians Care	
	Medstar Family Choice	MedStar Health
	Priority Partners	
	Riverside Health of Maryland	
	UnitedHealthcare Community Plan	UnitedHealth Group
Massachusetts	**6 Health Plans**	
	BMC HealthNet Plan	BMC HealthNet
	CeltiCare Health	Centene
	Fallon Health***	
	Health New England	
	Neighborhood Health Plan	
	Tufts Health Plan***	
Michigan	**11 Health Plans**	
	Blue Cross Complete of Michigan	
	CoventryCares of Michigan	Aetna
	HAP Midwest Health Plan, Inc.	
	Harbor Health Plan	
	McLaren Health Plan	
	Meridian Health Plan of Michigan	Meridian Health Plan
	Molina Healthcare of Michigan	Molina
	Priority Health Choice, Inc.	
	Total Health Care	
	UnitedHealthcare Community Plan	UnitedHealth Group
	Upper Peninsula Health Plan	
Minnesota	**9 Health Plans**	
	Blue Plus	
	HealthPartners	
	Hennepin Health	
	Itasca Medical Care (IMCare)	
	Medica	
	Metropolitan Health Plan	
	PrimeWest Health	

State	Medicaid MCO	Parent Firm
	South Country Health Alliance	
	UCare	
Mississippi	**2 Health Plans**	
	Magnolia Health	Centene
	United Healthcare Community Plan	UnitedHealth Group
Missouri	**3 Health Plans**	
	Aetna Better Health of Missouri	Aetna
	Home State Health Plan	Centene
	Missouri Care	WellCare
Nebraska	**3 Health Plans**	
	Aetna Better Health of Nebraska	Aetna
	Arbor Health Plan	Independence Health Group
	UnitedHealthcare Community Plan	UnitedHealth Group
Nevada	**2 Health Plans**	
	Amerigroup	Anthem
	Health Plan of Nevada	UnitedHealth Group
New Hampshire	**2 Health Plans**	
	New Hampshire Healthy Families	Centene
	Well Sense Health Plan	BMC HealthNet
New Jersey	**5 Health Plans**	
	Aetna Better Health of New Jersey	Aetna
	Amerigroup NJ	Anthem
	Horizon NJ Health	
	UnitedHealthcare Community Plan	UnitedHealth Group
	WellCare	WellCare
New Mexico	**4 Health Plans**	
	Blue Cross Blue Shield of New Mexico	Health Care Service Corporation
	Molina Healthcare	Molina
	Presbyterian Health Plan, Inc.	
	UnitedHealthcare Community Plan	UnitedHealth Group

State	Medicaid MCO	Parent Firm
New York	**25 Health Plans**	
	Affinity Health Plan	
	Amida Care SN	
	Capital District Physicians Health Plan	
	Crystal Run Health Plan	
	ElderPlan	
	Empire BlueCross BlueShield HealthPlus***	Anthem
	Excellus Health Plan	
	Fidelis	
	Guildnet	
	HealthFirst	
	HealthNow	
	HIP of Greater New York	
	Hudson Health Plan	
	Independent Health Association	
	Liberty Health Advantage	
	MetroPlus Health Plan	
	MVP Health Plan	
	NYS Catholic Health Plan	
	Senior Whole Health	
	Today's Option	
	Touchstone/Prestige	
	UnitedHealthcare Community Plan	UnitedHealth Group
	VNS Choice	
	WellCare of New York	WellCare
	YourCare Health Plan***	
North Dakota	**1 Health Plan**	
	Sanford Health Plan	
Ohio	**5 Health Plans**	
	Buckeye Community Health Plan	Centene
	CareSource	

