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TOUGH LOVE: THE EMERGENCE OF CRIMINAL STATUTES AND DISCIPLINARY ACTIONS AGAINST MANAGED CARE PLANS FOR INADEQUATE CARE

Brian Wilson*

"The courts should be used to redress harms and not as a vehicle to change the system."

INTRODUCTION

The ascent of managed care organizations (MCO) since the enactment of the Employment Retirement Income Security Act (ERISA) of 1974 is

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2. The terms “managed care organization,” “health maintenance organization,” “preferred provider organization” and “exclusive provider organization” are used interchangeably in this paper and abbreviated by the term “MCO.” Together they are defined as:

[...]ny health coverage arrangement in which, for a pre-set fee (i.e. the premium), a company sells a defined package of benefits to a purchaser, with services furnished to enrolled members through a network of participating providers who operate under written contractual or employment agreements, and whose selection and authority to furnish covered benefits is controlled by the managed care company.


well documented.⁴ ERISA, on the whole, has proved enormously confusing in the context of what legislation a state may enact and what issues may properly be brought against MCOs in a state court.⁵ State and federal courts and legislators have struggled with the general question of MCO accountability, specifically the bounds of MCO tort liability.⁶ There


5. BARRY R. FURROW ET AL., HEALTH LAW 424 (2000) (noting that the U.S. Supreme Court has decided almost twenty such cases).

6. Two Pennsylvania cases wrestled with the question of when and if tort charges can be brought against an MCO. The Pappas cases highlight the uncertainty over exactly what charges can be brought or even if a plaintiff can bring suit against an MCO for punitive damages in state court related to MCO conduct. Pappas I dealt with a charge of negligence against an MCO for delaying medical care for a plaintiff where the delay is alleged to have caused permanent quadriplegia. Pappas v. Asbel, 555 Pa. 342 (1998). Later, in U.S. Health Care Systems of Penn. v. Penn. Hosp. Ins. Co., 530 U.S. 1241 (2000), the Supreme Court vacated the court's decision in Pappas I and allowed a state action to proceed against the MCO for negligence in light of Pegram v. Hedrich, 530 U.S. 211 (2000). In Pappas II, the Pennsylvania Supreme Court again held that ERISA does not preempt state law where the defendant makes a "mixed eligibility and treatment decision." Pappas v. Asbel, 768 A.2d 1089, 1096 (Pa. 2001). See also Dukes v. U.S. Healthcare, Inc., 57 F.3d 350, 358 (3d Cir. 1995) (declining to preempt a state malpractice action when the issue is quality not quantity of care); Wickline v. California, 92 Cal. App. 3d 1630 (1987) (holding that a treating physician is ultimately responsible for determining whether something is medically necessary for a patient). But see Pryzbowski v. U.S. Healthcare, Inc., 245 F.3d 266, 274 (3d Cir. 2001) (holding a delay in service claim is preempted by ERISA because a "delay in limiting benefits [is] conduct that falls squarely within [an MCO's] administrative function"); Corcoran v. United HealthCare, 965 F.2d 1321, 1339 (5th Cir. 1992) (stating that the state tort action was preempted by federal statute even though the result is no meaningful remedy for an injured plaintiff).

The lawfulness of state legislation was recently litigated in Corporation Health v. Texas Department of Insurance, 220 F.3d 641 (5th Cir. 2000), petition for cert. filed,
is a slow and uneven trend toward allowing civil actions against MCOs.\footnote{7}{See Dukes, 57 F.3d at 350 (holding that federal preemption was not mandated when an MCO practices medicine rather than just making a coverage determination, and the issue is quality); Jones v. Chicago HMO Ltd. of Illinois, 730 N.E. 2d 1119, 1132 (III. 2000) (holding that a HMO could be liable under the theory of corporate/institutional negligence if it does not meet the standard of the “reasonably careful HMO under the circumstances”); Herrera v. Lovelace Health Systems, Inc. 35 F. Supp. 2d 1327, 1332 (D.N.M. 1999) (holding that the plaintiff’s claims against his MCO were not completely preempted because they were claims over medical services and not over the approval or withholding of benefits under the plan). However, MCOs still obtain some tort protection if the issue is framed as a coverage or eligibility decision as opposed to a treatment or mixed eligibility-treatment decision. See Pegram, 530 U.S. at 228; Danca v. Private Health Care System, 185 F.3d 1, 18 (1st Cir. 1999) (stating in footnote 10 that “W[e] recognize that the practical result of our decision is that no significant state or federal remedy exists for plan participants injured by the negligence of utilization review firms and insurers making quasi-medical decisions in the course of processing claims for payments and benefits.”); Pryzbowski, 245 U.S. at 275 (stating that “[w]e are not unaware that our holding may leave [the plaintiff], and other beneficiaries, without effective relief for the improper administration of benefits”). For a general discussion on the uneven trend toward allowing civil actions against MCOs see Robert Pear, \textit{Series of Rulings Eases Constraints on Suing H.M.O.s}, N.Y. Times, Aug. 15, 1999, at A1; Jason A. Glodt, \textit{Watch Out HMOs: The Future of Patients’ Rights Will Soon Be Determined}, 45 S.D. L. REV. 640 (1999/2000); David L. Trueman, \textit{Managed Care Liability Today: Laws, Cases, Theories, and Current Issues}, 33 J. HEALTH L. 191 (2000).}

