

The Impact of the Affordable Care Act on Clinical Trials

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The Affordable Care Act (ACA) implemented dramatic changes to our health care system, expanding coverage to more Americans and creating a host of new mandates for health plans. In the wake of all the health insurance exchange publicity, limited public attention has been paid to a new key requirement for insurers and group health plans to cover costs related to clinical trials.

Prior to January 1, 2014, when this provision took effect, many group health plans and insurers specifically excluded any costs related to “experimental” or “investigational” treatments from

their policies, effectively eliminating coverage for clinical trials. This issue brief examines how the new ACA requirements are changing the landscape for clinical trials, and how care management can help patients, providers and payors make sense of the decision making process under the new law.

The issue brief provides important information about how the clinical trial coverage landscape is changing, and provides useful insights for how health plan personnel, providers, case managers, benefit administrators, patients and others can proactively address these emerging issues. The analysis is broken down into six sections:

- Part I: A Primer on Clinical Trials
- Part II: The ACA Coverage Requirements
- Part III: Paying for Clinical Trials
- Part IV: The Role of Care Management in Clinical Trials
- Part V: Appeals
- Part VI: Final Thoughts

The issue brief also includes two interesting sidebars: a case study of the bone marrow clinical trial coverage in the 1990s, and a discussion of the emergence of personalized medicine, such as molecular profiling in the clinical trial coverage area.

Part I: A Primer on Clinical Trials

According to the National Cancer Institute, “Clinical trials are research studies that involve people. They are the final step in a long process that begins with research in a lab. Most treatments we use today are the results of past clinical trials.”¹



Clinical trials are performed to determine if new treatments and procedures, new drugs and combinations of drugs, or new devices are clinically safe and effective and should be used as a standard of care for future patients. They can also help determine whether a new treatment works as well as or better than an existing treatment. Participation in clinical trials is often considered when standard therapies have failed. Sponsorship of clinical trials can come from federal agencies like the National Institutes of Health, pharmaceutical and device companies, or individual or hospital-based researchers.

Clearly, clinical trials are essential to the advancement of medicine and the improvement of patient outcomes in countless areas of health care. Whether testing a new therapy or exploring a new way to use an existing therapy, clinical trials measure care and are responsible for landmark breakthroughs in science, as well as key information about treatment risks to different populations.

Clinical trials are typically divided into four phases of review:

- **Phase I:** Researchers test a new drug or treatment in a small group of people for the first time to evaluate its safety, identify side effects, determine a safe dosage range, and begin to uncover the specific patient population(s) for whom the therapy demonstrates activity.
- **Phase II:** The drug or treatment is given to a group of people with the same diagnosis to confirm that it has some benefit, identify the optimal dose and activity for a specific patient population, and further evaluate its safety.
- **Phase III:** The drug or treatment is given to a large enough group of people with the same diagnosis to confirm its effectiveness compared with the standard of care, monitor side effects, and collect information that will allow the drug or treatment to be commonly used safely. These are randomized, controlled trials where equal proportions of enrollees are given the standard of care with the experimental treatment as are given the standard of care alone. Patients with serious medical conditions are not given a placebo alone in a clinical trial when a standard of care exists; rather, it is only when no therapy has ever been proved effective that an experimental drug treatment is compared to placebo in a phase III clinical trial.
- **Phase IV:** Studies of the new treatment continue after receiving FDA marketing approval to gather additional information on the drug's effectiveness and side effects that are only revealed with long-term use in a large population.¹

Historically, many insurers and group health plans struggled with how to apply the exclusions of experimental and investigational coverage to clinical trials. In many cases, all costs related to the clinical trial were excluded from a patient's coverage. However, as trials moved into Phases III and IV and it became unclear when a new treatment actually lost its investigational status and became a standard of care, health plan decisions were often inconsistent. Lawsuits were filed on behalf of consumers who were denied access to clinical trial benefits by their insurers, typically casting the insurers as villains. These legal actions yielded inconsistent rulings and outcomes.