State	Medicaid MCO	Parent Firm
	Molina Healthcare	Molina
	Paramount Advantage	
	UnitedHealthcare Community Plan	UnitedHealth Group
Oregon	**16 Health Plans**	
	AllCare Health Plan, Inc.	
	Cascade Health Alliance	
	Columbia Pacific CCO, LLC	
	Eastern Oregon CCO, LLC	
	FamilyCare CCO	
	Health Share of Oregon	
	Intercommunity Health Network	
	Jackson Care Connect	
	PacificSource Community Solutions - Central Oregon	
	PacificSource Community Solutions - Columbia Gorge	
	PrimaryHealth Josephine County CCO	
	Trillium Community Health Plan	
	Umpqua Health Alliance, DCIPA	
	Western Oregon Advanced Health	
	Willamette Valley Community Health	
	Yamhill Community Care	
Pennsylvania	**9 Health Plans**	
	Aetna Better Health	Aetna
	AmeriHealth Caritas Pennsylvania	Independence Health Group
	AmeriHealth Northeast	Independence Health Group
	Gateway Health	
	Geisinger Health Plan	
	Health Partners Plans	
	Keystone First	Independence Health Group
	UnitedHealthcare Community Plan of Pennsylvania	UnitedHealth Group

State	Medicaid MCO	Parent Firm
	UPMC Health Plan	
Rhode Island	**2 Health Plans**	
	Neighborhood Health Plan of Rhode Island	
	UnitedHealthcare of New England	UnitedHealth Group
South Carolina	**6 Health Plans**	
	Absolute Total Care, Inc.	Centene
	Advicare	
	BlueChoice Healthplan SC	
	First Choice	Independence Health Group
	Molina Healthcare of South Carolina	Molina
	WellCare of South Carolina	WellCare
Tennessee	**4 Health Plans**	
	Amerigroup	Anthem
	BlueCare	
	TennCare Select	
	UnitedHealthcare Community Plan	UnitedHealth Group
Texas	**19 Health Plans**	
	Aetna Better Health	Aetna
	Amerigroup	Anthem
	Blue Cross Blue Shield of Texas	Health Care Service Corporation
	CHRISTUS Health Plan	
	Cigna HealthSpring	Cigna
	Community First Health Plans	
	Community Health Choice	
	Cook Children's Health Plan	
	Driscoll Children's Health Plan	
	El Paso First Premier Plan	
	FirstCare	
	Molina Healthcare of Texas	Molina

State	Medicaid MCO	Parent Firm
	Parkland Community Health Plan, Inc.	
	RightCare from Scott & White Health Plan	
	Sendero Health Plans	
	Seton Health Plan	
	Superior HealthPlan	Centene
	Texas Children's Health Plan	
	UnitedHealthcare Community Plan	UnitedHealth Group
Utah	**4 Health Plans**	
	HealthChoice Utah	IASIS Healthcare
	Healthy U	
	Molina Healthcare	Molina
	SelectHealth Community Care	
Virginia	**6 Health Plans**	
	Anthem Health Keepers Plus	Anthem
	CoventryCares of Virginia	Aetna
	INTotal Health (Inova)	
	Kaiser Permanente	Kaiser Permanente
	OptimaHealth	
	VA Premier Health Plan, Inc.	
Washington	**5 Health Plans**	
	Amerigroup Washington Inc.	Anthem
	Community Health Plan of Washington	
	Coordinated Care Corporation	Centene
	Molina Healthcare of Washington, Inc.	Molina
	UnitedHealthcare Community Plan	UnitedHealth Group
West Virginia	**4 Health Plans**	
	Coventry Cares of West Virginia	Aetna
	Health Plan of the Upper Ohio Valley	
	Unicare	Anthem
	West Virginia Family Health	
Wisconsin	**20 Health Plans**	

State	Medicaid MCO	Parent Firm
	Anthem Blue Cross and Blue Shield	Anthem
	Care Wisconsin Health Plan, Inc.	
	Children's Community Health Plan	
	Compcare	Anthem
	Dean Health Plan, Inc.	
	Group Health Cooperative of Eau Claire	
	Group Health Cooperative of South Central Wisconsin	
	Gundersen Lutheran Health Plan	
	Health Tradition Healthplan	
	Independent Care (iCare)	Humana
	Managed Health Services	Centene
	Mercy Care Insurance Company	
	MHS Health Wisconsin	Centene
	Molina Healthcare	Molina
	Network Health Plan	
	Physicians Plus Insurance Corporation	
	Security Health Plan of Wisconsin	
	Trilogy Health Insurance, Inc.	
	UnitedHealthcare Community Plan	UnitedHealth Group
	Unity Healthplans Insurance Corporation	

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