Several of these cases and other well-publicized instances of treatment denial decisions have served as catalysts for demanding even greater MCO accountability.\footnote{8}{For example, after being denied treatment for AIDS by an MCO, Daniel Jones held up a banner stating, “HMOs are in it for the money,” before setting himself on fire and dramatically shooting himself on a Los Angeles Freeway. See Daryl Kelley, \textit{The HMO Backlash}, L.A. TIMES, July 26, 1998, at B3; Heather Lourie, et al., \textit{Freeway Suicide Televised}, ORANGE COUNTY REGISTER, May 1, 2000.] This demand has led to dramatic movement in
legal actions and legislation against MCOs for conduct related to improper medical decisions or the underutilization\textsuperscript{9} or denial of medically necessary care that results in patient harm.\textsuperscript{10} In responding to this trend, however, it is imperative that legislators establish a uniform national standard for determining medical necessity, and address whether there should be a state-imposed minimum level of care.

Three cases highlight the new legal repercussions confronting managed care: \textit{Murphy v. Board of Medical Examiners},\textsuperscript{11} \textit{United States v. NHC 1998}. A study of four thousand heart attack patients concluded that patients enrolled in MCOs were twice as likely to die after a heart attack than those enrolled in fee-for-service health plans. \textit{Heart Attack Death Rate Higher in HMOs, at http://www.hmopage.org/higher.htm} (last visited Nov. 13, 2001) (citing \textit{News and Trends: Are HMOs Trouble for Cardiac Patients?, BUSINESS \\& HEALTH} (Dec. 1997)). For more information about the health threat posed by managed care, see \textsc{Jamie Court \\& Francis Smith, Making a Killing: HMOs and the Threat to Your Health} (1999); \textsc{Dorothy Cancilla, Death by HMO, The Jennifer Gigiello Story} (1999); \textsc{Barbara Johanna Janesick \\& Karen L. Goldsmith, Managed Dying: HMO Survival Guide} (2000); Eleanor D. Kinney, \textit{Tapping and Resolving Consumer Concerns About Health Care}, 26 Am. J. L. Med. 335 (2000).

9. See Krohn, supra note 4 at 446.

Underutilization can take many forms. Providers may cut corners or start viewing as elective those treatments that were previously considered necessary[,] delay or omit diagnostic tests or therapeutic procedures, or assume responsibility for care that should be referred to more expert and more expensive specialists . . . [or] by making patients wait long periods of time for appointments or by becoming inaccessible.

\textit{Id.}

10. See Jeffrey E. Shuren, \textit{Legal Accountability for Utilization Review in ERISA Health Plans}, 77 N.C. L. Rev. 731, 748 (1999) (stating that "[l]eaving the judiciary with the task of determining what duties apply to UROs [utilization review organizations] and third-party payers places an inappropriate burden on the courts to resolve the tension between the goal of containing costs and the goal of the tort system to compensate harmed individuals"); \textit{Patient's Rights Advocates Poised to Try Yet Again}, at http://www.cnn.com/2001/ALLPOLITICS/stories/02/06/congress.hmos.ap/index.htm (Feb 6, 2001) (discussing the latest proposals as the managed care reform debate continued into a fifth year); Harris Meyer, \textit{Fraud Storm Surges Towards HMOs, Hosp. \\& Health Networks}, Feb. 20, 1998, at 28 (noting the increase in fraud prosecutions in health care).

Healthcare and United States ex rel. Aranda v. Community Psychiatric Centers of Oklahoma. A New Mexico criminal statute and a proposed Maryland statute also highlight the trend in successful legal actions against MCOs.

In Murphy, the Arizona State Board of Medical Examiners (BOMEX) formally admonished an MCO medical director for making an “inappropriate medical decision” regarding medical necessity. The Arizona Court of Appeals affirmed BOMEX’s jurisdiction and admonition by holding that utilization review (UR) decisions that could affect the “health or safety of a patient or the public” are appropriate matters for review by the State board.

In 1997, New Mexico passed a criminal Medicaid fraud statute prohibiting “treatment that is substantially inadequate when compared to generally recognized standards within the discipline or industry.” In April 2001, the Maryland State Senate approved an unprecedented statute that would subject MCO directors to fines or license revocation for faulty medical necessity decisions that harm a patient.

