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Utilization Management Regulatory & Market Trends:

2016 Annual Report

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Foreword

The medical management system supporting health plans, providers, purchasers and consumers is both dynamic and complex. The payer-based component of the medical management system is comprised of many "managed care" functions including utilization review, case management, care management, population health management, disease management, independent and external review, and telephonic triage services. Today, patient care is coordinated through condition management programs that are evidence-based and supported by technology. The conditions and timing under which care is reimbursed by health plans, insurance companies, risk-bearing provider entities, self-funding employers and other payers remains a critical component of medical management systems, and is key to cost containment strategies.

As fee-for-service health care provides an incentive for over-utilization, the medical management system acts as a counterbalance to ensure that patients are not subjected to unnecessary and potentially harmful care. Balancing the need to pay for care with the need to ensure that the right level of care is being delivered can be a nuanced endeavor. Utilization review (UR) and utilization management (UM) programs have assumed a central role in helping determine the best balance between limited premium dollars while optimizing quality.

While the medical management system serves as a counterbalance against over-utilization by health care providers, UR/UM (hereinafter "UM") regulations in turn serve as a counterbalance against the "corporate practice" of medicine. The regulations were originally drafted to protect patients and ensure the integrity of the process through which benefit determinations are made, denied, and appealed.

Since medicine is constantly evolving and practice patterns vary from region to region, it can be complicated for the medical management system to determine what is "medically necessary and appropriate" or a "covered benefit". In practice, doing so involves a partnership between the sponsor of the health care coverage (i.e. payer or employer), the providers, and other stakeholders (e.g., plan medical directors, third party administrators, specialty societies, and others). While many hold that all medically necessary care should be delivered to the patient, sometimes that is not always a clear-cut decision: Is the treatment experimental? Does the literature show an improvement in health outcomes with the treatment? Will the management change as a result of the diagnostic test or treatment? Is the service safe and effective for the patient? Matters are complicated when there is conflicting evidence in the literature or an inconsistent standard of care nationally or internationally.

In addition to having to respond to changes in medicine, the medical management system is itself in flux. Payer-sponsored UM programs have had to respond to recent regulatory requirements and market trends, including:

- The expanded coverage requirements offered through the Patient Protection and Affordable Care Act (ACA);
- The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), originally adopted to end discriminatory health care practices against those with mental illness and/or addiction;
- The rise of genomics and other emerging personalized diagnostic and treatment options; and
- The increasing prevalence of high-cost specialty, oncology, and orphan drugs.

This *Trend Report* highlights the complex web of regulations and advisory opinions that impact how patients, providers, payers and others actually pay for care, and how appeals for adverse benefit determinations are decided. It is our hope that this *Trend Report* will stimulate public policy debate to identify best practices in terms of complying with regulatory requirements and updating key medical management practices by payers.

Garry Carneal, JD, MA
RegQuest Founder

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Mr. Atlas is President of EBG Advisors, Inc. He serves as an executive consultant on strategy, policy analysis, program development, and performance improvement for health providers, payers, policymakers, product markets, investors, and others. An expert in managed/accountable care, health care finance, and service delivery, he has more than 35 years of experience as an advisor to leaders and governing authorities in both the private and public sectors.

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Currently, Carneal serves as President and CEO, Schooner Strategies; Senior Policy Advisor, The Kennedy Forum; and Founder, RegQuest. Carneal has held a number of positions where he has helped form national standards for utilization management programs. In the early 1990s, he served as legislative counsel of the National Association of Insurance Commissioners (NAIC) where he served as primary staff drafting the Model Utilization Management Act, now called the Utilization Review and Benefit Determination Model Act. From 1995 to 2005, he served as President and CEO of URAC, where he oversaw the development and/or revisions of accreditation standards covering utilization management, case management, disease management, external review and nurse triage programs. He also served as executive editor for the three previous studies published by URAC in 1999, 2001, and 2005, examining UM regulatory and market trends.

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Executive Summary

This report entitled, *Utilization Management Regulatory & Market Trends: 2016 Annual Report*, provides a comprehensive update on a key element of the medical management system. To the best of our knowledge, this is the first and most complete report on utilization management trends in over ten years. Beginning in 2014, EBG Advisors and Schooner Strategies collaborated to update the 50 State Survey on utilization management laws and regulations. This 2016 report is provided exclusively through RegQuest, a joint venture between EBG Advisors and Schooner Strategies.

Over the years, utilization management has come to occupy a critical role supporting virtually all forms of managed care, including health maintenance organizations (HMOs), preferred provider organizations (PPOs), managed indemnity programs, third party administrator (TPA) offerings, workers' compensation programs and various medical management organizations. This critical role has expanded to the point where UM applies in virtually all health coverage contexts.

- Part I provides the history of UM as a cost containment tool in the early days of Medicare and Medicaid. Definitions of key terms are provided.
- Part II presents an overview of the appeals system associated with UM decisions.
- Part III summarizes the key findings from the 2015 UM Regulatory Survey covering the basic UM regulatory and licensing requirements, including a spotlight on selected states.[1]
- Part IV highlights several federal regulations impacting UM programs, including a look at the Federal HMO Act, Medicare and the Affordable Care Act.
- Part V analyzes current regulatory trends in the areas of accreditation, external review, mental health parity and specialty UM.
- Part VI examines key UM market and public policy trends including medical management integration, the corporate practice of medicine, patient safety issues, provider-based UM programs, and the role of guidelines and evidence-based medicine.
- Part VII assesses the return on investment (ROI) of UM and considers whether the true value of UM lies in measuring patient outcomes.
- Part VIII provides an overview of litigation in the field of UM.
- Part IX offers our perspective on the future of UM

The Appendices cover several important areas:

- Appendix A provides the methodology used for the regulatory survey.
- Appendix B contains a timeline of health utilization management trends.
- Appendix C contains an issue brief on population health management trends.

The goal of this report is to help the reader better understand both the ongoing evolution of UM functions and how to best navigate this complex regulatory environment.

Introduction

Managed care, defined as, "a method of health care delivery that focuses on collaboration among and coordination of all services to avoid overlap, duplication, and delays and to reduce costs," relies upon utilization management as a key tool to achieve its goals.[2] Utilization review/utilization management (UM) is the review of appropriateness and necessity of care provided to patients.[3] As a practice, UM interventions also are geared to standardize care, contain costs, improve quality and patient safety, and reduce unnecessary medical treatments. Today, UM covers pre-certification, concurrent review, discharge planning, retrospective review, and appeals of adverse benefit determinations. Ultimately, the primary objective of UM is to ensure that patients receive the appropriate level of care.[4]

As a practice, UM interventions also are geared to standardize care, contain costs, improve quality and patient safety, and reduce unnecessary medical treatments.

The interdependence of UM and managed care has existed for over forty years. As medical necessity and cost containment activities matured in managed care settings, policymakers supported the use of UM as the tool by which health care organizations can determine the type and intensity of services their covered lives receive. By regulating the UM process, government officials are working to limit perceived abusive or overly restrictive practices and to create a rubric through which patients obtain care through medical necessity determinations.

As highlighted throughout this *Trend Report*, many market and regulatory forces impact UM programs. This study focuses primarily on payer-based UM interactions, along with several related medical management systems.

Part I: Medical Management Overview

The creation and proliferation of what we now think of as modern health insurance did not generally occur in the United States until the 1930s. Prior to that time, if a patient could not pay for his or her care, providers largely absorbed these costs with some assistance from local governments, religious groups and private charities. Health insurance became more widespread during the Great Depression when private sector community groups began to accept premiums of roughly 50 to 75 cents per month to pay for hospital benefit plans. Following World War II, employer-sponsored coverage grew considerably as a way for businesses to enhance employee compensation during a government-imposed wage freeze; more than 30 million people gained private insurance.[5]

Some UM-like activities were sporadically used in an effort to cope with a shortage of hospital beds throughout World War II; however, the first explicit use of retrospective utilization review began in the 1950s. The 1950s also saw the first attempts to require second opinions, however these measures were not widely implemented until the 1970s. One of the first efforts to contain costs via use of a third party began with the organization of the San Joaquin County Foundation for Medical Care (FMC) in 1954. San Joaquin's model was quickly replicated and by 1973, there were 61 FMCs in 27 states. The roots of many utilization management practices are traced back to FMCs, including model treatment profiles used to assess physician performance, protocols for reviewing ambulatory care, and computerized screening of claims.[6]

The federal government turned to UM and cost containment practices as part of the creation of its Medicare and Medicaid programs in the 1960s (the Social Security Amendments of 1965, P.L. 89-97). In fact, to participate in the Medicare program, hospitals and extended-care facilities were required to have operational utilization review committees.[7] Initial cost containment strategies focused on expanding and strengthening provider-based utilization review. After those efforts proved inadequate to contain costs, Congress provided for the establishment of professional standards review organizations (PSROs) to control costs through independent peer review in the Social Security Amendments of 1972 (P.L. 92-603). These physician-controlled community organizations were required to perform preadmission review, concurrent review and retrospective review.

But, these efforts proved inadequate and Congress replaced PSROs with statewide utilization and quality control peer review organizations (PROs) in 1983 (P.L. 98-21).

The federal government continued to experiment with alternative methods of containing costs by examining new payment models. The passage of the federal Health Maintenance Organization (HMO) Act in 1973 (P.L. 93-222) demonstrated the government's commitment to curb inflation and control medical costs. Federal qualification required an HMO to have an ongoing quality assurance program and report information concerning the utilization of services to the Department of Health and Human Services (HHS).[8] In 1978, Michigan became the first state to create an independent medical review program.[9] As a result of these changes, in the 1980s and 1990s managed care emerged into the spotlight.

In the 1980s, participation in HMOs expanded dramatically – 236 HMOs served 9 million members in 1980. By the end of that decade, 591 HMOs covered over 34 million enrollees.[10] Businesses also shifted to providing HMO coverage to employees. The proportion of employees from large businesses (over 200 employees) enrolled in managed care plans grew from 5% in 1984 to 50% in 1993.[11]

As managed care continued to grow in popularity, critics became more vocal about its shortfalls, particularly as related to the control of health care utilization.[12] Consumer advocates cited concerns with the lack of due process within some of the utilization review functions by health plans, private review agents, and utilization review organizations. In many cases, clinical guidelines were not used consistently, non-physicians were increasingly denying claims, and no clear cut appeals process existed. These factors all impacted the integrity of the UM process.

Concerns over the integrity of UM led Maryland and Arkansas to establish the first registration and certification processes of utilization review organizations in the late 1980's. Organizations running UM programs were required to submit information on confidentiality policies, clinical review criteria, their staffing criteria, accessibility to patients and providers, and to report on their appeals process.[13] A wave of litigation in the 1990s led states to adopt regulations limiting potential abuses of managed care. The majority of these laws were passed between 1992 through 2002, with nearly all states having passed patient protection or consumer-oriented laws and/or regulations.[14]

Ongoing concerns about the integrity of the UM process prompted a wide group of stakeholders to form the Utilization Review Accreditation Commission in 1989, now URAC, as a way to create national standards addressing the anti-managed care backlash. In addition, the National Association of Insurance Commissioners (NAIC) published its first version of The Utilization Review Model Act in 1994. By the late 1990s, almost all states had adopted legislation governing UM functions which applied to different health carrier arrangements and standalone utilization review organizations.

In 2002, the regulatory environment for UM changed significantly with the implementation of the U.S. Department of Labor's (DOL) claims procedure regulations. These regulations, issued under authority created by the Employee Retirement Income Security Act of 1974 (ERISA; P.L. 93-406), were the federal government's first major foray into the oversight of medical management processes outside of Medicare and Medicaid. Under ERISA, self-insured plans, previously exempt from most state oversight requirements, now had to comply with the federal UM requirements.[15] However, the federal regulations were not as stringent as those proffered by URAC, the National Committee for Quality Assurance (NCQA), and many states. While the DOL claims procedure regulations were an important step forward, these regulations did not uniformly apply to all health insurance carriers. ERISA-covered group health plans were required to implement internal claims

and appeals processes in compliance with these regulations while other plans, such as those sponsored by state and local governments, were not. Issuers in the individual insurance market had to comply with state-based UM laws, but not with the federal DOL requirements.

Thus, the regulatory landscape existing prior to the enactment of the Patient Protection and Affordable Care Act (ACA, P.L. 111-148) left health plans operating in multiple states in a conundrum. These health plan sponsors and issuers were not uniformly required to implement claims and appeals processes. The applicability of regulations with which they needed to comply depended on the answers to several questions:

- Is the plan subject to ERISA?
- Are benefits self-funded or financed by the purchase of an insurance policy?
- If states had an internal claims regulation or an external review requirement, what was the scope?
- Did the regulation only apply to HMOs or also to other managed care plans?

Through the passage of the ACA, policymakers were attempting to unify these internal and external claims and appeals processes and to set a minimum standard of consumer protections across the country.

Definitions

Utilization Management/Utilization Review

The National Association of Insurance Commissioners (NAIC) defines utilization review as, "a set of formal techniques designed to monitor the use of, or evaluate the medical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings. Utilization management replaced the term utilization review in the mid-1990s as more programs implemented quality assurance protocols. UM techniques may include ambulatory review, prospective review, second opinion, certification, concurrent review, case management, discharge planning or retrospective review."