In litigation, the media and consumer-oriented literature, the health plan is often portrayed as the evil-doer that will arbitrarily deny clinical trial coverage to a desperately ill patient. However, in the vast majority of circumstances, that's not the case. Health plan coverage determinations must be made based on a number of factors, including:



- **Benefit Design:** This has traditionally provided the major limitation on scope of coverage. Prior to the ACA and other state laws designed to promote access to experimental treatments, some health policies were intentionally designed to limit or exclude coverage for the health plan portion of the clinical trial coverage. Although clinical trial sponsors typically cover the costs for the experimental treatment itself, the related costs associated with the trial can often escalate. Therefore, some benefit offerings were intentionally limited to keep the insurance coverage affordable.
- **Patient Safety:** This remains a chief concern for payors to ensure a patient's health is not being jeopardized. Many cases exist where clinical trials were stopped early when participants' health became compromised in the clinical trial intervention group.

- **Clinical Appropriateness:** Is the experimental procedure medically appropriate and/or necessary for the specific patient? This type of decision is further complicated by the fact that clinical trials are often the last resort for patients when established medical treatments have not helped.

In today's post-ACA environment, the landscape is only slightly more well-defined. It is important to note that ACA benefit design parameters, although broader, will still create some limits to the scope and duration of clinical trial coverage.

Part II: The ACA Coverage Requirements

How does the ACA affect coverage for clinical trials?

In an unusually short but sweeping amendment, Section 2709 of the Public Health Service (PHS) Act was amended by the ACA to mandate that as of January 1, 2014, non-grandfathered health plans (i.e. those that were not in place before March 23,

CASE STUDY: BONE MARROW CLINICAL TRIAL COVERAGE

In the 1990s, high dose chemotherapy with autologous bone marrow transplant (HDC/ABMT) became the poster child for the battle between insurers and patients and their physicians over clinical trials. Billed as a promising treatment for metastatic breast cancer, desperately ill patients and their physicians lobbied insurers for coverage of the treatment despite the fact that randomized clinical trials had just begun.

Patients sued their insurers for denying them access to the treatment as an experimental and investigational procedure. Waging a widespread media campaign villainizing the insurers for denying them treatment had extraordinary success in bypassing the clinical trials stage of research. Court decisions that determined that HDC/ABMT was in fact the "standard of care" resulted in mandated insurance coverage, widespread use of the treatment, financial settlements, and ultimately even some government mandates to cover the procedure, all without any credible scientific evidence to support it. Court decisions also varied greatly, and the uncertainty alone led many health plans to cover the treatment simply to avoid the potential of large litigation costs.

Ironically, the clinical trials that were so important to establishing the efficacy of the treatment had trouble recruiting patients. During a period when most women were able to obtain coverage for treatment outside of a trial, it was difficult to convince breast cancer

patients to participate in a clinical trial in which only half would be able to receive a transplant. Eventually, only 1,000 women participated in formal clinical trials. By the end of the decade, it was finally clear from those trials that HDC/ABMT was not an effective treatment for breast cancer, and even had the potential to do more harm than good. In addition, one of the five key studies that had initially promoted the efficacy of HDC/ABMT was shown to be completely fraudulent. However, by the time this information came to light, as many as 40,000 women had undergone this treatment outside of clinical trials despite the fact there was no research based evidence that it worked. The unfortunate result of this widespread usage of an ineffective treatment was not only a huge financial blow to insurers, but a high patient mortality rate of 3% to 15%.

Perhaps the most critical lesson learned from the experience with HDC/ABMT was the importance of ensuring new treatments are rigorously tested through scientific clinical trials before such interventions are paid for and commonly used as treatment in the general public. It also underscores the dangers of giving in to a push from the media and lobbyists, rather than relying on empirical evidence to make critical health care decisions. In many ways, the HDC/ABMT example led us directly to the more rigorous adherence to standards of evidence based medicine that we observe today.

2010) cannot deny a qualified individual participation in an approved clinical trial, or deny or limit the coverage of routine patient costs in connection with participation in the trial. In essence, the ACA expanded the scope of coverage for most existing health policies and prevented health plans and insurers from excluding clinical trial coverage under most circumstances. The amendment contains only a few qualifications and clarifications:

- **Qualified individuals** are defined as those eligible to participate in an approved clinical trial protocol for treatment of cancer or another life-threatening disease or condition.
- Trials must be **“approved”** clinical trials.
- Coverage can’t be denied for the **routine patient costs** for items and services furnished in connection with the trial, but may be restricted to in network providers.
- State laws requiring clinical trials are not preempted.