Underutilization claims involving Medicare/Medicaid patients have also been prosecuted under the False Claims Act (FCA) as fraud against the United States. FCA prosecutions are based on charges that Medicare or Medicaid reimbursement claims submitted to the government by a

16. Murphy, 949 P.2d at 441.
17. Id.
medical provider are false or fraudulent.\textsuperscript{21} \textit{NHC Healthcare} and \textit{Aranda} (both of which included claims under the FCA) underscore the damaging effect of underutilization or inadequate care and the extent to which some prosecutors will go to redress those injuries.\textsuperscript{22} In \textit{NHC Healthcare}, the prosecution asserted that the nursing facility patients “were in unnecessary pain . . . not given care up to the standards required under the Medicare and Medicaid programs, and ultimately died because of this care.”\textsuperscript{23}

The \textit{Aranda} court noted, “providers must assure that patient services ‘will be of a quality which meets professionally recognized standards of health care.’”\textsuperscript{24} Consequently, failure to provide patient care that meets those standards can open a facility to claims under the FCA. One legal commentator wrote, “[t]he theory behind managed care fraud is simple: plans and providers say they’ll provide all medically necessary care and are paid up front to do so. If there is a scheme that results in denial of appropriate care, the government and beneficiaries have been defrauded.”\textsuperscript{25}

Previously, consumer protection from health care misconduct was the domain of tort action in addition to state and federal legislation.\textsuperscript{26} Current state-enacted legislation includes the creation of a binding appeals system for MCO subscribers to contest treatment denial decisions; the direction of managed care health plans to cover certain conditions; and the direction to provide alcoholism treatment, mammography screening and forty-eight hour hospital stays for maternity patients.\textsuperscript{27}

\begin{footnotes}
\footnote{22. Meyer, \textit{supra} note 10, at 28. \textit{See also} C.R. Frost & D.H. Beck, \textit{Managed Care Fraud and Abuse Under Fire}, MANAGED CARE BRIEFINGS (1999), available at http://www.sdma.com/images/managed.html (stating that “claims submitted to the government for payment for coverage extended to managed care enrollees are generally viewed as necessarily including an implied warranty that all covered ‘medically necessary’ services were or will be rendered”).}
\footnote{25. Meyer, \textit{supra} note 10, at 28.}
\footnote{26. \textit{See generally} \textit{FURROW ET AL.}, \textit{supra} note 5.}
\footnote{27. \textit{Id. supra} note 5, at 474. Some of the state provisions, which number in excess of 1,260, include mandated provider statutes, mandated benefit provisions,}
There is no consensus over whether MCO misconduct warrants punitive action. Still, there is certainly a compelling state interest in ensuring health care is provided. Accordingly, any MCO reform involving criminal penalties must consider, in addition to the legal issues, the nature of health care and the effect of legislation on health coverage.

When considering criminal penalties, prosecutors and legislators should look at the danger posed to society, the deterrence value and the importance and impact of moral retribution. "The criteria of criminal responsibility also provide a laboratory for testing sensibilities of moral right and wrong." The imposition of criminal penalties against MCOs may be the ultimate legislative and prosecutorial acknowledgment that "[t]he current systems for tapping and resolving consumer concerns are uncoordinated, inaccessible, inequitable, . . . non-conclusive," and inadequate.

It could be argued that the state is now reliant on MCOs and would not be able to provide appropriate health care in their absence. Accordingly, with the number of uninsured at nearly 40 million, any legislation must consider the financial ramifications on health care plans.

The difficulty, as with any legislation, is finding the right balance to ensure that comprehensive, affordable and accessible health care is being provided along with appropriate accountability for MCO misconduct. MCO advocates assert that if legislative mandates become too burdensome and costly, the ability of MCOs to remain profitable, or even exist, could be jeopardized. For an industry that has already survived

mandated renewal provisions and mandated coverage for certain people. Id.


33. Amicus Brief, supra note 28. See also Bill Brubaker, Aetna's Unmet Claims, WASH. POST, Feb. 25, 2001, at H1. Brubaker quotes Stuart Steeles, President of the Medical Society of the District of Columbia, who compared an
staggering cost increases, any added financial pressures could be disastrous for millions of Americans who rely on MCOs for health coverage.\textsuperscript{34}

However, in instances of egregious MCO negligence and reckless mishandling of grave health care situations, many believe the increase in criminal prosecutions is appropriate and warranted.\textsuperscript{35} In part, this is because certain wrongful decisions to deny treatment may be so violative of societal norms, so contrary to acceptable morals and values, that no other mechanism for punishment seems appropriate.\textsuperscript{36}

While the status of corporate criminal liability is controversial and unsettled, criminal statutes against MCOs are appealing because MCO misconduct has the ability to inflict tremendous pain and injury, both in terms of human suffering and financial loss.\textsuperscript{37} Additionally, because the current tort and regulatory penalties apparently have not chilled MCO misconduct, legislators and prosecutors are looking to criminal prosecutions to vindicate state interests in the delivery of health care and the protection of citizens.\textsuperscript{38} Moreover, criminal penalties only address

\textit{HMO}

to an airline that’s filling its empty seats at deeply discounted fares. You only need to look at what’s happening to the deterioration of airline service . . . cramming as many people into these seats as we can. I think most of us would agree that flying today is no pleasure. If we continue to spiral downward, patients are going to start feeling like airline passengers at La Guardia Airport.

\textit{Id.} See also Jonathan P. Weiner, \textit{Stop Blaming HMOs}, BALT. SUN, July 21, 2000, at 23A.