Definitions of key UM functions include:

- Ambulatory Review is defined as, "utilization review of health care services performed or provided in an outpatient setting."
- Certification is often referred to in reference to a UM program as, "a determination by a health carrier or its designee utilization review organization that a request for a benefit under the health carrier's health benefit plan has been reviewed and, based on the information provided, satisfies the health carrier's requirements for medical necessity, appropriateness, health care setting, level of care and effectiveness."
- Concurrent Review is defined as, "utilization review conducted during a patient's stay or course of treatment in a facility, the office of a health care professional or other inpatient or outpatient health care setting."
- Discharge Planning is considered, "the formal process for determining, prior to discharge from a facility, the coordination and management of the care that a patient receives following discharge from a facility."
- Prospective Review is defined as, "utilization review conducted prior to an admission or the provision of a health care service or a course of treatment in accordance with a health carrier's requirement that the health care service or course of treatment, in whole or in part, be approved prior to its provision."
- Retrospective Review is referred to as, "any review of a request for a benefit that is not a prospective review request." This does not include the review of any claim that is limited to veracity of documentation or accuracy of coding.
- Second Opinion is defined as, "an opportunity or requirement to obtain a clinical evaluation by a provider other than the one originally making a recommendation for a proposed health care service to assess the medical necessity and appropriateness of the initial proposed health care service."[16]

Independent and External Review

In its Uniform Health Carrier External Review Model Act, the NAIC defines an Independent Review Organization (IRO) as, "an entity that conducts independent external reviews of adverse determinations and final adverse determinations." An adverse determination is, "a determination by a health carrier or its designee utilization review organization that an admission, availability of care, continued stay or other health care service that is a covered benefit has been reviewed and, based upon the information provided, does not meet the health carrier's requirements for medical necessity, appropriateness, health care setting, level of care or effectiveness, and the requested service or payment for the service is therefore denied, reduced or terminated."[17]

In the current marketplace, "external review" typically refers to a state or federal mandated appeal where a third party handles the external appeal after the UM internal appeal process is completed. The phrase "independent review" also can mean the same thing as an external appeal; but it also can describe the activities of a third party utilization management organization that is coming in to help run all or part of a UM program for a health plan.

Grievance Procedure

Grievance is defined by the NAIC as, "a written complaint or oral complaint if the complaint involves an urgent care request submitted by or on behalf of a covered person regarding:

- Availability, delivery or quality of health care services, including a complaint regarding an adverse determination made pursuant to utilization review;
- Claims payment, handling, or reimbursement for health care services; or
- Matters pertaining to the contractual relationship between a covered person and a health carrier."[18]

Both through federal and state laws, all health plans offering group and non-group insurance coverage must offer customer service support through a grievance procedure program. However, it is important to differentiate between an adverse determination complaint or appeal that is based upon a medically-necessary decision (e.g., a UM appeal) versus a coverage or payment issue (e.g., a grievance appeal).

Case Management

The Case Management Society of America (CMSA) defines case management (CM) as a, "collaborative process of assessment, planning, facilitation, care coordination, evaluation, and advocacy for options and services to meet an individual's and family's comprehensive health needs through communication and available resources to promote quality, cost-effective outcomes."[19] The NAIC defines CM as, "a coordinated set of activities conducted for individual patient management of serious, complicated, protracted or other health conditions."[20] If UM is considered the overarching process to control costs and access to care, case management can be viewed as one of the tools within that process. In other situations, UM decision-making can be viewed as a sub-routine within the CM process. Statutory definitions often reflect the duality of this relationship.[21] Clearly, UM and CM activities are often intrinsically linked.

One key difference between UM and CM programs is the duration of care that they consider. UM is typically an episodic transaction, which involves a combination of management and clinical decision-making practices to ensure care is appropriate and medically necessary pursuant to the scope of coverage offered by an insurer; whereas CM takes place over a period of time to help coordinate clinical service for targeted populations enrolled in a health plan.[22] UM and CM programs also take place in provider-settings with more of a focus on discharge planning and transitions of care.

Disease Management

According to the Centers for Disease Control and Prevention (CDC), about half of all adults, approximately 117 million people, have a chronic condition.[23] These adults will, on average, utilize more health care services than their counterparts that do not have a chronic condition, thus making disease management a crucial component to controlling costs.[24] Over the past several decades, disease management programs helped manage these populations. Today, disease management interventions are also covered by care management and population management programs. Disease management programs are quite targeted. Scholars have found eight elements throughout the various disease management definitions: 1) focus on a target group, 2) of persons with chronic diseases, 3) with the goal to improve clinical outcome and quality and 4) cost-effectiveness of care 5) by means of a systematic approach 6) with preventive and curative interventions 7) in which self-management by patients is important 8) supported by a multidisciplinary professional team.[25]

Today, chronically-ill populations are managed through programs more commonly referred to as "care coordination," "care management," and "population health management. These programs typically incorporate disease management functions.

Population Health Management

In recent years, the term "population health management" has become a common concept in the medical management field. It was originally used frequently in the field of epidemiology and public health, but now has become a phrase used to describe a more comprehensive and outcomes-based approach to offering care management services. The goal of population health management interventions sponsored by health plans is to maintain or improve the physical and psychosocial well-being of individuals through cost-effective and tailored health solutions. The Population Health Alliance defines it as follows:

A population health management program strives to address health needs at all points along the continuum of health and well-being through participation of, engagement with and targeted interventions for the population.

For a detailed discussion on the rise of population health strategies in managed care, an informative issue brief published in 2014 titled "Population Health Management: New Perspectives on a Familiar Concept" is attached in Appendix C.

A population health management program strives to address health needs at all points along the continuum of health and well-being through participation of, engagement with and targeted interventions for the population.

Part II: Understanding the Appeals System

The UM process starts with a request or a claim for services or benefits on a prospective, concurrent or retrospective basis. When an adverse determination or denial is made, the patient or the attending provider has a right to appeal the health plan's decision.

Internal Appeals

Clinical UM appeals: A utilization management appeal allows patients, attending providers and family members to challenge an adverse determination based upon a finding by the health plan that the care is not medically necessary or clinically appropriate. The health plan must explain the entire process of how to file an appeal within the applicable timelines. In some cases, a health plan might offer a second level UM appeal process.

Expedited versus standard UM appeals: The insured or the attending provider must be informed by the health plan about their rights to file an expedited appeal for urgent cases (where the patient's life or limb is in imminent danger) or a standard appeal for non-urgent cases. Timeframes and requirements should be modified accordingly.

Administrative/grievance appeals: If an adverse determination or denial for the requested health services involves an administrative policy, the insured, the attending provider or representative may file a grievance with the health plan. In most states, administrative appeals cover a range of issues such as an adverse determination or denial of care related to payment or the scope of services.

Mental health parity appeals: Often, decisions by health plans are challenged when an adverse determination or denial of care related to mental health and substance abuse disorders is made. Federal and state mental health parity laws allow insured individuals or their providers to challenge a coverage determination if the plan does not offer the same level or scope of services for behavioral health services or treatments as medical/surgical benefits.

Specialty appeal: Depending on the type of medical management services being rendered by the health plan or specialty care organization, additional clinical and administrative appeals processes may be required. For example, many states have adopted separate procedures for workers' compensation cases. Other states also have specific appeals procedures for drug, dental and other specialty utilization review programs.

External Appeals

What does an external review appeal do? Section 2718 of the Public Health Service Act (PHS Act) establishes standards for group health plans and health insurance issuers offering coverage in the group and individual markets regarding both internal claims and appeals process and external review. Specifically, plans must comply with a state external review process that includes, at a minimum, the consumer protections set forth in the Uniform Health Carrier External Review Model Act, as written by the NAIC.[26] These requirements are discussed in further detail below.

What are the new federal external review appeals? Since September 23, 2010, all health plans and insurers issuing new policies and offering "non-grandfathered" coverage must provide an expanded claims and appeals process that meets the U.S. DOL and HHS regulations, including the external review requirements as required by the ACA.

What is the difference between an external and independent review? Regulatory agencies use different names for various types of appeals, which can become confusing. For example, some ambiguity exists between the terms "external review" and "independent review." One way to distinguish the terms is to think of "external review" as the process covering the steps that take place after the internal health plan appeal is completed. "Independent review" refers to any activity where a third party is coming in to support an internal or external appeal.

To ensure due process, there are a number of types and levels of appeals that can be filed, which health plan officials, employers and others need to track and monitor. These typically can include:

- Internal Health Plan Appeals
  - Clinical/UM Appeals (e.g., "medical necessity" appeals)
  - Administrative/Grievance Procedure Appeals (e.g., payment or scope of coverage related to the plan documents disputes)
  - Mental Health Parity Appeals
  - Other Specialty Appeals
- External Appeals
  - External Review Appeal
  - Regulator Complaints
  - Accreditation Audits
  - Arbitration Hearings
  - Judicial Hearings
- Retrospective Appeals
  - Medical Claims Review
  - Auditing Services Related to Appeals

Part III: State Regulatory Survey

Most states have adopted laws and regulations impacting UM transactions. In many cases, the legislation enacted by states has not changed much over the past several decades (some exceptions are noted later in this section). Many of the rules focus on basic "process" requirements that health plans, third party administrators, and private review agents must comply with to become licensed in a particular jurisdiction, such as paperwork to be submitted, licensing or registration fees, and clinical requirements.

A primary focus of this *Trend Report* was a survey examining the UM regulatory requirements in all 50 states and U.S. territories. Of the four U.S. Territories and the District of Columbia, only Puerto Rico has adopted some level of UM regulations.

Scope and Applicability

While health care regulations and legislation seem to have proliferated, the landscape is largely colored by the passage of the ACA. UM regulations have often failed to keep pace with some of the current health insurance offerings, such as accountable care organizations or specialty services/networks.

The scope of utilization management regulations varies, and some states that choose not to regulate the basic process have enacted legislation governing specific types of UM. For example, while the District of Columbia does not have an overarching UM statute in place, the DC Code contains specific requirements that govern utilization review in workers' compensation cases.

Of the 55 states and territories surveyed, 48 currently regulate UM functions. Of those 48 jurisdictions, UM laws/regulations applied to the following types of insurance coverage:

- Health Maintenance Organizations (HMOs): 45 states and Puerto Rico
- Preferred Provider Organizations (PPOs): 42 states
- Insurers: 45 states and Puerto Rico
- Utilization Review Organizations (UROs): 38 states and Puerto Rico
- Accountable Care Organizations (ACOs): 41 states
- Third Party Administrators (TPAs): 37 states

It is important to note that these figures do not include specialty UM legislation impacting areas such as prescription drug coverage, workers' compensation, or mental health coverage.

Licensure and Certification Requirements

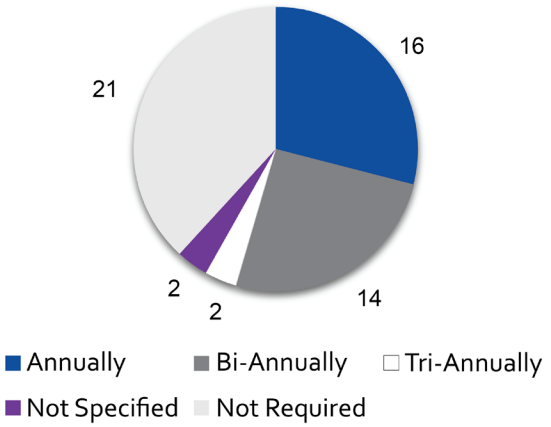
To ensure that "adverse benefit determinations" are properly handled, many states have enacted licensing or certification requirements for those performing UM services. Modern day UM laws emerged in the late 1980s and national standards were established by URAC and the NAIC in the early 1990s.

The terms "licensure" and "certification" are often used interchangeably. Licensure is a mandatory certification process where individuals are required to submit information to the state to gain permission to work in their designated profession. While certification may be required by the state, it does not, in of itself, grant the authority to perform UM functions. Additionally, some states have required certification by a national accreditation body, such as URAC and NCQA, to be approved to provide UM services.

Currently, 47 out of 50 states regulate one or more activities associated with UM. The three states that do not regulate UM functions at the state level are Florida, Utah and Wisconsin. In addition, the District of Columbia and the majority of U.S. Territories (American Samoa, Guam, and the U.S. Virgin Islands) do not regulate UM.[27] Of those states that regulate UM functions, most actively regulate the different forms of insurance, including HMOs, PPOs, and TPAs.

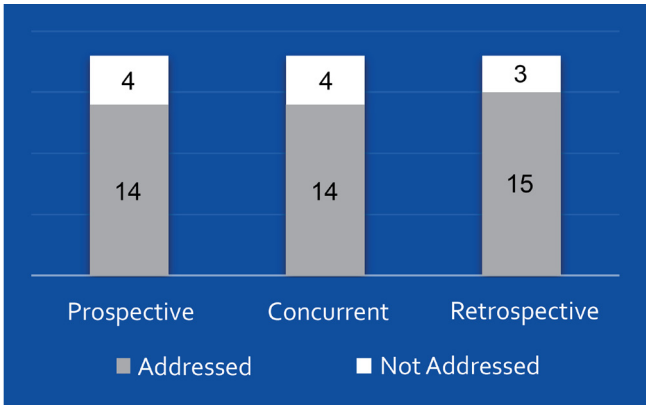
Although the vast majority of states regulate UM functions in some capacity, 34 states actually require licensure and/or certification. Of those states, the renewal periods are as follows:

Figure 1: Renewal Periods for UM Agents



Eighteen states have adopted regulatory provisions that impact the timing and workflows associated with UM Functions. Of these states, references to specific types of UM include:

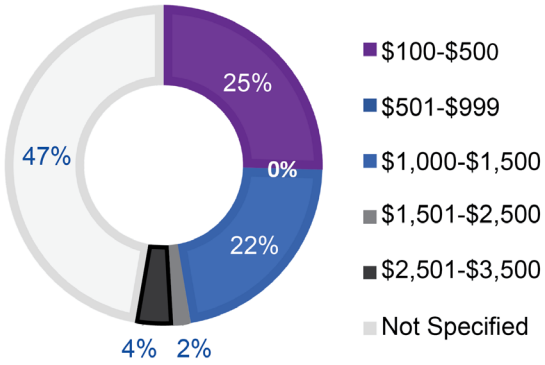
Figure 2: Regulatory Provisions by UM Type



In cases where states do not specify the specific type of UM function, it is safe to assume the UM regulations apply to all three types.