Will the federal government issue additional regulations in the short-term?

The federal government does not plan to issue any regulations in the near future that would further clarify the limits of these definitions. In an online FAQ regarding Affordable Care Act implementation, published jointly by the Departments of Labor, Health and Human Services (HHS) and the Treasury, the agencies deem the language of the law “self-implementing.” Until further guidance is issued, health insurers are “expected to implement the requirements of PHS Act section 2709 using a good faith, reasonable interpretation of the law.”²

What other sources of regulation impact clinical trial coverage?

The U.S. Food and Drug Administration (FDA) has primary authority to regulate clinical trials taking place within the country. This also includes an opportunity to file a complaint regarding clinical trial coverage if a patient or provider has concerns regarding an issue associated with a trial. The FDA has an active blog that is worth monitoring by health care professionals. For example, the FDA recently announced “plans to enhance the collection and availability of clinical trial data on demographic subgroups—patient populations divided by sex, race/

ethnicity or age.” Clinical trial oversight also can be impacted directly and indirectly through other federal agencies and at the state level.

How do state laws impact the ACA coverage requirements?

Because the ACA does not preempt state law, states may impose additional requirements above those specified at the federal level. The PHS amendment was very specific that state requirements do supplement the ACA baseline requirements. For more information, see States that Require Health Plans to Cover Patient Care Costs in Clinical Trials.

Who is a “qualified individual” under the new ACA clinical trial requirements?

A “qualified individual,” as defined for the purposes of the new ACA clinical trial requirements, can be any individual enrolled in health plan coverage who is deemed eligible to participate in an approved clinical trial according to the trial protocol, specifically with respect to treatment of cancer or another life-threatening disease or condition. Further, the individual’s participation in the approved clinical trial must be appropriate to treat the disease or condition, which can be determined through a clinical conclusion supplied by the referring health care professional, or based on medical and scientific information provided by the individual.³

What is an “approved” clinical trial and who enrolls the patient?

The law also raises the question of what constitutes an “approved” clinical trial as defined in the law. The clinical trial must be approved or funded by at least one of several listed government agencies including, but not limited to, the National Institutes of Health (NIH) and the Centers for Medicare & Medicaid Services (CMS), or conducted under an investigational new drug application reviewed by the Food and Drug Administration, or exempt from having this type of application. Clinical trials are also effectively governed by institutional review boards.⁴

Health plans are not required to cover treatments or care that fall outside the designated class of approved clinical trial. In addition, a health plan can also require a patient to partake in the approved clinical trial through a participating in-network provider, according Section 2709 of the PHS, as long



as the provider will accept the individual as a participant in the trial in accordance with the trial protocol.

Although the in-network language is a correct restatement of the new ACA requirements, this provision is at odds with real-world practice. A patient's treating physician cannot enroll a patient in a study unless they are already a designated investigator for that particular trial.

Because cancer represents hundreds of rare diagnoses, each with a different standard of care, there are likely to be very few sub-specialists signed on as investigators to each clinical trial. Therefore, the odds are remote that an appropriate cancer clinical trial will be offered by an in-network provider. Furthermore, the size of a health plan's provider network will determine whether it contains subspecialists qualified to treat patients with rare cancers or serve as investigators in clinical trials.

With Section 2709's short amendment, ongoing state preemption issues, real-world practice and no future planned guidance, confusion remains about when, where and how health plans and insurers should pay for routine patient care that accompanies a clinical trial.

Part III: Paying for Clinical Trials

Generally speaking, there are two types of costs associated with a clinical trial: patient care costs and research costs. As highlighted by the National Cancer Institute (NCI), the costs are broken down as follows:⁵

Patient care costs are those related to treating the disease or condition, whether the patient is in a trial or receiving standard therapy. These costs are often covered by health insurance. They include:

- Doctor visits
- Drugs and biological therapies deemed standard of care
- Hospital stays
- Lab tests
- X-rays and other imaging tests

Research costs are those related to taking part in the trial, and are traditionally not covered by health insurance, but may be covered by the trial's sponsor. Examples include:

- The study drug, device or service
- Lab tests performed purely for research purposes
- Additional x-rays and imaging tests performed solely for the trial
- Data analysis

The NCI points out that when patients take part in a trial, they also may have extra doctor visits typically not included with standard treatment. Transportation and child care costs also may increase.