34. Amicus Brief, \textit{supra} note 28.
35. Humphreys, \textit{supra} note 29, at 351-53. Humphreys' discussion of the social, policy, and legal implications of environmental criminal penalties has many parallel concepts and arguments with health care.
36. \textit{Id.} at 351-53.
37. \textit{Id.} at 353.
38. \textit{See} Dent v. West Virginia, 129 U.S. 114, 122 (1889) (affirming the right of a state to require physicians to be licensed or else face criminal misdemeanor charges). The court said:

\begin{quote}
Few professions require more careful preparation by one who seeks to enter it than that of medicine. It has to deal with all those subtle and mysterious influences upon which health and life depend, and requires not only a knowledge of the properties of vegetable and mineral substances, but of the human body in all its complicated parts, and their relation to each other, as well as their influence upon the mind.
\end{quote}
specific instances of concrete harm without directing how MCOs structure their company or whether MCO financial incentives should continue. Nor do they prevent MCOs from attaining as much profit as they can legally reap. Furthermore, because criminal statutes are designed to prevent harm, address culpability and deter proscribed behavior, they are now being viewed as an entirely appropriate supplement to existing tort and civil remedies to ensure MCO accountability.39

MCOs are currently accountable under tort law, state-ordered mandates and possibly through criminal sanctions. The recent development of prosecutions and administrative actions against MCOs for underutilization evinces a growing recognition that civil actions and state-ordered mandates may not be enough to protect state interests.40 This is in contrast to the legal focus of fee-for-service (FFS). FFS provided medicine focuses on overutilization and physicians who perform unnecessary or unsuccessful operations, versus the traditional health coverage of quality, cost and access.41 This transformation from concern over providing excessive care to concern over receiving coverage underscores the dominant market presence and strength of MCOs in

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41. See Aranda, 945 F. Supp. 1485. Note that fee-for-service is still an integral part of Medicare and Medicaid provided medicine today. However, in traditional employer's health care plans, FFS is virtually nonexistent, having been replaced with managed care provided health care. Krohn, supra note 4, at 472.
American health care.  

As the Supreme Court acknowledged in Pegram v. Hedrick, legislators may ultimately have to make the difficult assessment of the value and utility of MCOs. In the context of criminal penalties, legislators must re-evaluate the benefits of managed health care. Specifically, in drafting criminal legislation, lawmakers must determine if the harm resulting from willful or negligent misconduct should be excused. 

Currently, criminal actions could proceed against MCOs for certain misconduct based on existing statutes and common law offenses. However, to effectively prosecute MCOs, it is vital to establish uniform standards of medical necessity and determine the standard for liability. It is essential that criminal statutes regarding health care providers focus on delivering a legal framework that ensures consistency and uniformity.

This article will explore the emergence of prosecutions and administrative actions against MCOs for conduct related to treatment decisions, and discuss their value, utility and lawfulness.

I. OVERVIEW OF MANAGED CARE AND CRIMINAL PROSECUTIONS AGAINST HEALTH CARE PROVIDERS

As we explore the next stage of MCO regulation, it is helpful to begin by examining the societal mindset that led to the development of managed care tort law. In general, critics of managed care assert that MCOs are corrupt, greedy and provide dangerously unsafe health care. However,
supporters contend that criticism of managed care is misplaced and marvel at the ability of MCOs to provide comprehensive health care to millions despite increasing medical costs.48

Perhaps this disparity in views stems from consumers' unrealistic expectations that MCOs should cover all treatment costs, colliding with the business reality that most MCO's are for-profit companies, rationing health care costs to remain solvent.49 This inevitable collision results from MCOs vaguely defined contract provisions regarding what are necessary and appropriate medical procedures.50 In other words, individual MCOs

mechanisms for volunteers to become involved in reforming managed care. Also see the numerous support groups and web sites that exist to share information about securing necessary medical treatment from managed care companies. One site, www.hmopage.org, even has a section titled "Atrocity of the Month," where aggrieved parties can share their MCO stories.

48. A recent Kaiser Family Foundation/Consumer Reports survey found eighty-three percent of those questioned who had contact with their managed care health plan in the last year said their experience was positive. See Press Release, Kaiser Family Foundation, Most Consumers Generally Positive About Their Health Care Plan, But Fifty-One Percent Report Having Some Problem in the Past Year, available at http://www.kff.org/content/2000/20000607a/; http://www.pwc.org/kaiser.html. See also Richard A. Epstein, HMO Lawsuits: A Liability for Patients Too, WALL ST. J., Dec. 28, 1999, at A26. According to Epstein, it is important to focus on the numerous success stories of managed care particularly their ability to provide effective care at low prices, and not be blurred by the inevitable "injustices." See id.

49. Most MCOs are publicly traded companies with market caps in the billions that are, like any other stock, frequently volatile and reactive to quarterly earnings reports. According to Standards and Poors, the health and managed care industry outlook was stable because of a "greater industry focus on profitability through premium rate increases and by competition based on factors other than price."