Twenty-eight states and territories require fees for licensure. Four states have reduced fees or waived fees for entities having URAC accreditation. The remaining licensure fee range:

Figure 3: License Fees by States and Territories



Program Requirements

Several states have also adopted various program requirements for UM practices. Many of these provisions mirror portions of the Utilization Review and Benefit Determination Model Act issued by the NAIC. The NAIC has created several model acts with the goal of establishing national standards consistent with best practices. Some of these best practices include: confidentiality provisions, clinical review requirements, and delegated oversight requirements. Many jurisdictions have adopted program requirements, including some contained in the NAIC Model Act. Some of these program requirements govern the following:

- Clinical Review: 44 States and Puerto Rico
- Prohibition Against Financial Incentives: 31 States and Puerto Rico
- Telephonic Coverage: 40 States and Puerto Rico
- Quality Control Assurance: 36 States
- Delegated Oversight: 28 States and Puerto Rico
- UM Reviewer Requirement: 43 States
- Medical Director: 21 States
- Same State Licensure: 25 States

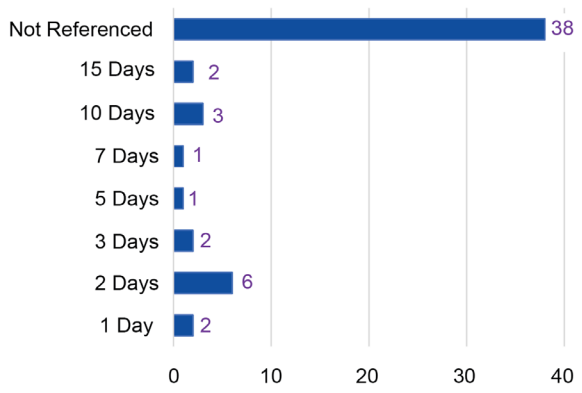
Interestingly, with the expansion of UM offshore reviews by certain health plans, no state purportedly regulates this activity directly with the exception of existing licensure requirements for clinical staff. For example, UM nurses working offshore must hold a nursing state license to engage in some key UM functions.

Review and Appeals

While many critics argue that state control of the review and appeals process is crucial, the variation of timelines and the number and types of appeals has proved to be difficult to track for UM providers and issuers that do business in multiple states. The lack of uniformity has permeated almost every facet of the review process from the nature of internal UM appeals, and the number of levels that are required, to the timeframe for various types of appeals, and notification requirements.

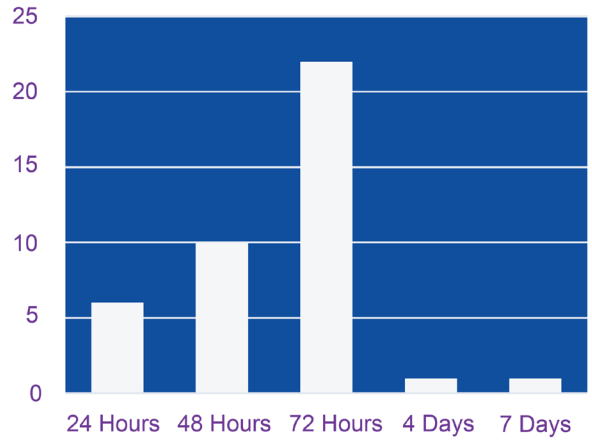
A total of 17 states regulate the timeframe of the initial UM determination:

Figure 4: Timeframe for Initial Determination



Thirty-nine state and Puerto Rico have established time frames for expedited UM appeals:

Figure 5: Timeframe for Expedited Appeals



In the NAIC Model Act, health carriers are encouraged to make a prospective review determination within 15 days and a retrospective review determination within 30 days. The Model Act provides for extensions of this time period in certain circumstances and encourages expedited appeal decisions to be issued within 72 hours.

State Highlights

In the previous decade, several states have made considerable changes to their UM regulations. While many states expanded the scope of their UM statutes, some have ceased to regulate these functions altogether. The states with the most significant revisions over the past decade were Wyoming, Florida, Montana, Hawaii, and West Virginia.

Wyoming

House Bill 0057 makes considerable changes to Wyoming's UM structure. As of July 1, 2015, Wyoming has extended the time to request an external review from 60 days to 120 days within receipt of the notice of claim denial following the completion of an internal review. In addition, the law now requires the independent review organization to forward any documentation it receives from an insurer or claimant to the opposing party within one business day. Most importantly, the bill extends these requirements to any insurance policy that provides for claim settlement for services provided by a health care provider that uses "medical necessity" or similar language. Wyoming had not previously regulated utilization review activities or organizations, beyond regulating workers' compensation plans.

Montana

Effective January 1, 2016, Montana will be considered an NAIC-parallel state, which means that the new regulations will mirror the NAIC Model Act.[28] Changes include adding a prohibition on financial incentives, requiring a quality assurance program, and changing the timeline for issuing a decision from 60 days to 15 days for a prospective determination and 30 days for a retrospective review determination.

Hawaii

Hawaii has similarly moved from a state that did not regulate UM practices, save for mental health, alcohol,

and substance abuse treatment, to an NAIC-parallel state. Hawaii now requires every managed care plan to establish procedures for continuous review of quality of care, performance of providers, utilization of health services, facilities and costs. Hawaii's external review laws apply to all health carriers, with certain specified exemptions. Independent review organizations must apply for approval with the state, and must demonstrate compliance with a myriad of requirements, including telephone access standards, reviewer qualifications, and requirements for final notification.

West Virginia

West Virginia has recently expanded its UM requirements beyond the 2005 structure. Originally, West Virginia regulated UM as a component of quality assurance programs in HMOs and prepaid limited health service organizations. Now, West Virginia's rule applies to any issuer offering a health benefit plan that provides or performs utilization review services. The state is also considered NAIC-parallel.

Florida

In contrast to other states, Florida has chosen to de-regulate UM practices. In 2005, Florida had a comprehensive UM regulation scheme that applied to private review agents conducting utilization review services in the state. The statute governing private utilization review was repealed effective July 1, 2009. In the staff analysis of H.B 651, the rationale for the deregulation of their private utilization review agents is more clearly delineated. Florida had 111 registered utilization review agents at the time, 75 of whom were located outside the state. These individuals did not incur any penalties for non-compliance, were not subject to inspections, and the registration process was found to offer no regulatory protections. By repealing the $514 biennial registration fee, the bill saved the registered agents $57,054 in fees.[29] Florida is now one of six states utilizing the HHS-administered Process/ Independent Review Organization Process.

Florida continues to regulate utilization management in some situations; namely, in Medicaid services, workers' compensation claims, and some mental health contexts.

Part IV: Federal Regulations

Over the years, the regulation of UM functions has been shared by both the federal and state levels of government. While states have taken the lead in regulating commercial insurance carriers who are licensed in their state for UM activities, the federal government has assumed a leadership role in establishing minimum federal standards through several key legislative and regulatory activities for Medicare beneficiaries, self-funded plans, mental health parity requirements, and several key provisions under the ACA.

Medicare

The Centers for Medicare & Medicaid Services (CMS) is the single largest payer for health care in the United States. As the administrator of Medicare, Medicaid and the State Children's Health Insurance Program (SCHIP), CMS acts as the payer for nearly 90 million Americans. In 2015, Medicare provided health insurance to 55 million Americans—48 million people age 65 and older and seven million younger people with disabilities.

Medicare, signed into law in 1965 by President Lyndon B. Johnson, provides care to some of the most vulnerable Americans, including:

- People age 65 or older
- People under age 65 with certain disabilities
- People of all ages with End-Stage Renal Disease

Given its mission of ensuring that these care-intensive populations continue to receive high quality care, cost containment mechanisms quickly became an integral part of Medicare. Strategies include post-payment review in original (fee-for-service) Medicare or

prospective and concurrent UM in Medicare Advantage. Just as health care costs have continued to spiral out of control in the private market, Medicare costs are also increasing. Total Medicare spending is expected to increase from 3.5% of GDP in 2014 to 5.4% in 2035.[30] As such, utilization management practices are a crucial part of Medicare. Although active in fighting costs, CMS has also issued a number of requirements to ensure Medicare beneficiaries are provided with appropriate care.

Medicare Administrative Contractors

In large part, the UM functions of Medicare plans have now been outsourced to third parties. Under Section 911 of the Medicare Prescription Drug Improvement, and Modernization Act (MMA) of 2003, CMS now contracts with Medicare Administrative Contractors (MAC) - multi-state and regional contractors who are responsible for administering Medicare Part A and B claims.[31] These contractors serve as the primary operational contact to process Medicare claims, processing nearly 4.9 million claims each business day and disbursing more than $365 million annually in program payments. In fiscal year 2013, these contractors processed almost 1.2 billion fee-for-service claims and received approximately $1.3 billion from CMS.[32]

In determining whether a particular medical service is reasonable and necessary, Medicare contractors and adjudicators rely upon national and local coverage determinations. A national coverage determination (NCD) is a determination by the Secretary of HHS on whether a particular item or service is covered nationally under Title XVIII of the Social Security Act.[33] These determinations are made through an evidence-based process, with opportunities for public participation.[34] If there is not an NCD in place, an item or service may be covered at the discretion of the Medicare contractors based on a local coverage determination (LCD). Whereas NCDs are mandated at the national level, LCDs apply only to a MAC's specific coverage area. In situations where coverage is not granted, appeals may be filed. The original Medicare appeals process has five levels: a redetermination by the MAC, a reconsideration by a Qualified Independent Contractor (QIC), a hearing before an Administrative Law Judge, a review by the Medicare Appeals Council, and finally a judicial review by a federal district court.

MACs may have a difficult road ahead in containing Medicare costs. A 2015 study found that between 25% and 42% of Medicare beneficiaries had received at least one medically unnecessary test. The findings suggested that 30% of all health care spending could be eliminated without decreasing the quality of care.[35] While utilization management systems play a role in reducing the level of medically-unnecessary care, there continues to be room for improvement.

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U.S. Department of Labor

As highlighted in Part I, the regulatory environment for UM programs changed significantly with the implementation of the U.S. Department of Labor's claims procedure regulation in 2002.[36] These regulations, issued under authority created by ERISA, were the federal government's first major entry into the oversight of medical management processes (outside of Medicare and Medicaid). As a result, self-insured plans, which previously had been exempt from most state oversight requirements now had to comply with the federal UM requirements.[37] In addition, insured plans must reconcile federal and state regulations in each state where they operate. Thus, understanding and implementing the DOL regulations is an essential component of an effective UM compliance program.

Affordable Care Act

An additional fifteen million individuals gained health insurance coverage with the passage of the ACA on March 23, 2010.[38] The goal of the ACA was not only to expand insurance coverage, but also to reduce the growth of health care costs.[39] Health care spending

increased to approximately 17.9% of gross domestic product (GDP) as of December 2014,[40] which represents an increase of 16% from December 2007.[41] Given new devices, diagnostics, and therapeutics, as well as market consolidation leading to skyrocketing costs, health insurers must allocate resources wisely.

The ACA, with its emphasis on quality over quantity of health care services, has led to an increased interest in utilization management, as the percentage of medical claims reporting prior authorization increased by 2.3% from 2011 to 2013. Additionally, payers have increased the number of care events that require prior authorization, in some case by double or triple. As discussed in this report, a likely reason for the increase in UM activities is due to the need to contain costs in response to the enhanced benefits mandated by the ACA.

An important consumer protection provision included in the ACA pertains to consumer coverage appeal rights. Under the ACA, non-grandfathered health plans were required to revise their internal appeals process and adopt a new external review procedure. The ACA requires that claimants are ensured of the right to appeal an issuer's decision to deny payment for a service or treatment, or to rescind coverage.[42]

In general, group health plans often have two levels of internal appeals, while individual insurers often have only one level of internal appeal, after which the claim is sent to an independent review organization for external review.[43] For internal appeals, plans usually have 30 calendar days to issue a pre-service or prior authorization decision, 60 calendar days to issue post-service decisions, and 72 hours or less for urgent care appeal decisions.[44]

Section 2719 of the ACA mandates that group plans and health insurance issuers have an effective internal claims and appeals process.[45] The interim final regulations set forth specific standards, including, but not limited to:

- Notice requirements for adverse benefit determinations - information to be included and how notices should be conveyed to claimants (i.e., in a culturally and linguistically appropriate manner);
- The types of claims that can be appealed (all denials, reduction, termination, or failure to provide or make payments for a benefit; rescissions; medical necessity denials; etc.);
- The process a claimant must follow to file an appeal (along with requisite timeframes);
- Special urgent care provisions (claimants may initiate an internal appeal simultaneously to an external review);
- Situations in which the internal appeal is deemed exhausted (urgent care situations);
- Processes to follow when the health plan needs additional information to conduct a review; and
- Clarifications regarding conflicts of interest.[46]

An important requirement to note is that a plan must provide continued coverage pending the outcome of an appeal—if the plan or issuer has approved an ongoing course of treatment, the plan is prohibited from reducing or terminating coverage of the service before the claimant has had an opportunity to appeal or have the decision reviewed.[47]

Mental Health Parity

The Paul Wellstone and Pete Domenici Mental Health Parity and Addition Equity Act of 2008 (MHPAEA, P.L. 110-343) was passed to end discriminatory health care practices against those with mental illness and/or addiction and their families. The statute provides that plans cannot apply financial requirements or treatment limitations to mental health or substance use disorder (MH/SUD) benefits that are more restrictive than those applied to medical/surgical benefits. Further, plans

cannot apply separate treatment limitations only to MH/SUD benefits. Most notably, the law aims to remedy both the financial ("quantitative") and non-financial ("non-quantitative") ways that plans limit access to addiction and mental health care services more so than they do for physical medical services. Final implementation of the regulations went into full effect January 1, 2015 for all plans covered by MHPAEA.

The fact that MHPAEA addresses non-quantitative treatment limitations has been viewed by some as a restriction on the use of managed care tools including medical necessity, prior authorization and utilization review.[48] The restriction of these services, it was argued, would increase expenditures for health care services.[49]

While multiple governmental bodies are responsible for enforcing MHPAEA, there has been an effort to coordinate enforcement behavior. The U.S. Departments of Labor, Treasury and Health and Human Services have jointly published regulations and other guidance, to ensure consistency.[50] The primary enforcer of these regulations depends on the type of insurer—states have primary enforcement responsibility with respect to health insurance issuers; the Departments of Labor and the Treasury are responsible for enforcing the requirements for private, employment-based group health plans.[51]

Individuals can bring a cause of action against their health plans for a violation of MHPAEA. As this new body of case law takes shape, it is likely that plan beneficiaries will continue to explore their legal options. In the first legal challenge to MHPAEA, *N.Y. State Psychiatric Ass'n v. UnitedHealth Group*, the court found that a third-party claims administrator could not be sued for violating MHPAEA.[53] In that case, the Court found that MHPAEA applies to group health plans, but that an entity processing claims and making coverage determinations and not offering coverage in connection with that plan is not subject to MHPAEA.[54]

Subsequently, several courts have taken the position that entities who are making coverage determinations like a third party administrator or who are handling appeals like an external review organization may be liable under MHPAEA (and ERISA, as a fiduciary). These cases are new and should be watched carefully.