What are the costs that health plans must cover?

The intent of PHS section 2709 is to cover the patient care costs incurred in clinical trials, while excluding the research costs. In addition to mandating participation in clinical trials, the ACA goes further in its extension of consumer protections. Health plans must also cover "routine patient costs" for a patient participating in an approved clinical trial. These costs include services that would be provided in the plan for an individual who is not enrolled in the clinical trial. Examples of these types of routine costs include physician visits, laboratory tests, drugs or procedures, and other items or services that are provided for those undergoing the standard of care.

Health plans are not required to provide benefits for routine patient care services rendered outside of the plan's services or network area unless out-of-network benefits are covered under the plan. As referenced above, this ACA requirement does not necessarily reflect the real world practice of how routine patient costs are covered by health insurance for patients with serious, rare medical conditions.

It is important to note that the language in PHS section 2709 specifically excludes coverage for the investigational item, device or service itself, as well as items and services provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient.

A final exclusion leaves a lot of room for interpretation by excluding "the cost for a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis."

If a patient had to be hospitalized to receive an investigational drug treatment, the clinical trial sponsor would cover the costs of the medication, but it is not always clear how much the insurer versus the clinical trial sponsor would have to cover the costs of any related hospitalization or physician fees. Prior to the ACA, the health plan might have denied the additional medical expenses associated with the investigational drug unless the patient would have had the admission or procedures anyway as part of standard of care. Under the new provisions, the clinical trial sponsor will continue to fund the drug costs for the trial, but the health plans might have to cover all the ancillary costs, including the hospitalization and the physician costs related to the care.

A common interpretation of Section 2709 of the PHS Act suggests the measure is intended to serve as the minimum requirement for plans and insurers, and should not be used to limit coverage that may have already previously exceeded these requirements. Therefore, a plan may choose to offer greater coverage than what the ACA requires, including coverage for costs associated with trials relating to different conditions and conducted for different purposes. In response, a number of health plans are broadening the definition of “experimental/investigational” treatments and “other life threatening conditions” policy definitions. These changes help cover the insurance costs and expenses associated with preventive, diagnostic and therapeutic clinical trials, along with complying with federal and state mandates. With the expanded coverage, premiums will be raised by those insurers in many instances to cover the additional benefits.

Part IV: The Role of Care Management in Clinical Trials

In the post ACA world, case managers and care management programs are uniquely positioned to help coordinate with doctors, financial counselors, the clinical trial research team, health plan administrators, hospital staff, both network and non-network providers, and others to make sure the right information is getting to the right person at the right time.

What Are the Key Questions for Care Management to Address?

A multitude of factors will come into play as a case manager works with the patient, the attending provider, clinical trial coordinator and others to determine if the patient should be placed into a particular clinical trial. Factors to consider include:

Clinical Appropriateness

- Is the patient a “qualified” individual to participate in the clinical trial based on the trial sponsor’s criteria? (This is something that the patient, attending physician and clinical trial coordinator would consult with together.)
- Is the trial clinically appropriate for the patient based on their ongoing health needs and current treatment status?

Coverage Requirements

- Is the trial appropriately vetted by an independent review board (IRB) and operated under jurisdiction of the applicable government agencies?
- What are the coverage requirements under the approved clinical trial?
- What part of the patient’s care is covered by the trial sponsor? What routine and ancillary care must a particular health plan cover?
- What out-of-pocket costs will the patient incur?
- When can a health plan require that care in a clinical trial be provided in-network versus out of network?
- What is the language in the health insurance policy in terms of covering routine costs?

Regulatory and Legal Criteria

- How do experimental/investigational coverage limitations interface with the new ACA requirements?
- What additional state or other regulatory requirements might apply?

THE EMERGING ROLE OF MOLECULAR PROFILING TO IDENTIFY APPROPRIATE CLINICAL TRIALS & TREATMENTS

Personalized medicine—the practice of combining a molecular-level diagnosis with a therapy that targets the precise molecular change—now dominates cancer research and new drug approvals. It is accelerating the demand for clinical trial participation and pressuring health plans to quickly formulate processes for complying with the new ACA mandated clinical trial coverage requirements.