50. Sara Rosenbaum et al., Who Should Determine When Health Care is
can generally dictate what medical treatment they will cover based on their funding power.\textsuperscript{51}

While the funding power of insurance carriers has always existed, MCOs differ from insurance carriers through their use of URs.\textsuperscript{52} Unlike insurance carriers, MCOs typically exercise treatment authority prior to the administration of treatment. Moreover, MCO’s are able to exert more control over physicians than insurance carriers.\textsuperscript{53} Furthermore, URs are widely recognized as an effective tool in reducing unnecessary care and saving money.\textsuperscript{54} Typically, an individual other than the treating physician conducts URs. Unfortunately, due to the high cost of health care, a treatment denial results in the patient not receiving the physician’s recommended treatment.\textsuperscript{55}

Of course, not every UR decision to deny coverage results in patient


Because the costs of health care have become so prohibitive that realistically most patients simply cannot afford to pay for medical care without insurance coverage and because physicians and other health care providers cannot afford to provide care without receiving payment, third-party payors who ‘pay the piper’ often ‘call the tune’ by deciding which medical treatment will be covered.

\textsuperscript{52} Shuren, \textit{supra} note 10, at 741; Glodt, \textit{supra} note 7, at 653-54.

\textsuperscript{53} Kinney, \textit{supra} note 8, at 337.

\textsuperscript{54} See Trueman, \textit{supra} note 7, at 193. It is important to note that prospective utilization review is just one of three types of UR; the other two being concurrent review and retrospective review. See Shuren, \textit{supra} note 10, at 742-43. See also Jennifer M. Jendusa, \textit{The Denial of Benefits Quandary and Managed Care: McGraw v. Prudential Insurance Company}, 3 DEPAUL J. HEALTH CARE L. 115 (1999). UR “assures that payment is only made in cases where the services are medically necessary and appropriate given the patient’s needs and the play policy.” \textit{Id.} at 123.

\textsuperscript{55} See Jendusa, \textit{supra} note 54, at 126. See also Shuren, \textit{supra} note 10, at 772.
harm.\textsuperscript{56} For MCOs to be financially viable, a physician’s recommendation for treatment cannot bind the MCO.\textsuperscript{57} In addition, MCOs acknowledge that the structure of their business discourages underutilization, primarily due to their desire to have satisfied customers.\textsuperscript{58}

Patient frustration has spawned litigation against FFS and MCOs and ERISA has effectively shut down many of the actions brought against MCOs.\textsuperscript{59} ERISA, which applies to most employee-sponsored health plans, seeks to protect employees from fraud and mismanagement in their employee benefit plans and to provide limited remedies.\textsuperscript{60} An MCO benefits under ERISA because: “(1) state law is preempted by federal law; (2) there are no jury trials; (3) there are no compensatory or punitive damages; (4) relief is usually limited to the amount of the benefit in question; and (5) claims against administrators may receive a deferential standard of review.”\textsuperscript{61}

\textsuperscript{56} Krohn, supra note 4, at 446. A recent University of California, San Francisco study found that MCOs provide the same level of care and quality as fee-for-service payers. Rovner, THE DAILY RECORD, May 18, 2001, available at http://www.kff.org. The study noted that MCOs “do considerably worse in patient satisfaction and access to care.” Id. Some of the reasons for treatment denial decisions are: “lack of medical necessity; unapproved or nonformulary drugs; referral requirements no being met; out of network services; contract interpretation; benefit exclusions; billing and coding discrepancies; and lack of coverage for durable medical equipment.” Ann H. Nevers, Consumer Managed Care Appeals: Are the Available Procedural Protections Fundamentally Fair?, 33 J. HEALTH L. 287, 88 (2000).


\textsuperscript{58} Krohn, supra note 4, at 452.

\textsuperscript{59} Fact Sheet, Why Must HMOs be Liable?, at http://www.consumerwatchdog.org/fs/fs000207.php3 (last visited Dec. 18, 2001) (stating the problem with ERISA is that “[u]nder ERISA, HMOs have no incentive to provide expensive, medically appropriate treatment, because they are not held accountable for the consequences of their denials. If ERISA rules applied to bank robberies, convicted thieves would simply have to give the money back.”).

\textsuperscript{60} See Pear, supra note 7, at A1 (noting the limitations of ERISA in that, “the law (only) allows patients to recover . . . the value of denied benefits, not punitive damages or compensation for lost wages or pain or suffering.”).

\textsuperscript{61} Jamie Court, Internal Memo Shows Insurer Tries to Reclassify Cases Under ERISA, Seeking “Gray Areas” where “ERISA . . . May Influence Our
Although judges have lamented ERISA for its lack of a meaningful remedy for otherwise valid claims, plaintiffs’ attorneys have not been deterred. In fact, civil plaintiffs have experienced some degree of judicial success in civil actions. In addition, civil actions filed against MCOs have asserted the following legal theories: (1) medical malpractice; (2) negligence; (3) gross negligence; (4) corporate negligence; (5) intentional infliction of emotional distress; (6) breach of good faith and fair dealing; (7) negligent hiring, retention, or supervision; (8) bad faith; (9) breach of an insurance contract; (10) breach of a fiduciary duty; (11) interference with the physician-patient relationship; (12) misrepresentation; and (13) utilizing the Racketeer Influenced and Corrupt Organization (RICO) statute.