Case Study: Oregon's Parity Laws

While some studies have shown an increase in the use of management techniques when implementing mental health parity, one study of Oregon's parity laws found there was no substantial increase in these practices, and in some cases, they declined. Oregon implemented a similar statutory interpretation to MHPAEA that required an 'apples to apples' test of the non-quantitative treatment limitations (NQTL) methodology used to asses the parity between behavioral health services and medical/surgical services. The study ultimately found that it was not necessary to impose onerous managed care utilization methods on behavioral health services, but that some UM practices should be utilized. As an aside, the federal government encouraged the increased use of utilization management practices in order to avoid cost increases after the Federal Employee Health Benefits Program (FEHBP) implemented parity requirements.[52] While this study has some limitations, its findings are interesting and indicate a further need for study in how utilization management practices can be best implemented when it comes to parity.

Part V: Current Regulatory Trends

Given the plethora of regulations facing managed care in general, and utilization management practices specifically, the following outlines several key regulatory trends in the field.

Accreditation

The rise of accreditation programs has been found to have a positive impact on the quality of health care services. Usually a voluntary program, accreditation is sponsored by a non-governmental organization where experts evaluate a health care organization's compliance as compared to predefined performance standards.[55] General accreditation programs have been shown to improve clinical outcomes in addition to the structure and process of care.[56] The federal government has called for the use of accreditation to help ensure quality in managed care settings, and specific provisions within the ACA call for the use of accreditation programs in the areas of medical homes, case management and disease management, wellness programs, medication therapy management services, pharmacy benefit management and utilization review.[57] The use of accreditation helps to reduce the burden of state oversight, as states can choose to focus limited resources on specific issues, and can be used to supplement state regulations.[58]

Usually a voluntary program, accreditation is sponsored by a non-governmental organization where experts evaluate a health care organization's compliance as compared to predefined performance standards.

Over a dozen accreditation agencies exist that certify different types of health care organizations and a range of functions. Three organizations—URAC, NCQA, and the Accreditation Association of Ambulatory Health Care (AAAHC)—offer accreditation standards impacting UM functions in a managed care setting. All three accreditation programs offer basic standards addressing the need for written policies and procedures, use of clinical review criteria, timeframes for processing different types of review, clinical director oversight, privacy and confidentiality provisions, requirements on how to make an adverse benefit determination, details on how to issue a denial notice or appeal rights, how to process an appeal, guidelines on how to oversee delegated UM functions to third parties, as well as guidelines for quality improvement activities.

URAC

URAC was formed in the late 1980s by industry, provider and consumer stakeholders to help create a more uniform approach to regulate UR functions through accreditation. The first set of URAC UM standards was published in 1989, and URAC has released and updated several revisions over the past 25 years. URAC assumed a central role in creating a more uniform approach to how payers make medically necessity determinations through the UM process; today, URAC offers over 30 accreditation programs in health care. Over the coming years, URAC will likely need to integrate its approach to quality benchmarking of different medical management functions such as UM, case management, disease management, external review, and nurse telephone triage programs.

NCQA

Founded in 1990, NCQA also helped to create a uniform set of standards surrounding quality measures in health care. Currently, NCQA offers the "Utilization Management and Credentialing" Certification Program.[59] Similar to URAC, these standards address the underlying processes associated with UM functions, especially within a health plan. NCQA also is known for its widely accepted outcomes measures, the Healthcare Effectiveness Data and Information Set (HEDIS), which offers an array of quality indicators for health plans.[60] The 2015 HEDIS measures include several guidelines relative to utilization and relative resource use, including inpatient utilization—general hospital/acute care, mental health utilization, and antibiotic utilization.[61] NCQA also offers accreditation programs for health plans, provider organizations, health plan contracting organizations, and wellness organizations. Critics of NCQA standards express concerns that the NCQA focuses mostly on integrated health plans, and not enough on specialty carve outs.

AAAHC

Formed in 1979, the Accreditation Association of Ambulatory Health Care (AAAHC) currently accredits more than 6,000 organizations in a wide variety of ambulatory health care settings including ambulatory surgery centers, community health centers, medical and dental group practices, medical home practices, and managed care organizations. AAAHC offers UM standards as a component of its core accreditation requirements for health plans.[62] Similar to URAC and NCQA, AAAHC incorporates a number of process and structural measures to assess the integrity and appropriateness of a UM program. Unlike the others, AAAHC does not offer a standalone UM accreditation, offering such as part of its health plan accreditation. AAAHC is a relative newcomer to the managed care and payer-based accreditation field.

Strengths and Weaknesses of the Accreditation Model

Over the past quarter century, the leading accreditation agencies, including CARF International and the Joint Commission, have assumed an important role in filling regulatory gaps by establishing quality standards before similar provisions are adopted by states and federal governments. Supporters of private sector accreditation programs note that these nonprofits can work more efficiently create quality standards that fill important gaps in the health care delivery system. They also are known for moving the ball forward in ensuring meaningful compliance by the industry.

However, critics of the accreditation model, relating to UM oversight, have expressed concerns about the price of accreditation, which has increased exponentially over time, and the regulatory "deemer" status that is often given to the accreditation agencies by state and federal regulatory agencies. Regarding the former, some believe the cost to pay for an accreditation application and the administrative costs associated with carrying out the review far exceed the value. Regarding the latter, some policy experts believe that the government is inappropriately delegating regulatory oversight responsibilities to private entities. Some also comment that even though most accreditation agencies are non-profits, they excel at generating revenue and creating quality-assessment monopolies.

Critics also express concerns that UM standards do not go far enough in holding health plans and other organizations accountable in today's value-based purchasing environment. Going forward, the challenge is to transition from "process" and "structure" metrics to a more outcomes-based approach to assessing quality, clinical efficacy, and financial performance. The move toward a value-based purchasing approach provides a dynamic to assess the return on investment (ROI) associated with UM programs, in addition to creating incentives to advance more cutting-edge care management and population health programs.

External Review

As part of the ACA's effort to expand consumer protections and level the playing field between patients and insurers, the health care reform law included a new requirement for plans to include an external review procedure. In many cases, after the plan's internal appeal process has been exhausted, the claimant is now permitted to request a review by an independent external review organization.[63] This decision is then binding on the health plan.

As a practice, UM interventions also are geared to standardize care, contain costs, improve quality and patient safety, and reduce unnecessary medical treatments.

Prior to the passage of the ACA, while some plans had utilized independent reviewers to assist in making decisions on claims and appeals, the ultimate decision on the claim was left in the hands of the health plan.[64] Many states had regulations in place prior to the ACA that required fully-insured plans to maintain an external review procedure—the ACA expanded this requirement to self-insured plans.[65]

States are free to maintain their own external review procedures so long as they meet or exceed the

consumer protections as set forth in the NAIC Uniform External Review Model Act. However, if HHS determines that a state has not implemented the appropriate consumer protections, issuers in that state can either participate in the HHS-administered external review process or contract with an accredited Independent Review Organization.[66]

In general, plans must now provide for a standard external review and an expedited external review.[67] Among other requirements, the following must be included in a standard external review (as a floor – states can still impose more stringent conditions):[68]

- The external review may be requested by a claimant within four months
- An IRO tasked with reviewing a claim must be accredited by URAC or another national organization
- The decision must be made by the IRO within 45 days
- The review of the claim will be performed on a de novo standard and the IRO will not be bound by the previous decisions of the health plan
- If the IRO reverses the plan's decision, payment must be rendered immediately

The following non-comprehensive list includes requirements for expedited external review processes:

- The IRO must make a determination within 72 hours
- Claimants are not required to exhaust the internal claims process if doing so would seriously jeopardize their life, health or ability to regain maximum function[69]

The Consumer Information and Insurance Oversight (CCIIO) division of CMS maintains a list of the external review requirements of states considered "NAIC-parallel," "NAIC-similar," and those that are not in compliance, where issuers may choose to utilize either the HHS-administered federal external review process or to contract with accredited independent review organizations. States are considered NAIC-parallel if they meet all 16 minimum consumer protections included in the Department of Labor's July 2010 rules, based on the NAIC External Review Model Act. NAIC-similar states are those that operate an external review process under similar standards, which can apply until January 1, 2016. As of August 21, 2015, 35 states and one territory are considered NAIC-parallel; 10 states are considered NAIC-similar; and six states and four territories are not in compliance, using the HHS-administered or independent review organization process.[70]

Specialty Utilization Management: Workers' Compensation

Several types of specialty utilization management interventions exist, including workers' compensation and drug UM programs. For both programs, the core structure of UM remains the same; as an example, in workers' compensation UM pre-certification review, concurrent review and retrospective review are still present with the ultimate goal of determining whether treatment is medically necessary. The question of what care is medically necessary continues to be critically important in workers' compensation claims. The focus often centers on what treatments are necessary to help an injured employee return to work. The U.S. Department of Labor's Office of Workers' Compensation Programs had a total of 182,650 cases as of November 1, 2015 with total compensation and medical bills paid equaling almost $12 billion.[71]

In a study conducted by Health Strategy Associates, utilization management practices related to workers' compensation matters were demonstrated to directly affect productivity, losses, compliance, marketing and profitability.[72] The study found that no single vendor was recognized as the industry leader for UM practices and, in fact, many respondents chose to conduct their UM practices in-house. The study highlighted that

regulatory compliance to state workers' compensation laws remains a top priority. Respondents ranked which states have the best and worst approach to workers' compensation UM: for the best approach, the top choice was none followed by Texas and California.[73] The state ranked with the worst approach to workers' compensation UM was New York, followed by Illinois and California. The rationale for these ratings included poor construction, execution, enforcement and accountability.

Specialty Utilization Management: Drugs & Pharmaceuticals

The Academy of Managed Care Pharmacy (AMCP) defines drug utilization review as, "an authorized, structured, ongoing review of prescribing, dispensing and use of medication."[74] Patient prescription and medication data is monitored before, during, and after the drugs are dispensed, then examined in conjunction with patient outcomes. The goal of drug UM practices is to prevent unnecessary or inappropriate drug therapy, improve drug effectiveness and prevent adverse drug reactions.

In terms of the typology, drug UM practices mirror general UM practices in many respects, including its division into three categories based on timeframe: prospective, concurrent, and retrospective.[75] Prospective review often takes place in the form of prior authorization; here, criteria can be universal or nearly universal. As an example, universal criteria can take the form of FDA indications which would apply to 100% of covered lives, whereas a compendia listing established by the provider or specialty pharmacy group could apply as nearly universal criteria and apply to 85% of covered lives.[76] Clinical pathways are also used in drug UM, albeit with less consistency and more variable results.[77]

Drug utilization management plays a vital and important role in patient care; so much so that the Social Security Act requires each state's Medicaid agency to implement a Drug Utilization Review (DUR) program, and annually report on the program. These reports must include prescribing habits, cost savings generated from the program, and information on the program's operations.[78] As of 2014, states must also include specific information related to an expanded fraud and abuse section, managed care organizations, and their prescription drug monitoring program.[79] The Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003 likewise requires plans offering a drug benefit to offer medication reviews and appropriate interventions, particularly for at-risk beneficiaries.[80]

These UM programs are critically important, particularly when viewed in light of the fact that spending on specialty pharmaceuticals increased by 19.6% from 2006-2010.[81] Specialty drug spending is rapidly increasing with no end in sight; studies have shown that spending on these pharmaceuticals accounted for 16.3% of plan costs in 2010.[82] The high cost and growing utilization of these drugs has increased the importance of an effective utilization management program for plan sponsors, although some studies have found that these efforts have proved challenging and oftentimes unproductive.[83]

Some argue that pharmacy benefit managers (PBMs) are particularly impacted by the challenges of containing costs while providing appropriate care.[84] Their role is increasing, as is evidenced by prior authorization requirements in Medicare Part D. In 2006, 8% of brand-name medications required prior authorization and 18% were subject to some form of utilization management. By 2013, these numbers increased to 21% and 35%, respectively.[85]

Enforcement Trends

After the managed care backlash during the 1990s, state departments of insurance actively regulated health plans and UMOs of all stripes that made "medical necessity" determinations and related decisions under the auspices of being a peer review or utilization review agent. Through state licensure requirement and accreditation standards, most of the 'bad actors' were weeded out of the marketplace.

Given the aging of the original UM laws (i.e. most were adopted during the 1990s), the efficacy of the UM requirements have diminished slightly and enforcement efforts have become less effective. This is due to several factors:

- The use of care treatment plans that factor in the comorbidities of a patient, making traditional UM decision-making less effective
- The lack of transparency underpinning UM criteria has made it more difficult for regulators to track negligence and errors
- Difficulty that patients experience in filing a UM appeal with their health plan or government agency
- The increased complexity of how some UM decisions are made, such as a mental health parity analysis involving a non-qualitative treatment limitation test (NQTL)
- The shifting of some enforcement activities to the U.S. DOL and HHS, which have limited resources

Some enforcement activities have been supplemented by attorney general (AG) actions and litigation. The New York AG's fines and class action lawsuits questioning how some of the major health plans and specialty benefit management firms handle mental health and substance abuse disorder coverage determinations are a prime example.[86]

Part VI: Market & Public Policy Trends

In this section, we highlight several key trends impacting UM programs due to market and public policy forces.

Integration

A number of forces have converged to promote the integration of UM programs and services, both horizontally and vertically. An example of horizontal integration is the blending of UM functions to manage both medical/surgical services with behavioral health services. Horizontal integration is being driven by the federal parity law, as it calls upon health plans to complete a non-quantitative treatment limitation analysis which requires a similar medical necessity determination process for mental and non-mental health. An example of vertical integration is the convergence of the payer and provider functions through delivery systems such as ACOs. In this circumstance, the, "corporate practice" of medicine embedded in a UM program is merged at the point of care, where the attending provider sees the patient. Other forces at play promote the creation and expansion of integrated delivery systems that impact UM programs, such as technology platforms that promote interoperability between workflows and the creation of customized care treatment plans that incorporate clinical pathways from a number of specialties.