Testing informs determination of who is a qualified individual

Along with the new ACA coverage requirements, clinical trial coverage coordination is becoming more complex, as highlighted by molecular profiling. The new wave of testing is becoming the foundation of personalized medicine, creating new challenges to make sure the right patient is enrolled in the right clinical trial at the right time.

Molecular profiling reveals the differences between a patient's normal cells and cancer cells. Specifically, profiling tells us exactly what has changed in the cancer cell's genetic blueprint (genomic profile) or its proteins (molecules that are manufactured from the genetic blueprint). Targeted therapies are only indicated when a cancer cell has the alteration targeted by the new drug—it's the mechanism by which the two connect.

As a result, genetic testing and molecular profiling is becoming an invaluable resource in determining whether an approved targeted therapy is clinically appropriate or medically necessary. Likewise, this relatively new diagnostic tool can be viewed as the starting point for clinicians, researchers

and health plans in determining whether a patient is a *qualified individual* for a clinical trial testing a targeted therapy.

Targeted therapies drive demand for clinical trials

Patients have been interested in clinical trials of targeted therapies for well over a decade, but the odds of finding an appropriate clinical trial was remote when a patient's tumor was tested for one molecular change at a time. Today a patient's tumor can be analyzed for hundreds of molecular changes simultaneously, and these results are being used to instantly identify trial matches nationally. Support services are now available to facilitate clinical trial matching and help physicians manage the referral process because clinical trials typically have short eligibility windows.

The evolution of childhood leukemia research and treatment is illustrative of the changing landscape of clinical trial coverage and treatment. By 1980, physicians and researchers increased the cure rate for childhood leukemia to over 80% from a virtual death sentence in the 1950s. How did they do it? Nearly every child with leukemia was enrolled in a clinical trial. Using the same basic drugs and procedures, pediatric oncologists gradually adjusted and measured every incremental change in dosage, timing and therapeutic combinations. They shared results from every case, and this evidence-based, continuous learning strategy remains the standard of care today with over 85% of children with cancer enrolling in clinical trials.

As a result of these and other enhancements, the world of clinical trials is changing quickly through genetic testing and gene expression profiling, which in turn is promoting customized treatment strategies with targeted therapies at the molecular level. Helping coordinate care for each patient through the continuum of care, including personalized medicine, is now an important medical and public policy objective.

—Courtney Hudson, CEO, EmergingMed*



Care Coordination

- Can the patient fully participate in the clinical trial (e.g. location)?
- How is the patient transitioned after the clinical trial is completed?
- How is care coordinated during the clinical trial for a patient's additional co-morbidities?
- If there is an adverse effect to the clinical trial, does health insurance cover additional care?
- Is a patient's right to PHI protection and disclosure safeguarded throughout the clinical trial? (Is the patient given constructive notices to opt out and/or opt in?)
- How is patient safety adherence ensured before, during and after the clinical trial, especially through the transitions of care?
- How is compliance with prescribed medication ensured during and after the clinical trial?

Health plans and providers must be ready to help patients navigate the new ACA requirements regarding clinical trials. For each patient that might qualify for clinical trial coverage, care management experts should be consulted to help explain what benefits are covered pursuant to the ACA (and other government requirements) and the plan documents, as well as through appropriate clinical review criteria. The case manager can help the patient understand the costs related to the trial and can help coordinate with the applicable doctors and the trial's contact person about the costs that must be covered by you or your health insurance. A case manager also can help coordinate any insurance authorizations that are required through a utilization management or similar program.

Part V: Appeals

When a health plan elects to not provide coverage related for a patient requesting a clinical trial, a patient or a provider may file an appeal. This is a normal part of the process.

Internal Appeal

The patient or attending provider must submit an appeal to the health plan that denied the coverage, requesting they reconsider the denial and provide coverage for the requested treatment. The appeal

should be based on the medical necessity of the clinical trial and why the physician feels a clinical trial is the best treatment option for the patient. The adverse coverage determination itself also can be appealed based on the policy itself or the summary of benefits (SOB) document.

If there is enough information to show that the approach is safe and effective, the health plan may consider the approach "established" and cover some or all of the costs. The appeal also should consider any expanded coverage requirements established by the ACA.