Much of the managed health care debate has focused on reforming ERISA to allow injured subscribers greater access to courts, thus ostensibly increasing MCO accountability. The forthcoming discussion

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64. See Kuhl v. Lincoln Nat’l Health Plan, 999 F.2d 298 (8th Cir. 1993) (affirming a judgment for the MCO). The case, which was filed in state court but preempted to federal court pursuant to ERISA, involved a patient who died waiting for his MCO to authorize funding for a heart transplant. The court noted in dicta that, “in a different case, the cancellation of a beneficiary’s surgery by an ERISA benefits provider may lay the basis for nonpreempted state law claims.” Id. at 303.
will not address whether health care should be a right, whether Congress needs to overhaul ERISA, nor whether the managed care structure is somehow intrinsically flawed. Rather, the discussion will focus on the emerging trend of criminal and administrative actions against MCOs.

Implicit in a prosecution or administrative action against an MCO is the acknowledgment that—while dealing with an industry that has distinct issues—it is ultimately just another industry held responsible for its actions and criminally accountable when it causes harm. Given that states generally assert an unqualified interest in the preservation of human life, it is a state's obligation to enact legislation regulating conduct that causes either a wrongful death or injury.65

However, civil litigation cannot remain the only avenue for redress against MCOs for several reasons. First, critics have expressed skepticism that quality medical care will be obtained through the tort system. Other critics contend that litigation will not have an appreciable impact on MCOs. For instance, some critics argue that MCOs would most likely react to unfavorable court decisions by reducing care. Undoubtedly, the reduction of care will ultimately result in an increase of uninsured Americans.66

Moreover, the tort system has proven to be inadequate in preventing instances of undertreatment or denial of necessary care.67 For example, as demonstrated by the increasing cost of prescription drugs, MCOs will


66. See Frank Diamond, Liability's Jaws Closing on HMOs, (Mar. 1999) at http://www.managedcaremag.com/archives/9903/9903.liability.shtml (last visited Dec. 18, 2001)(quoting Kevin Outterson, Vice Chairman of the American Bar Association's Managed Care Committee: "There have been some estimates that health care premiums could rise 10% or more if HMOs are held liable for treatment decisions."). See also Humbach, supra note 45; David Priver, HMO Suits That Help Lawyers Harm Health Care Consumers, Scripps Howard News Service, Apr. 1, 2000, available at http://www.aetna.com/legal_issues/saying/hmosuits.htm (stating that "the money HMOs spend to defend against lawsuits, plus any potential settlement payments must be accounted for, and at least a portion of this expense will end up tacked on to our health care bills.").

67. Humbach, supra note 45.
simply raise premiums to cover the added expense.\textsuperscript{68}

Civil penalties are also inadequate to completely deter and punish MCO misconduct, given that the benefits outweigh the penalties. In other words, civil remedies, "fail to provide adequate incentives for compliance."\textsuperscript{69}

Congress could certainly restructure managed care, but in view of their inaction on this issue over the last several years, meaningful legislative relief may need to come from the states.\textsuperscript{70} Several states have either passed laws or are considering laws to create external statutes.\textsuperscript{71} A state-created external statute allows an MCO subscriber to appeal a treatment denial decision to an independent panel of physicians who would render binding opinions.\textsuperscript{72} But external physician reviews will not address all improper MCO treatment decisions, nor will they ensure that MCOs are held accountable for their improper decisions that cause harm.

Moreover, the Supreme Court has not considered the issue of whether state-created external review statutes violate ERISA. Federal appellate opinions on the lawfulness of these statutes are mixed, thus the continued viability of external reviews in their current format is uncertain.\textsuperscript{73} While ERISA seems to permeate almost every managed care legal issue, it will not impact criminal statutes. Since ERISA does not apply to criminal statutes, state-enacted criminal laws will not be preempted.\textsuperscript{74}

To ensure that criminal statutes targeting improper treatment denial decisions are lawful, it is imperative that legislators formally clarify the

\begin{itemize}
\item 68. Julie Appleby, \textit{Health Guides Could Raise Premiums}, USA TODAY, May 17, 2001, at B1. ("Managed care is no longer trying to control costs," says Todd Richter of Banc of America Securities. 'Insurers will simply take whatever they have to pay for these drugs and pass that cost along directly to employers, who will raise co-payments and deductibles for their workers.").
\item 69. Humphreys, \textit{supra} note 29, at 319.
\item 71. Cramer, \textit{supra} note 6, at 45.
\item 72. \textit{Id.}
\item 73. Corporate Health Ins., Inc. v. Tex. Dept. of Ins., 220 F.3d 641, 644-45 (5th Cir. 2000); \textit{see also} Moron v. Rush Prudential HMO, Inc., 230 F.3d 959, 969, 971-72 (7th Cir. 2000).
\end{itemize}
duty MCOs owe their subscribers by:

(1) Defining uniform standards/guidelines of medically necessary care (to establish a minimum MCO duty of care); and