Corporate Practice of Medicine

Although human physiology does not vary between states, there are regional differences in practice patterns. Utilization review performed by providers licensed in another state has turned into a hot button issue in recent months. In an article titled "Is Utilization Review in the Cards for 2015?" Dr. Robert Weinmann discusses the problem:

"Under current California law, the UR physician does not have to be licensed to practice medicine in California – any state license suffices. Proponents of the current system argue in support of the position that where a physician is licensed is beside the point… What matters, they say, is that he is knowledgeable… Opponents point out that the UR physician is actually practicing medicine and should be just as responsible to the state medical board as the primary treating physician."[87]

Utilizing a physician who is not accountable to the state medical board to perform UM services enables insurers to hire physicians who are more likely to deny more diagnostic services and treatments than their colleagues, argues Dr. Weinmann.[88] This willful or wrongful denial of care could be construed as unprofessional conduct in California, and actionable by the state medical board. On the flip side, some argue that by imposing same-state licensure requirements, states are limiting insurer access to national experts.[89]

As previously mentioned, payers often cite increased patient safety as a key benefit of maintaining utilization management programs, in spite of their costs.

The National Association of Independent Review Organizations (NAIRO) argues in a white paper that restrictive laws increase conflict of interests, hurt consumers, decrease quality and dismiss nationally recognized standards.[90]

Patient Safety

As previously mentioned, payers often cite increased patient safety as a key benefit of maintaining utilization management programs, in spite of their costs. For example, in April 2015, UnitedHealthcare began to require prior authorization for certain hysterectomy procedures in order to more closely align with a

position statement issued by the American Congress of Obstetricians and Gynecologists (ACOG).[91] This coverage decision was made after patient safety concerns were raised over the use of power morcellators for vaginal hysterectomies.[92] Additionally, a study performed by researchers at the University of Michigan found that approximately 20% of

hysterectomies are avoidable.[93] Thus, UnitedHealthcare may be relying upon UM practices not only to avoid unnecessary costs, but also to ensure appropriate care is provided.

Provider-Based Utilization Review

Hospital-Based UR

Historically, provider-based utilization review programs have existed to help manage hospital lengths of stay and other services, in addition to ensuring that the provider will be reimbursed for the care provided. These programs, along with case management interventions, also have been used to manage patient transitions of care from different settings, meet patient safety requirements and address other quality assurance or regulatory requirements. In these settings, a provider system will employ a UM expert to ensure that it manages the patient based upon "medical necessity" criteria from different vantage points.

The Ordering Provider

Attending providers who order services often interface with payer-based UM programs to certify that the recommended care will be compensated. They may deal with the UM system prospectively, concurrently, or retrospectively. In many cases, providers solicit additional authorizations during a patient's on-going medical treatment. In addition to or in lieu of UM, some providers are required to use appropriateness criteria systems before providing care. Such criteria has been produced by medical professional societies, and may be less restrictive than UM programs serving similar purposes. Very little research exists examining both provider-sponsored UM programs and how providers interact with payer-based UM programs.

UM Review Criteria

Traditionally, UM criteria governing medical necessity decisions were developed by several commercial review criteria company vendors such as InterQual, MCG (formerly Milliman Care Guidelines) and ReedGroup. Many health plans also hire their own experts to develop criteria. Information sharing about how the criteria are developed has proved to be a challenge in many situations because of the complexity of the process and the lack of transparency behind it. Guidelines may be held confidentially in order to gain a competitive advantage or to protect the UM system from gaming.

Evidenced-Based Medicine

UM programs are becoming more dynamic and objective due to the rise of the evidence-based medicine movement. Evidence-based medicine is often defined as the, "conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients."[94] As one expert notes, to "satisfy employer demands for appropriate care and lower costs, health plans are transitioning from managed utilization to evidence-based care management." He also observes:

> *Coverage and denial management is a pivotal area for application of evidence-based guidelines and presents an opportunity to clearly demonstrate that a plan's rulings are evidence-based. Coverage is allowed when evidence is strong that a given treatment is effective for a given condition but disallowed in favor of more cost-effective options when evidence is not strong.*

Of course, medical management decision-making becomes much more difficult when there is no evidence or limited data to make an assessment, or the evidence that does exist is contradictory.

Data Analytics

Data analytics is now routinely being used in conjunction with medical management services to identify and stratify high cost patient cases. For example, predictive modeling applies rule-based clinical logic to help grapple with mountains of health care data and make decisions about how to lower costs and promote optimal outcomes. Data analytics are now widely implemented through integrated medical management systems where a wide array of data and departmental resources can be used to support informed decision making by payers, employers and others. Claims and UM transactional information also are important for generating data points to help compute population trends, impact assessments, and other reports to help manage care.

Population Health

Population health management has become a buzz phrase for what many believe is a transition to a more outcomes-based approach to tracking and measuring health. This approach to managing care has become more formalized as a tool of health care delivery and payment systems. Population health is dependent upon UM interventions to optimize its clinical and financial goals.

Under population health programs, payment is made mostly for achieving quality outcomes using valid methodologies within a population rather than for performing specific services. Determining the right population, what the appropriate intervention is, and measurably affecting the population are therefore the most important aspects of population health.

Advanced population health management programs will test and then expand the limits of UM to function in a more effective and dynamic way. To learn more about population health, see Appendix C.

Coverage and denial management is a pivotal area for application of evidence-based guidelines and presents an opportunity to clearly demonstrate that a plan's rulings are evidence-based.

Part VII: The Value of UM

For some time, experts have expressed varied opinions regarding the return on investment (ROI) of utilization management programs, as well as their impact on the value of health care delivered. Early on, UM interventions were designed more for cost containment purposes, but over time, UM interventions were modified to better support quality-based outcomes as well. Thus, the focus has moved from pure financial ROI to health care value. For example, national accreditation agencies such as NCQA and URAC have expanded their UM standards to require quality improvement initiatives that are developed, implemented, monitored and tracked.

As part of the background research for this report, the authors interviewed several UM medical directors who have worked for a wide range of health plans, both at the state and national levels. These interviews confirmed that the integrity and functionality of UM programs vary greatly in different health plan settings. Some health plans offer cutting-edge and evidence-based UM programs, while others offer antiquated approaches to making UM decisions. One of the exposure points is that regulations and accreditation standards can only go so far in measuring the integrity, quality and effectiveness of UM transactions.

THE BALANCE BETWEEN UM'S FOCUS ON FINANCIAL ROI AND HEALTHCARE VALUE HAS EVOLVED

1970's 1980's

During the advent of managed care in the 1970's and 1980's, UM was used effectively to help control costs by payers. While UM enjoyed a crucial role in medical management during this time period, beyond addressing obvious patterns of over-utilization, the clinical and financial efficacy of UM interventions produced mixed results.

1990's

During the 1990's, a backlash emerged from consumer advocates, provider groups and others against UM programs, which sometimes appeared to put corporate profits above the best interests of patients. Over time, UM interventions were upgraded through quality assurance programs and other regulatory requirements to help address the concerns by critics.

2000's

The value of UM diminished once again with the rise of complex condition management and population health programs, which relied on data analytics and predictive modeling to manage targeted populations.

Today

Now, UM appears to be back in vogue due in part to the passage of MHPAEA and the ACA. The rise of ACOs has moved utilization considerations into more provider organizations. A number of studies have been recently published showing how the emerging marketplace is changing utilization patterns.[95] Lower utilization patterns in many populations in fact may be due to more aggressive and/or effective UM programs. However, consumer and legal advocates are raising concerns about the lack of transparency and accountability of "adverse benefit denials." Because of the complexity of the appeals process, advocates are concerned that health plans, insurers, UMOs, TPAs, and others can functionally deny care and hide behind the complexity of the UM process. In response, there is a growing call to reevaluate the process measures that underlie most regulatory and accreditation standards.

AliCare Medical Management: An Industry Pioneer

As utilization management (UM) services have waxed and waned in popularity, many companies have found it difficult to adapt their business plans to accommodate the needs of patients and providers. One company that has successfully adapted their business model to account for these ebbs and flows is AliCare Medical Management (AMM). Founded in 1990, the company was launched to offer UM services to self-funded Taft-Hartley Plans.

AMM's Utilization Management Program provides professional medical oversight designed to promote optimal medical outcomes through proper utilization of medical resources. The services are provided in accordance with standards issued by URAC. In total, the company holds four URAC accreditations that encompass their Utilization Management, Case Management, Health Call Center and Independent Physician Review services. These services have a strong return on investment: case management has a return of $9 savings for every $1 spent. The ROI for UM services is $4 of savings per every dollar spent.

AMM is truly a testament of a traditional UM company that continuously adapts to meet the needs of an evolving U.S. medical management system. Julie O'Brien, BSN, RN, MS, President of AMM notes, "AMM has changed to meet our clients' growing list of requirements. Among other enhancements, we offer an innovative suite of programs that is available 24 hours a day, 7 days a week, 365 days a year. These programs utilize clinical staffing on-site in U.S.-based call centers. Around-the-clock access supports our clients with effective patient care coordination while meeting regulatory compliance turnaround times."

While perfecting their existing services, AMM also took a leadership role in bringing new products to market. "During my tenure as President and CEO of URAC, I often looked to AMM to better understand how the medical management system was changing," notes Garry Carneal, JD, MA. "URAC turned to AMM over the years to learn about case management and external review services as accreditation standards were drafted." In addition to its URAC accreditations, O'Brien is serving as the volunteer President of the National Association of Independent Review Organizations (NAIRO).

An industry pioneer, AMM partners with health plans, utilization management companies, third party administrators, insurance companies, travel assistance companies, labor unions, employee assistance programs, hospitals and physician practices to enhance their programs. With a national footprint and 24/7 operations, several health plans utilize AMM's services for out-of-state UM support and/or after hour call center needs. Employers and others use their nurse telephonic and online triage services to provide a benefit to employees, who can chat with a nurse anytime, anywhere.

AliCare Medical Management is a part of the Amalgamated Family of Companies, which includes Amalgamated Life Insurance Company, an A.M. Best's "A" rated New York life insurance company founded in 1943.

The Move to Outcomes Measurement

The need to document outcomes for medical management interventions is paramount in today's marketplace. For example, health care purchasers (e.g., employers) and regulators like CMS are becoming more vocal about the need to demonstrate positive business and health outcomes from investments made in medical management services.

No matter the type of medical management intervention being measured, methodological challenges must be addressed to clearly establish the ROI. These challenges include:

- Clearly identifying the causal relationship between the intervention and the outcome (e.g., the need to actually touch the patient).
- When appropriate, establishing a control group for comparison purposes, or analyzing the same group over a period of time (i.e., both before and after a specified intervention). Among other benefits, this helps account for the natural regression to the mean that typically occurs over time for most population-based groups.
- Clearly differentiating between "process" and "actual" health outcomes (e.g., an improved immunization rate for a defined population is a "process" outcome measure; the actual drop in the incidence of Lyme disease for the same population represents an improved health outcome).

The need to document outcomes for medical management interventions is paramount in today's marketplace.

Expectations vary depending on whether the health plan is employing traditional UM services or using a more comprehensive population health management program. Documentation may include:

- UM Outcome Measures: Regarding basic UM interventions, outcome reports could include measuring reduced lengths of stays, lower admission or readmission rates, timely and appropriate specialty referrals, reduced costs for a particular procedure, and so on.
- Population Health Measures: An advanced care coordination approach that utilizes UM interventions along with other medical management activities, could report on the UM outcome indicators just referenced but also report on an array of additional outcome measures tracking the progress of individual patients and the targeted populations after a baseline has been established. Examples include scores associated with symptom rating scales, changes in clinical values such as blood pressure and Hemoglobin A1c levels, reductions in insurance costs, and changes in patient satisfaction levels.

UM Pressure Points

Given the increased spending on health care in the United States, and the pressures facing insurers to allocate resources as judiciously as possible, utilization management should be viewed as a potential solution to help insurers gain a competitive advantage.

Measuring the advantage is challenging, however, as an examination of utilization management practices through a traditional ROI perspective may not give a complete picture. A white paper produced by Optum explains:

> *In the past, many employers implemented health management programs and incentives primarily as a way of stemming the rise in health care costs. Although that is still an important objective, many employers are now broadening their vision by building a culture of health, safety, productivity and enhanced quality of work life – and they want health management programs to be key enablers of these.*[96]

In the past, many employers implemented health management programs and incentives primarily as a way of stemming the rise in health care costs.

Optum proposes expanding the metrics universe to include both people metrics (quality of life, energy level, personal health care expenditures, health benefit program satisfaction, etc.) and business metrics (company stock price, health care costs, absenteeism, health care utilization and recruitment, etc.) to gain a more complete picture of ROI.[97]

The use of utilization management techniques has not been met with applause by all. Physicians have often expressed frustration over time spent pursuing prior authorizations. A 2010 American Medical Association survey found that physicians spend, on average, about 20 hours per week on prior authorization activities. In terms of dollars, a 2011 study published by Health Affairs found that physicians spend about $83,000 per year interacting with insurance plans, which brings the total annual cost for all physicians to $69 billion.[98]

Given these staggering costs, physicians argue that the price of utilization management practices far outweigh the benefits. Payers, however, counter that UM practices are critical for efficacy and patient safety.

Value-Based Purchasing

In an effort to contain health care costs, the federal government has expressed interest in shifting from reimbursing based on quantity to quality, and has instituted an incentive system for providers based on this methodology. In "Mastering Change: Succeeding in Healthcare's New World Order," Matthew Zubiller, McKesson's vice president of strategy and business development argues that utilization management practices are key to succeeding in the shift from volume to value-based care.[99] In particular, Zubiller argues that the authorization of medical services could shift from an adversarial approach between payers and providers to open the door to a collaborative process.

While the shift toward value-based purchasing seems like a logical next step in health care delivery, Zubiller argues that the fractious payer-provider relationship coupled with siloed technological systems and organization infrastructures that foster resistance to change have made parties hesitant to embrace this new methodology.[100] The hesitation on the part of payers and providers, while understandable, may no longer be a justification to resist change. The ACA is forcing the issue, requiring new delivery systems that shift some of the financial risk to providers.[101]

Academic Research

Assessing the Efficacy of UM Programs

Overall, few research studies have examined utilization management as a comprehensive practice. Studies will often focus on a particular type of specialty UM, the effect of one type of UM, such as prior authorization, or its impacts on patients with a specific type of disorder, such as mental health. When the studies are viewed in combination, there is substantial evidence that UM and prior authorization programs are effective at reducing utilization. Utilization management and prior authorization programs have recently been found to be associated with lower volumes of inpatient testing[102], genetic reference laboratory testing[103], downstream cardiovascular imaging[104], high-tech imaging [105, 106, 107, 108, 109], and imaging by an entire academic neuroradiology department[110]. There are opportunities for pharmacy-related savings as well. Recent studies have found that utilization management programs focused on cyclooxygenase-2 inhibitor[111], epoetin[112], and proton pump inhibitors[113] have generated reductions in utilization.