One of the biggest challenges for patients participating in a clinical trial is when a health plan denies coverage for those charges that would otherwise be covered if the patient was receiving standard treatment. For example, the insurer may deny charges for blood work or radiology exams if the tests are ordered more often than deemed necessary. The health plan's medical experts may consider the additional medical services or tests as "experimental/investigational"—being done to monitor the trial.

A host of state, federal and accreditation agency criteria will affect the specifics of the appeals process. Having access to an impartial expert in most cases to assist with process coordination is critical.

External Appeal

Once the internal appeal options are exhausted without a satisfactory outcome, the patient or their attending physician is permitted to file an external appeal based upon rights established both by federal and state law. In fact, the ACA expanded the rights for most individuals to file an external appeal outside of the health plan. In such cases, an independent review organization can act as a third-party medical review resource that provides objective and unbiased opinions that support effective decision making, based only on medical evidence and/or coverage documents. Independent review organizations deliver conflict-free decisions that help clinical and claims management professionals better allocate health care resources and reduce waste. This is especially important for clinical trial coverage disputes.

Part VI: Final Thoughts

Many of the challenges and opportunities to promote new treatments for patients through clinical trial coverage in a post-ACA environment have been discussed in this issue brief. However, many practical questions and implications remain. Understanding all of the key

changes brought on by health care reform, along with the changing environment of clinical trial coverage and personalized medicine, means that we must stay vigilant.

As a result, patients, providers and other stakeholders should reach out to experts to help navigate the health care system. As trained and certified professionals in helping patients obtain and manage the care they need, case managers are uniquely positioned

to serve as a resource and intermediary between patients, payors and providers. Care management firms can use their utilization management, case management, and external review expertise to steer patients toward the best care options, address questions regarding medical necessity and scope of benefits, and act as an invaluable partner for anyone seeking guidance on their clinical trials coverage.

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Ms. Levitt is an Executive Vice President at Amalgamated Life Insurance Company where her responsibilities include oversight of health related operations including claims processing, customer service, implementation and mergers, actuarial, provider relations, and managed care. Since 2013, she has also served as Executive Director of the Amalgamated National Health Fund, a large multiemployer trust fund covering over 25,000 members where she



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Julie O'Brien, Senior Vice President/Chief Operating Officer of Alicare Medical Management, has worked for Alicare Medical Management (AMM) since 2002. Ms. O'Brien brings over 25 years of business and clinical management as well as nursing experience to her position at AMM. Her responsibilities include oversight of the day to day operations and clinical management for the Salem, NH, and King of Prussia, PA, locations.



She has extensive clinical and medical practice management experience at Health Dialog, Massachusetts General Hospital, Partners, North Shore Medical Hospital, Beverly Hospital, as well as clinical nursing experience in Emergency Nursing. Ms. O'Brien recently spoke in Washington DC on Healthcare Reform. Ms. O'Brien serves as Vice Chair of the RadSite Accreditation Committee and also serves on URAC's Accreditation Committee.

Courtney Hudson, CEO and Founder of Emerging Med, provided additional insight for the sidebar *The Emerging Role of Molecular Profiling* in this issue brief. Her experience creating managed care organizations in the 1990s proved an ideal background for forming innovative solutions



to manage the complexities of identifying, recruiting and retaining patients for clinical trials.

Endnotes:

- ¹ <http://www.cancer.gov/clinicaltrials/learningabout/what-are-clinical-trials>
- ² <http://www.dol.gov/ebsa/faqs/faq-aca15.html#footnotes>
- ³ <https://www.accc-cancer.org/advocacy/pdf/PPACA-Coverage-for-Approved-Clinical-Trials.pdf>
- ⁴ <http://www.fda.gov/forconsumers/consumerupdates/ucm134723.htm>
- ⁵ <http://www.cancer.org/acs/groups/cid/documents/webcontent/002552-pdf.pdf>

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The company's services include: 24-hour Nurse HelpLine, Utilization Management, Maternity Management, Case Management, Disease Management, Health Coaching and Wellness, Independent Physician Review, Medical Claims Review and Hospital Bill Auditing. AMM holds four URAC accreditations for Utilization Management, Case Management, Health Call Center and Independent Review.