(2) Proscribing conduct that displays an intentional (whether knowingly, recklessly, or with criminal negligence) disregard to medically necessary and appropriate care standards where that decision causes harm.75

With criminal statutes structured to guarantee a minimum level of care, the state need not worry about MCOs contracting to a lower or dangerously inadequate standard of health care—a current concern.76 As discussed above, concern for the financial welfare of MCOs is not a valid legal, social or policy reason to exempt MCOs from punitive exposure for intentional acts of misconduct that cause injury.77

To be sure, MCO criminal liability could emanate today from either state or federal law, or as a result of a specific contract provisions. The court in Commonwealth v. Pestinikas,78 a case involving two men hired to care for an elderly man, held that “where one person owes to another either a legal or a contractual duty, an omission to perform that duty resulting in... death” could result in a homicide conviction.79 The Pestinikas court affirmed a murder conviction for a breach of contractual duty to provide life-sustaining care—essentially a crime of omission.80

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75. See generally United States ex rel. Aranda v. Cmty. Psychiatric Centers, 945 F. Supp. 1485, 1487-88 (W.D. Okla. 1996), United States v. NHC Healthcare Corp., 115 F. Supp. 2d 1149, 1156 (W.D. Mo. 2000); Humbach, supra note 45. See also Commonwealth v. Pestinikas, 617 A.2d 1339, 1345 (Pa. Super. 1992) (upholding a criminal conviction for murder in the third degree and for recklessly endangering another person. In assessing whether a breach of a contract could result in criminal charges, the court answered in the affirmative, holding that when a defendant fails to perform a contract to provide care for another and that failure causes the death of the other person, culpability may follow); Morreim, supra note 4, at 942.

76. Dukes v. U.S. Healthcare, Inc., 57 F.3d 350, 359 (3d Cir. 1995). ("It may well be that an employer and an HMO could agree that a quality of health care standard articulated in their contract would replace the standards that would otherwise be supplied by the applicable state law of tort.") (emphasis added).

77. Humbach, supra note 45.


79. Id.

80. Id. at 1345, 1350. Judge Tamilia, in a concurring opinion, noted the absurdity of holding otherwise: “[W]e can be punished for throwing trash on a
Note that while the term "medical necessity" is frequently used, there is no consensus on its definition. Some define "medically necessary care" as: "care for which (1) the benefits outweigh the risks . . . (2) the benefits to the patient are likely and substantial, and (3) physicians have determined that not recommending the care would be improper." Others advocate linking medical necessity to professional practice standards — with great deference to the recommendations of the treating physician. In any definition, MCOs would most likely seek a distinction between medically beneficial and medically necessary care, along with a continued ability to contain costs.

However medical necessity is defined, a consistent approach is essential to avoid the sort of patchwork managed care regulations that have developed through litigation and state legislation. State-enacted statutes that define both medical necessity and the required elements for a criminal conviction may be just the approach that is needed.

The proposition that corporations may be liable for the acts of its agents, under certain circumstances, would certainly apply in the managed care arena. Similarly, as seen with environmental law violations, corporate officers in a position to have prevented an incident can be held criminally liable, even if they did not participate in the improper action. Hence, criminal statutes may be the inevitable remedy for a system where lives hang in the balance of what is ultimately a business decision. However, it is important to remain focused on treatment decisions contrary to articulated professional practice standards that cause harm to patients and not to adverse medical results or malpractice cases.

sidewalk yet may suffer no penalty for discarding a human life by denying him sustenance and deliberately causing his death." Id. at 1354.

81. Steven M. Asch et al., Measuring Under Use of Necessary Care Among Elderly Medicare Beneficiaries Using Inpatient and Outpatient Claims, 284 JAMA 2325-26 (2000).
82. Rosenbaum, supra note 50, at 229.
83. See generally McGraw v. Prudential, 137 F.3d 1253 (10th Cir. 1998).
84. In United States v. NHC Healthcare Corp, 115 F. Supp. 2d 1149, 1152 (W.D. Mo. 2000), (noting, "it is not the place of this Court to exempt an entire industry from FCA liability because it may be hurt by such suits.").
85. See generally Boise Dodge v. United States, 406 F.2d 771 (9th Cir. 1969); United States v. Beusch, 596 F.2d 871 (9th Cir. 1979); United States v. Johnson & Towers, Inc., 741 F.2d 662 (3d Cir. 1984).
86. Kelley, supra note 8, at B1. ("What I say to my friends when these cases come up is, 'what happened to the good old-fashioned concept of malpractice?'"
The managed care concept was initiated in the 1920s by a group of California doctors who persuaded an insurance company to pay them a fixed amount of money to provide health coverage to thousands of designated employees.87 The doctors believed they could lower expenses for insurers by focusing on preventive health and safety, rather than just treating specific injuries or illnesses.88

Despite this early initiative, until recently, the dominant form of health coverage in the United States continued to be fee-for-service.89 Fee-for-service (FFS) basically allows a physician to decide what treatment, if any, is provided to the patient.90 The physician is then compensated according to the number of services he provides.91 "In the past half-century an extraordinarily generous, uncritical reimbursement system has empowered physicians to define and deliver quality . . . "92 Thus, this method of payment allows physicians to tailor the care they give to their patients with little regard for cost.