Complementing this siloed research, one comprehensive study has touched upon on the most important aspects of UM. Researchers at the University of Washington published a study in 2002 titled, "Utilization Management: Issues, Effects, and Future Prospects". The research examined:

> *The operation and effects of three widely used utilization management procedures: prospective utilization review, case management, and physician gatekeeping problems. In addition, it explores the future role of utilization management in the health care system and outlines a set of principles that we believe should be used to guide the development of utilization management strategies in the future.*[114]

The study demonstrated at least one positive impact of UM programs: length of stay in hospitals has been steadily declining in the United States in part because of UM techniques. It also examined applications of UM interventions that became more stringent and restrictive in terms of approving cases during a four-year period (from 1990-1993). As a result of UM, length of stay authorization decreased by almost 50% for mental health cases and 25% for medical cases.

The operation and effects of three widely used utilization management procedures: prospective utilization review, case management, and physician gatekeeping problems.

However, not all of the findings were positive. For example, the researchers discovered an increased relative risk of readmission within 60 days, especially for cardiovascular patients who had a surgical procedure for which the requested length of stay in the hospital was reduced by up to two days through a UM program. Similar patients were 2.7 times as likely to be readmitted within 60 days as patients that had no reduction in requested lengths of stay, which made the authors wonder about the potential effects of UM on quality of care for some patients or targeted populations.

Guidelines

Further, available research findings suggest that current UM decision making is not always reliable and valid for evaluating the need for hospital admission and additional hospital days. The validity and reliability of length of stay guidelines have been widely criticized. For example, the most broadly used guidelines (produced by InterQual and MCG) vary in practice across different hospital systems, with a large variance in length of stay data and guidelines.

These findings have led researchers to question the application of the guidelines, as many physicians have reported that they are inflexible and fail to take into account important patient clinical characteristics or

limitations of community-based health care resources. Also, questions have been raised about how utilization reviewers apply the guidelines.

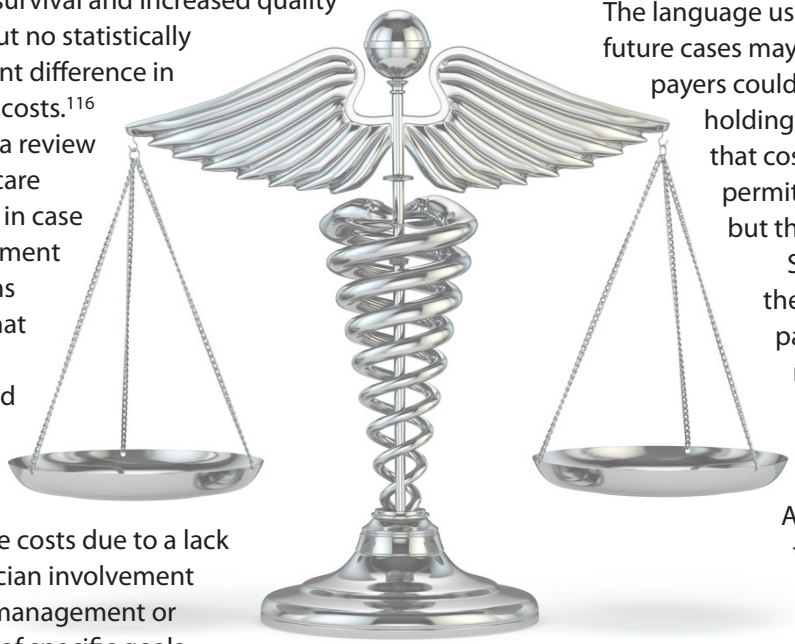
These concerns have led to calls for more evidence-based length of stay requirements in order to ensure that similar cases are being determined with similar outcomes. In fact, a national survey of utilization review organizations found that IROs varied greatly in their denial rates and were significantly influenced by nonclinical considerations such as financial incentives.

Lastly, the use of utilization management seems to directly correlate with the dissatisfaction of physicians. Part of the reason for this is due to what is known as the "sentinel effect", which claims that physicians will change their practice style knowing that the cases will be reviewed. Another complaint is that physicians say they have spent substantial time seeking approval for care, sometimes three hours per week.

Case Management

Interestingly, the academic research on case management, which is closely tied to UM activities, appears to be more limited than published UM studies. A clinical case management trial conducted in 1996 through primary care settings found that none of the programs affected health care costs, but several did improve health outcomes and satisfaction measures.[115]

In addition, a study from 1990-1994 discovered that case management was associated with improved patient survival and increased quality of life, but no statistically significant difference in medical costs.[116] Further, a review of Medicare patients in case management programs found that no site improved self-care or reduced Medicare costs due to a lack of physician involvement in case management or the lack of specific goals.



Part VIII: Litigation

Perhaps the single biggest legal question facing utilization management is the issue of liability. Starting with the case of *Wickline v. California*, litigation focusing on the liability of issuers for improper utilization management issues has developed with some interesting consequences.

In *Wickline*, the plaintiff, a Medicaid patient, sued the state of California for harm caused when she was discharged from a hospital after the state authorized only four days as opposed to the eight requested by her treating physician, resulting in an infection and ultimately the loss of her leg. The Second District Court of Appeal in California recognized this was the first attempt to tie a health care payer to a medical malpractice claim, and that the Court was, in essence, balancing the public interest in properly allocating health care resources with the need for an appropriate and robust quality assurance mechanism.[117]

In *Wickline*, the Court held that the third-party payer could not be held liable for the plaintiff patient's injuries, as it was not a party to the medical decision to discharge her. The Court examined various statutory and administrative rules and found that the third-party payer had acted in accordance with all pertinent requirements, particularly that coverage determinations were made in accordance with community standards of care, and that her treating physician had satisfied the medical standard of care. The language used by the Court did suggest that future cases may present instances where third-party payers could be held liable for injuries. In its holding, the Court relayed that, "it is essential that cost limitation programs not be permitted to corrupt medical judgment," but that in this case, the program had not.[118]

Subsequent cases have further clarified the *Wickline* holding in relation to third-party payer liability for adverse medical outcomes arising from improper utilization management decisions. In *Wilson v. Blue Cross of So.Cal.*, the Second District Court of Appeal in California again addressed the notion of third-party payer liability. In this case, however, the Court rejected the payer's argument that, "the *Wickline* decision can be construed

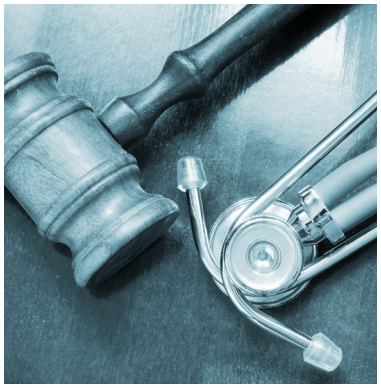
to extend an immunity to a health care payer which refuses to provide insurance benefits on the advice of an entity…because of "public policy" considerations which support the use of the concurrent utilization "process."[119] The Court found that immunity from traditional tort liability could only exist where a clear public policy requires an exception to be made.[120] In *Wickline,* a clear public policy was delineated in statute that necessitated a departure from traditional tort liability; however, there was no such policy in place for *Wilson.*

Following the holdings in *Wickline and Wilson*, the U.S. Supreme Court issued its decision in *Pegram v. Herdrich*.[121] While this case brings up important considerations about the implications of ERISA on utilization management practices, it also provides guidance as to the types of utilization management decisions for which managed care organizations can be held liable. In *Pegram*, the Court discussed three categories of utilization management decisions: eligibility decisions, treatment decisions, and a mix thereof. Eligibility decisions largely focus on the specific coverage of the plan—if an eligibility decision results in injury, the question of liability focuses on whether the patient was entitled to the treatment under the plan's terms. Treatment determinations consider the patient's symptoms and appropriate treatment—liability can arise from these decisions if it is not in accordance with the appropriate standard of care.

Often, the Court notes, decisions are inextricable from one another—many coverage decisions simply cannot be decided with a yes or no. In these cases, the Court concludes, "these eligibility decisions cannot be untangled from physicians' judgments about reasonable medical treatments."[122] Because many of the decisions made by managed care organizations are mixed eligibility decisions, they often raise questions about the appropriateness of care, thus opening up questions of liability for incorrect or improper decisions. Thus, when engaging in utilization management decisions, issuers must consider the question of liability not only with respect to correctly determining plan coverage requirements, but also in ensuring that appropriate care is provided at the right time. This necessitates considering the issuers' duty to the insured from a breach of contract perspective, but also in a traditional negligence approach.

The ACA has also prompted some litigation regarding external review requirements. In *Bailey v. Chevron Corp. Omnibus Health Care Plan*, the California Central District Court considered whether the plaintiff was required to complete an external review in addition to two mandatory internal appeals before being permitted to sue the issuer under ERISA.[123] The Court held that while the Affordable Care Act required plans to implement an external review process, plans cannot necessarily require it in addition to two mandatory internal appeals.[124] Additionally, in *Goldman v. BCBSM Foundation*, the Court similarly held that although health plans are required to have an internal and external review process, a claimant need not be constrained by completing both before being able to bring suit under ERISA.[125]

Parity Cases



As previously noted MHPAEA, was enacted to ensure that individuals with mental health (MH) or substance use (SU) disorders receive the same insurance protections as medical/surgical benefits. Insurers are not permitted to apply different treatment or financial limitations for MH/SU disorders.

Efforts to enforce MHPAEA through the court system have been ongoing since the law's inception in 2008. Several of these challenges include:

- A federal lawsuit against Anthem Health Plans filed by the American Psychological Association (APA) alleging that the health plan has manipulated its billing codes to unfairly burden mental health care patients;[126]
- A federal class-action lawsuit filed by the New York State Psychiatric Association against United Health Group alleging that United applied prior authorization requirements exclusively to MH/SU and other violations;[127] and
- Class action suits filed against Cigna and Aetna for denying depression treatment.[128]

The first federal ruling implementing the parity law was issued in April 2013 by a district court in Vermont.[129] There, the court ruled that the insurance plan bore the burden of establishing clinically appropriate standards of care to justify treating MH/SU differently from other medical/surgical claims.[130] These challenges simply skim the surface of the ongoing litigation battle that will likely ensue in the coming years.

Part IX: Future of UM

Looking to the future, it is clear that UM practices will remain a key component of managed care. In their landmark 2002 study on UM, Wickizer and Lessler proposed five principles to improve UM for the future.[131] These include:

- Promoting quality of care in addition to cost containment
- Basing UM upon valid and reliable clinical data and scientific evidence
- Minimizing administrative burdens for providers
- Considering the patient's ethnicity, income, age and gender
- Increasing transparency

Today, UM practices have largely met these goals as quality of care is now a critical indicator of success and clinical guidelines are widely used. That is not to say that UM practices do not have further to go, as the administrative burdens are still widely felt by providers and issuers alike.

Post Regulatory Environment

As technology continues to evolve at lightning-fast speeds, it is painfully clear that regulations simply cannot keep the pace. By all measures, UM regulations have proved to be fragmented and overly complex. Looking ahead, it is apparent that the field of utilization management has moved to a "post-regulatory" environment that will necessitate either self-regulation, or regulation via an independent third party that is not constrained by the legislative process, such as accreditation.

Genomics

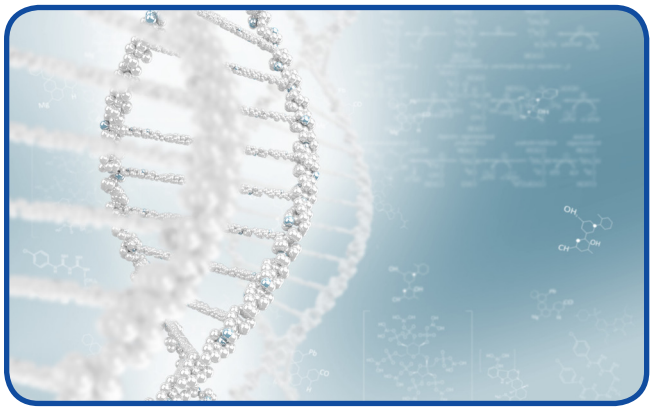
The rise of genomics has been one of the most exciting developments in medicine over the past century. The ability to sequence and map DNA and other bioinformatics has revolutionized health care in many ways. As a result, health plans have struggled to determine the types of genetic tests they should cover.

David Patrick Nixon, Chief Executive Officer of InformedDNA, notes that his organization, "coined the term Genetic Benefits Optimization to reflect our clinically- driven, proactive approach to genetic testing utilization management." He adds, "Our approach engages genetics experts within the clinical process, ensuring that only clinically valid genetic test requests are made and thus avoiding the need for costly and reactive administrative review or claims adjudication processes for complex and expensive genetic tests."[132] Payers are just as focused on quality (e.g., right test, right interpretation) as they are on cost because the downstream impact on health care spending following genetic testing is so profound. As a result, one could argue that InformedDNA represents the next generation of a UMO.

The company specializes in advising payers and others on whether genetic tests or certain experimental procedures are clinically appropriate. The key components of InformedDNA's Utilization Management program include timely medical/payment policies, clinical genetic counselling (patient decision support), expert administrative reviews (provider decision support), claims data analysis, and technical assessments.[133]

As InformedDNA maintains a quality improvement focus, it even offers its genetic counselling services directly to consumers. Amber Trivedi, M.S., CGC, InformedDNA's Senior Vice President, Provider & Client Services, explains, "Our clinical genetic counselling services empower patients to make knowledgeable decisions about complex genetic tests for cancer, heart disease, and diabetes, among other disease states. When patients understand the downsides of tests that are not medically necessary, they make decisions that both improve their individual outcomes as well as reduce health care costs."

InformedDNA's program represents a transformation of traditional UR/UM processes into a highly sophisticated genetic counseling enterprise. By utilizing the UM framework at both the macro and micro level, each payer can systematically evaluate their population and determine the types of genetic tests that are medically appropriate for the population as a whole and/or covered under the specific terms of an individual beneficiary's plan. InformedDNA has recast utilization review from being a potential obstacle to care to a useful service, which some consumers will personally pay to receive.



Technology

Technology has proved to be a central catalyst for the continued evolution of UM functions. Gone are the days where the majority of UM approvals and denials are processed by fax machine. Technology will undoubtedly change the face of UM as we know it over time. Mobile technology applications, the convergence of provider and payer electronic medical records, the ability to search the web to learn about a medical condition, the great number of Americans purchasing their own insurance through the Exchanges, and the move to high deductible plans are all spurring change and evolution.

In addition, technology solutions are essential for medical management programs, such as population health. By promoting timely and meaningful deployment of data analytics and predictive modeling applications, patients do not fall through the cracks. Further, the interoperability of health information technology systems is important to ensure that providers can take advantage of new and existing digital tools and other resources to support patients. An important goal is to transfer actionable information to the patient and provider in real time.

Part X: Final Thoughts

As demonstrated throughout this *Trend Report*, utilization management can be an effective method to promote quality, contain costs and protect consumers. However, regulations and quality standards for the most part have remained fragmented by taking a modular approach to overseeing the medical management system. This is highlighted by the thousands of different regulatory provisions governing the medical management system both at the state and federal levels for different health plan marketplaces. The findings of this UM survey are just the tip of the iceberg.

In addition, UM regulations traditionally have focused on fundamental processes such as UM licensing requirements, UM personnel qualifications, timing requirements for different types of UM reviews, and appeal options. Most of the UM statutes and regulations were adopted by state insurance departments over two decades ago, without any major changes in the underlying regulatory constructs. The same can be said for the federal government, which last revised comprehensive UM requirements in 2002.[134]

As a result, the current regulatory paradigm for UM transactions has not kept pace with the constantly-evolving delivery of health care and innovation in the industry. The next generation of UM practices, and any accompanying regulations, must address the following limitations:

- Fragmentation. The fragmentation of medical management regulations can create unnecessary complexity for consumers, providers and payers as they navigate a tangled web of conflicting managed care appeal requirements governing UM processes, external review, grievance procedures, and access requirements. Although we can understand how this ad hoc system evolved, technology applications, population management strategies and other recent improvement can help us create an integrated medical management system going forward.
- Medical Complexity. The delivery of health care has become more complex; there now exists the need and ability to create customized care treatment plans that control for the comorbidities of each patient in need. Traditional UM determinations and

the regulations no longer match the sophistication of today's medical system and must be able to adapt more quickly, in view of the need to coordinate patient care across multiple settings (e.g., inpatient, outpatient) and across multiple providers (e.g., owned, contracted, network, academic, etc.)

- Value-Based Standards. The move to value-based purchasing will demand more transparency and accountability of how the corporate practice of medicine impacts health care quality. UM standards will play an increasing role in determining the value of clinician services for overutilization of services (e.g., laboratory, imaging) and appropriateness of services (e.g., emergency department visits, surgical services, etc.) which are inextricably linked with clinical, financial, and risk expectations of value-based care.
- Parity Enforcement. MHPAEA, the new federal parity law, is forcing a more integrated UM process between mainstream medicine and behavioral health care, with the need for payers to demonstrate both quantitative and qualitative (e.g., NQTL) comparisons. The need to level the coverage playing field due to this federal mandate is now opening up a dialogue by policymakers and others about how the corporate practice of medicine works and it can be improved, including UM workflows and the documentation of UM transactions.
- Outcome Metrics. Government and accreditation agencies are no longer providing state-of-the-art quality benchmarking in large part because regulators and accreditors rely primarily on basic process measures which are inherently limited in today's fast-moving, ever-changing health care delivery system. A new outcomes-based measurement system must be imagined and implemented that takes a deep look at the financial and clinical efficacy of how and when care is paid for through insurance.

Without a doubt, the role of utilization management in payer, health care professional, hospital and risk-bearing provider settings will continue to play a pivotal role. The need to make sure that care is being delivered in an appropriate manner in the right setting will always be a top priority. As one health care professional put it recently, "We have population health analysis but not population health management."[135] While many providers may scoff at the concept of utilization management, it is a necessary practice both to protect patients and to manage both the over and underutilization of care. Policymakers and others do not like to address the "R" word, i.e., the need to "ration" care. But UM medical directors, and the programs they run, do assume an important role to ensure some logic behind how health care dollars are spent.

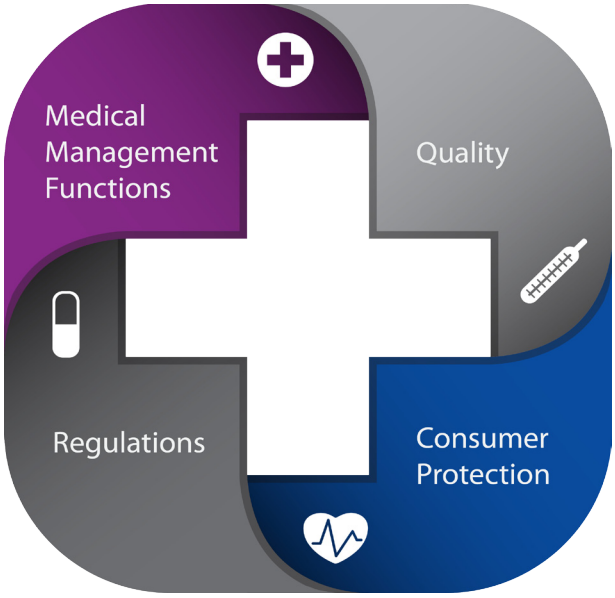
A decade ago, it appeared that UM programs had hit a point of diminishing returns with the rise of data analytics and new complex condition management strategies (along with the costs associated with maintaining a comprehensive UM program, and both patients and providers pushing back against tight UM). As a result, many payers moved to a more selective UM process that targeted high cost items, emerging services, or more medically complex situations.

In the past few years, though, the explosion of specialty pharmaceuticals, personalized and genomic diagnostics, and minimally invasive devices, along with market consolidation, has caused payers to rethink that strategy. We see the resurgence of UM in 2016 tied to the need to control costs in response to market dynamics, health care reform, and advancements in medical care.

Here are a few key public policy recommendations to address the current and future needs of UM:

Medical Management Functions

- Utilize Integrated Care Management. Implement a more integrated approach to medical management, moving from case to care management, including more emphasis on population health management programs which will positively impact both clinical and financial incomes across all care settings. It is imperative that we promote interoperable and seamless workflows to create a "care continuum" for patients.
- Ensure Integrated Benefit Determinations. Improve the interface between "medical necessity" determinations and "benefit coverage"determinations to increase coordination. For example, we need to address the UM and financial challenges when patients seek care from out-of-network providers. We also need to do a better job mapping out the decision-making process between the "scope of coverage" that is promised to be paid for by the insurer and the "scope of care" that is clinically appropriate or warranted in any given case. Bifurcating this decision making process is not in the patient's best interest.



- Better Understand the Corporate Practice of Medicine. Conduct more research to better define the proper parameters for the corporate practice of medicine, including the legitimate role of UM programs to control costs and oversee the distribution of care. Society needs to do a better job talking about the corporate practice of medicine and the actual practice of medicine. For example, we need to better understand how and when we shift financial risk to downstream providers from a licensed health plan, and how coverage determinations are ultimately made. The same pressure points exist both in traditional insurance arrangements and the new accountable care organizations.

Quality

- Increase Transparency. Improve the transparency of how medical necessity decisions are made to ensure inter-rater reliability and promote evidence-based care within UM programs. As financial and quality information is increasingly being made available to patients and purchasers, position UM as the 'third leg' of transparency reporting to help consumers make better and more informed decisions, especially in view of patients in high-deductible plans bearing an increasing amount of the costs of care.
- Move to Performance Indicators. Ensure that regulators, accreditors, and purchasers of care move to a new generation of outcome measures that reflect the effectiveness of UM programs and providers. The continued primary reliance on UM process measures and licensing requirements is no longer sufficient to optimize how care is compensated or delivered. UM outcome measures are essential to ensuring that UM activities are having a positive impact.

Consumer Protection

- Promote More Consumer Education. Increase the interactive and educational nature of UM systems, and provide real and actionable information to patients, family members and caregivers. We need to strike a balance between the legal and humanistic needs. Disclosing esoteric or volumes of clinical review information in a denial letter is often meaningless to patients, but sharing targeted and clear information explaining the reason for the adverse benefit determination can be extremely

helpful. In addition, consumers often do not understand why a service could be 'medically necessary' for one product line (e.g., Medicare) but not for another (e.g., commercial).

- Improve the Appeals Process. Improve the current appeals process as it is ineffective and outdated. Clarify meanings of appeal terms (e.g., reconsideration, first/second/third level appeals, independent medical review, etc.) and applicability across product lines (e.g., original Medicare, Medicare Advantage, standard Medicaid, managed Medicaid, commercial, exchange, Tricare, worker's compensation, ACO's, delegated risk, global capitation, auto liability, etc.). Leveraging technology to help patients and their providers navigate the appeals process also can be very helpful moving forward.

Regulations

- Update the UM Regulatory Paradigm. Regulators, policymakers, industry leaders, provider experts and other must convene to update the outdated UM regulatory paradigm that exists today. Although this task will not be simple, it is recommended that a new set of regulatory guidelines be developed that integrate the different medical management functions referenced in this report, including case management and external review. Through one seamless system of regulations, all stakeholders should benefit. As part of this process, there should be an acknowledgment that some activities cannot be effectively regulated. But in those areas, where we may be in a post-regulatory environment, the hallmarks of value-based care such as transparency, accountability and innovation, still play an important role.

The corporate practice of medicine will remain a fundamental pillar of health care delivery for years to come. The more that we can promote quality, openness, standardization and innovation within UM programs, the more all stakeholders will benefit. The next generation of medical management regulations can play a key role in this effort.

Appendix A: Survey Methodology

This survey was conducted by RegQuest in conjunction with EBG Advisors and Schooner Strategies, and was supported by private funding. The survey methodology builds from the first *Utilization Management Guide* published by URAC in 1999, with subsequent editions published in 2001 and 2005.

Sampling Technique

EBG Advisors and RegQuest collectively updated the information on all 55 states and territories from the 2005 *Utilization Management Guide, 3rd Edition* to reflect current regulations. Once the state and territory surveys were updated, a member of the research team reached out to each state insurance regulator to allow for formal review of the information collected and to ensure accuracy.

Regardless of whether the regulator replied or not, RegQuest's staff performed a thorough review of each state to ensure information was current and accurate. RegQuest staff maintained communication with regulators to confirm that the laws included the most up-to-date regulations.

Survey Participants

Out of a total of 55 states and territories, 35 regulators responded to our request for review with edits and/or confirmation of accuracy (Alabama, Arizona, California, Colorado, Connecticut, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Kansas, Kentucky, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, New Mexico, North Dakota, Oklahoma, Puerto Rico, Rhode Island, South Dakota, Texas, Utah, Vermont, Washington, West Virginia, Wisconsin and Wyoming). As of December 2015, responses for 20 states and territories were pending (Alaska, American Samoa, Arkansas, Delaware, Guam, Idaho, Iowa, Louisiana, Maine, Montana, Nevada, New York, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Virginia and the U.S. Virgin Islands).

Research

In addition to the state survey, research staff reviewed key journal articles, interviewed industry leaders including UM medical directors and legal experts, and studied other materials to help identify key regulatory and industry trends. The report authors also interjected their insights based upon decades of experience on the subject-matter.

The following UM Trend Report Quick Reference Tables are located and kept up-to-date in the Resources section of www.RegQuest.com and are included in the UM Module subscription. To subscribe or login, go to www.RegQuest.com. The Quick Reference Tables include:

- UM Regulations: State Scope & Applicability
- UM Regulations: Organizational Registration/Licensure Requirements
- UM Regulations: Key Program Requirements
- UM Regulations: Review & Appeals

Appendix B: Timeline of Utilization Management Trends

Health Utilization Management Trends

Time-frame	UM Activity	Mode of Communication	Explanatory Notes
1970's	• Emphasis on retrospective review.	• Claims	• UR emerged from examining/evaluating utilization costs after medical services had been rendered.
Early 1980's	• Majority of UR decisions still retrospective, but some programs begin to rely on prospective (i.e., precertification) and concurrent reviews.	• Claims • Phone	• After the introduction of phone-based communications, some UR decisions were now being made prior to or concurrent with medical treatment.
Mid-1980's	• General expansion of UR programs.	• Claims • Phone • Some facsimiles and letters (used typically for notifications)	• In part, the emphasis on precertification requirements was spread from HMOs to an industry-wide platform.
Late 1980's	• State legislatures begin to pass laws to regulate UR. • Industry convenes several meetings through the American Managed Care Review Association (AMCRA) to consider establishing a voluntary accreditation program.	• Phone usage expands	• Concerns are expressed about the integrity of some UR programs. As a result, several states pass UR/UM legislation (i.e., Arkansas, Connecticut, Iowa, Louisiana, Maryland, and North Carolina).
Early 1990's	• Continued growth of precertification and concurrent reviews. • URAC incorporated in 1990, adopts first set of UR Standards in 1991 (version 1.0). • Additional states pass UR laws. • Introduction of case management (CM) by managed care companies, especially for catastrophic, high cost cases.	• Continued use of claims, phone, facsimiles, and letters. • Health call centers or demand management services employed as well.	• Although case management (CM) has been used in other fields such as workers' compensation and behavioral health for some time, the introduction of CM into the managed care system did not occur until the early -to-mid-1990's. Traditionally, managed care organizations maintained two separate departments for UR and CM. • Length-of-stay rates drop due to UR. • URAC requires that non-cert decisions be communicated in a timely fashion via facsimile or letter.

Appendix B: Timeline of Utilization Management Trends (continued)

Health Utilization Management Trends			
Time-frame	**UM Activity**	**Mode of Communication**	**Explanatory Notes**
Mid-1990's	• UR offerings on more advanced information systems (IS) or information technology (IT) platforms thrive. • UM/CM integration expands; departments are sometimes consolidated. • NAIC adopts Utilization Review Model Act.	• Some companies begin using e-mail as a supplementary mode of communication.	• Mid-1990's marks the beginning point of rapid evolution in the UR field. The previous 10 years did not experience drastic change compared to late 1990's. • Access to data relating to clinical outcomes, patient records, and other information increases dramatically. • URAC's revised UR standards emphasize clinical oversight of UR process. • E-mail transmissions begin to shorten approval times for medical necessity approvals. • "Utilization Management" (UM) becomes preferred term over "Utilization Review" (UR) by many. UM denotes a more comprehensive approach to medical necessity review determinations including quality oversight assurance monitoring.
Late 1990's	• Disease management also introduced by some MCO's as a way to improve medical management. • External Review requirements added to the UM process in many states. • The interaction between UM and CM better understood leading to more focused CM applications. • Increasing interest in identifying better outcomes by managing specific disease states through disease management programs.	• Although phone calling still common, e-mail transmissions expand. • Telephonic dial-in capabilities allow automated precert for some medical treatments. • New internet communication links under development. • UM program personnel begin communicating with providers and other stakeholders via Internet-based software applications. • Sophisticated phone/IT systems employed to track abandonment rate and wait times.	• The efficiency of the medical necessity determination process continues to improve. • URAC's revised UR standards recognize limited use of "scripted clinical reviews" by administrative staff. IT/IS systems provide support. • URAC requires that non-cert decisions be communicated in a timely fashion via facsimile, letter, or electronically (e.g., e-mail). • Many MCO's begin to offer web-enabled communication links that have potential for real time approval and denials. • Population-based disease management expands. • Medical management approach customizes services for each client.

Appendix B: Timeline of Utilization Management Trends (continued)

Health Utilization Management Trends			
Time-frame	**UM Activity**	**Mode of Communication**	**Explanatory Notes**
2000 – 2004	• Scripted screening rises to help automate UM systems. • Precertification and concurrent reviews drop off significantly for routine procedures. • UM is customized into various medical management applications which include both integrated care coordination models and traditional siloed UR applications, but UM interventions typically focus on high cost cases.	• Most communication links described above still are in use. • Web-enabled communications links gain momentum supporting UM systems.	• Medical management model more appropriately utilizes the various UM/CM/DM services available, and is able to customize application to individual patient. • Consumer empowerment movement begins. • Greater reliance on evidence-based medicine, predictive modeling and outcomes reporting. • Offshore operations for certain managed care functions are launched (e.g., staffing for health call centers, claims processing).
2005 - 2010	• The care coordination approach becomes more dominant with UM, CM and DM each having defined (and sometimes over-lapping) roles. • UM interventions include patient safety indicators. • ACA adopted requiring additional UM and external review requirements.	• Wireless technologies will eventually overtake hard-wired applications. • Some traditional modes of communication such as fax transmissions begin to drop off significantly.	• The goal of inter-operability between medical management systems continues to be a challenge. • Marriage of UM data with electronic health record (EHR) application will eventually create a seamless data stream for health care organizations, providers and patients. • Efforts continue to link the UM process with objective evidence-based treatment protocols.
2011-2015	• UM integration through population health management programs. • Traditional disease management programs begin to be phased out. • Rise of UM oversight of genetic testing.	• Move to tablets and smartphones.	• UM benefiting from enhanced data-analytic solutions, EHR applications supplement traditional UM software applications, and genetic testing.
2016 & Beyond	• Move to true UM outcomes metrics. • UM services regularly generate performance and quality outcomes data (where appropriate).	• Communications through machine learning.	• The ROI of UM interventions will continue to be an issue, but UM programs will gain additional support in the future through the introduction of new business and clinical outcome indicators. • UM interactions occur in real time and offer stakeholders a seamless experience
Source: Original table was published in the 2005 edition of the UM Guide and was drafted by Garry Carneal. Carneal has updated this table based upon the current research initiatives.			

Appendix C: Population Health Issue Brief

Issue Brief: Population Health Management: New Perspectives on a Familiar Concept

Published by EBG Advisors, PHI Institute and Schooner Strategies

Introduction

Over the past several years, population health management (PHM) has become a catchphrase for what many believe is a transition to a more outcomes-based approach to health care. While there has been a renewed focus on outcomes and treatment of entire patient populations, this is hardly a new phenomenon. Managing population health in various ways has been used for decades as a way to address public health concerns, along with use in areas outside of the traditional "health care" realm. PHM has become more formalized as a tool of health care delivery and payment systems. According to the Department of Population Health at the New York University School of Medicine, "Population health complements the individualized practice of clinical medicine by placing its focus on the health—both determinants and outcomes—of entire populations of persons, promoting proactive approaches to disease prevention and management at the community, health system and policy levels."[1] Many modern definitions of population health and PHM use similarly broad terms, acknowledging that this paradigm of health care should not be restricted to one purpose or goal.

In order to understand the emphasis on population health management, it is important to know how "population health" is distinguished from "individual health," how it has been defined in the past, what it constitutes today, and the benefits of its use to stakeholders.

Individual vs. Population Health

Modern health care has centered on treatment of the individual patient. In what we think of as traditional medicine, a patient sees a doctor or other clinician who performs a given procedure, test or other service based on the characteristics of that patient. Treatment is based on prior evidence or professional experience or opinion that the clinician believes will result in a positive outcome for the patient. Payment is generally made on a fee-for-service (FFS) basis; doctors are paid based on how many services, procedures and tests they provide.

The transition to population health is, in part, a result of the problems that have emerged from the individual health model. Under the FFS model, clinicians are incentivized to provide services rather than focus on outcomes. PHM often shifts the focus away from a service-intensive intervention and toward interventions that create quality outcomes for the largest number of people. Additionally, while preventive services are often a part of individual-based health, intervention is most often reactive. PHM that maintains a focus on outcomes allows clinicians to focus even more on prevention.

PHM, conversely, involves analysis and intervention for a group of individuals—it can be targeted directly to the group, without knowledge of the individual, or it can be targeted to individuals within a pre-defined group.

The group can be chosen for a specific reason that the intervention is designed to address. In this instance, a professional identifies multiple individuals at risk for a given malady, and implements an intervention that has worked for this type of individual in the past, or is hypothesized to work based on evidence or professional opinion. Payment is made mostly for measurably achieving quality outcomes using valid methodologies within a population rather than for performing specific services. Determining the right population, what the appropriate intervention is, and measurably affecting the population are therefore the most important aspects in PHM.

Because PHM is so broad, it can also involve a population that is not targeted, but instead blanket entire communities or even nations. Most commonly, these types of interventions have been associated with public health issues.

Historical Perspective

While historical efforts to improve the health of populations have not been called "population health management," people have been using techniques to make these improvements for centuries. The most common type of PHM in this sense is public health.

Public health interventions have been used throughout the world as civil society has acknowledged a need to improve the quality of life for communities. Public health interventions focus on entire populations and do not usually target specific groups of people or specific individuals.

One of the most well-recognized and important population health interventions in modern times was the establishment of sanitation systems. The widespread use of modern sewer systems in the Western world during the late 19th and early 20th Centuries led to dramatic reductions in diseases like typhoid and cholera.[2] While it is not a health care intervention in the obvious sense, providing sanitation for different populations addressed one of the most serious health issues of the time. And like many other public health issues, sanitation systems help entire communities and are not targeted to specific people based on their conditions or other factors.

Similarly, the advent of motor vehicle safety measures during the 20th century can be considered a health intervention, albeit a nontraditional one, government and private industry have taken to reduce mortality and injury rates among the public. Speed limits, guardrails, seatbelts and other precautions have positively affected population health, despite the fact they do not treat any disease or ailment.

History contains an enormous number of interventions that sought to improve the health of entire populations. PHM as we know it today, however, is a more modern phenomenon, and one that often targets smaller, more specific individuals.

Population Health Management Today

The prevalence and popularity of PHM has grown exponentially over the past several years, including the establishment of organizations like the Population Health Impact Institute in 2003.[3] Several factors have contributed to this phenomenon, including passage of the Patient Protection and Affordable Care Act (ACA) in 2010. No factor, however, has had more of an impact in the move to implement PHM practices than the increasing costs associated with FFS medicine. By practicing PHM, advocates believe that not only can unnecessary health care services be curtailed, but outcomes, measured in defined population and using valid methods, can be improved. Altering payment structures to incentivize positive outcomes within a population, for example, should lead to a greater effort to improve outcomes across the board.

Improving outcomes and reducing costs by intervening in a given population is, of course, an admirable goal. However, for health care delivery systems seeking to implement PHM strategies, the question becomes how to create and validly measure an effective program.

By its nature, PHM must involve strict measurement and accountability. When attempting to impact the health of a large group of individuals, it is essential the correct population is chosen, an effective intervention implemented, and the effectiveness appropriately determined by measuring outcomes. PHM programs break down if measurement and analysis are not conducted accurately.

In measuring the process of PHM, a potential program must determine who is being placed into a population and how to ensure they are receiving the intervention. Does the patient population exhibit attributes the intervention is meant to address? Are there engagement metrics that provide detailed analysis of how effective strategies were to reach a population? This aspect becomes especially important in care management PHM.

Just as important as process measurement is outcomes measurement. A program must define outcomes as well as targets to reach those outcomes. An effective PHM program will state a specific goal to reach through the intervention. The program must also be able to measure whether the outcome achieved is attributable to the intervention used and what effect confounding factors may have had. Because confirming causality is difficult in any study, this can be one of the more challenging tasks. Without the confidence that an intervention is effective in achieving an outcome, however, the usefulness of PHM as a way to improve the health of populations breaks down.

Not only have PHM programs become more common in the past several years, they have also grown more sophisticated. Many believe the use of epidemiological techniques to measure "success" within health care systems has the potential to bring more accountability to the health care field and result in better, less expensive outcomes. Two of the main vehicles of PHM growth are accountable care organizations (ACOs) and Patient Centered Medical Homes (PCMHs).

Care Management & Population Health

The emerging PHM approach today overlaps and supports existing care management programs, but also includes additional tactics to improve clinical and financial outcomes. Among other benefits, this allows for the customized management of targeted individuals in designated populations.

With the advent of managed care in the 1970s, we have seen an evolution of different types of care management activities, starting with utilization review. Although payers, providers and others began with a focus on managing the population through actuarial criteria, the care management system evolved into more dynamic management models, such as case and disease management programs.

Today, care is coordinated through robust and complex condition management programs that are evidence-based and supported through technology. This new approach allows PHM programs to create customized care treatment plans that control for co-morbidities throughout the continuum of care. Simply put, PHM strategies are re-writing how medical care is delivered and managed, a scenario in which fragmented or episodic care is no longer in vogue.

Like case management, this model is based on utilizing a team of caregivers including case managers, attending physicians, nurses, relatives and others. Populations and individual patients are targeted across a wide range of medical conditions and social/physical environments. Having access to a data-rich environment also is a key element used in care management programs that support PHM goals.

When PHM programs rely on care management techniques, a dynamic array of solutions can be deployed. Examples include:

- Using population risk identification and access to stratification processes;
- Assessing physical, psychological, economic and environmental needs;
- Managing high-risk patients to prevent acute episodes;
- Accessing evidence-based protocols to diagnose and treat patients in a consistent, cost-effective manner;
- Creating customized care treatment plans that control for the patient's co-morbidities;
- Promoting transitions of care to reduce unnecessary hospital readmissions;
- Relying on patient engagement strategies promoting personal responsibility and self-management; and
- Integrating and using dashboards and reports to use as feedback loops for patients, providers and program sponsors.

Among other market drivers, PHM is more important than ever due to shifting reimbursement strategies such as performance-based compensation. For example, hospital revenues are shifting from inpatient care to outpatient, and physician reimbursements are moving from individuals to entire patient populations and from volume to value. In addition, the emergence of value-based purchasing criteria is promoting both quality-based and more cost-effective solutions.

ACOs and PCMHs

Among many reforms instituted by the ACA aimed at helping encourage cost-effective health care solutions, ACOs stand out as a noteworthy change that is bringing PHM to areas throughout the country. ACOs are an attempt to coordinate care among different clinicians by providing services that are as integrated as possible. The premise is to allow clinicians to work together for the benefit of the patient, reducing costs and focusing on a more holistic approach to treating individuals and, while procedures may drop, ensuring payments to ACOs are still robust enough to encourage fee for outcomes, rather than fee-for-traditional services.

The Centers for Medicare and Medicaid Services (CMS), which is running the government's main ACO programs, has called these organizations "groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high quality care to their Medicare patients."[4] PHM factors into the ACOs because of the emphasis on coordinated care and departure from the traditional fee-for-service model, but also because a specific population of at least 5,000 seniors are chosen to participate in the program. Providers focused on these groups can use population-based interventions including an emphasis

on chronic care, which may disproportionately benefit the older population being treated.

The number of ACOs nationwide has risen dramatically and networks not associated with the CMS program have also been established, meaning private parties see the potential for cost savings even without the benefit of government incentives. Another health care delivery system with goals that dovetail with those of PHM is the Patient Centered Medical Home (PCHM). Medical homes share many of the same characteristics as ACOs—they both emphasize the importance of coordinated care and positive outcomes. Unlike ACOs, however, PCHMs are not comprised of hospitals and other varying types of providers. The emphasis is on primary care, with a primary care physician acting as the hub of a patient's health care experience. Care is coordinated between specialists and other clinicians, but centered on the importance of primary care and prevention. As we see in many of the models using PHM, a population of patients is treated in a coordinated manner, engaged by a primary care provider during and between visits. This differs greatly from the FFS model where patients are treated on more of a case-by-case basis.

ACOs and PCHMs are just two of the models being tested by health care providers nationwide. As PHM continues to grow, we will likely see similar strategies being deployed in varying contexts.

Conclusion

As the health care field continues to evolve in the coming years, PHM will likely play a central role in how health care delivery systems function. In recent years new, innovative health care models have emerged, such as ACOs, PCHMs and others. As in any industry, some of these models will succeed by using valid tools to measurably reduce costs and improve outcomes. Others will prove to be unpopular or unworkable, but learning will result from these as well. The key is establishing appropriate metrics to measure the process and outcomes of these models and the interventions they implement compared to valid expectations of outcomes had these not been implemented.

Many advocates believe PHM has the potential to make systemic change in health outcomes. By treating entire populations and focusing on the entire continuum of care, instead of simply treating individuals on a strictly fee-for-service basis, advocates of PHM claim clinicians can make meaningful improvements to the health status of large populations.

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