Under FFS, the insurance companies were left to pay for this generous and liberal method of medical coverage.93 Doctors, of course, prefer such a system since the physician determines whether treatment is provided and specifies what type of treatment is given.94 With skyrocketing medical costs and millions of people uninsured, change in the medical care delivery system was inevitable.95 The change was managed care, and insurers hoped this new plan of delivering health care, while keeping prices down, would transform the health care industry for the better.96

Managed care advocates claimed their method of reimbursement would save costs by following five basic principles: "(1) a focus on wellness and prevention; (2) a drive for 'appropriate' treatments, meaning the most

88. Id.
89. Id.; FURROW ET AL., supra note 5, at 492-96.
90. Law, supra note 87.
91. Id.
92. Id.
93. Id.; Jendusa, supra note 54, at 121.
94. Glodt, supra note 7, at 645.
95. Id.
96. Id.; FURROW ET AL., supra note 5, at 492.
cost-effective care; (3) integration of services; (4) transfer of financial risk from the insurer to provider to the greatest extent possible; and (5) security of access to health care for the consumer-employee at a fixed price.97 These methods of curtailing insurer costs proved to be so successful that the insurers began to see profits.

Managed care systems have been able to earn profits primarily because of: (1) down-streaming or "cost containment financial arrangements with providers" and (2) prospective review of physician recommended treatment to reduce unnecessary care to patients.98 The primary vehicle for implementing managed care has been the Health Maintenance Organization (HMO).

"HMOs take away doctors' and hospitals' financial incentive to overtreat patients with costly tests and surgeries, since they don't get paid more for ordering more tests. HMOs provide not only cheaper medical care, but also better treatment . . . because they encourage checkups and immunizations to keep patients healthy."99 HMO oversight of physician care has been instrumental in making this delivery system successful. However, evaluating the relative success of this delivery system depends on one's perspective.

Managed care is essentially a system where an attending doctor's recommendations do not always control the course of treatment.100 Many physicians react with tremendous disappointment and concern when their recommendations are not followed. Furthermore, patients often become incensed and confused when their doctor's course of treatment is denied by the MCO.101

97. Goldt, supra note 7, at 645.
98. Kelley, supra note 8, at B3; Trueman, supra note 7, at 192.
99. Kelley, supra note 8, at B3.
100. Patricia Mullen Ochmann, Managed Care Organizations Manage to Escape Liability: Why Issues of Quantity vs. Quality Lead to ERISA's Inequitable Preemption Claims, 34 AKRON L. REV. 571, 572 (2001).
101. In a letter to the editor of AMA News, Dr. Ronald Bronow said, "we physicians should stop selling our souls to the HMO devils and begin protecting out patients' rights." AMA News, June 15, 1998, at http://www.hmopage.org/selling.html. See also Paul Zielbauer, Doctors Sue Health Plans Over Coverage, N.Y. Times, Feb. 5, 1998, at B1 ("Two groups representing 7,000 Connecticut doctors filed a battery of lawsuits today against six large health maintenance organizations, claiming that the companies 'systematically harmed' patients by arbitrarily denying crucial medical treatment and illegally withholding millions of dollars in payments they owe doctors.").
“The managed care delivery system has created a situation where nobody is happy,” said one hospital administrator.102 “Doctors are angry because they used to be the seat of all power, and now they are stuck rationing care. Hospitals do not like it because they’ve had to cut their costs and push patients out the door. And patients say they’re getting worse care.”103 Thus, despite the initial optimism that managed care would ameliorate the problems of high medical costs, the delivery system is fraught with many serious problems.

Congress acknowledged the importance of basic treatment principles for certain medical conditions and healthcare concerns by enacting corrective legislation.104 For the most part, the legislation has been criminal in nature and has not been tailored specifically to target managed

102. Kelley, supra note 8, at B3.

103. Id. Another concern is that the managed care system inherently presents a conflict of interest for the MCOs, because if they (MCOs) provide fewer services, they will make a larger profit, or save more money. This directly, and deliberately, creates the opposite incentive to the incentives in a fee-for-service system where a providers income increases if more services are furnished. See Bazelon Ctr. for Mental Health Law, Defining “Medically Necessary” Services to Protect Plan Members, (Mar. 1997), available at http://www.webcom.com/bazelon/mhcare.html (last visited Dec. 18, 2001). Doctor frustration may be reaching its apex with a pending RICO allegation against several MCOs in Federal District Court in Miami. The plaintiffs include the state medical associations of California, Georgia, and Texas and individual doctors from seven states. In part, the complaint alleges that MCOs, “had used cost-based criteria to approve or deny claims for payment and had offered cash incentives to claim reviewers who would deny or limit tests and treatments that doctors felt were necessary.” See Milt Freudenheim, 3 State Groups Join Doctors in Insurer Suit, N.Y. TIMES, Mar. 27, 2001, at C13.

104. Along with state mandates for coverage of certain conditions, the Emergency Medical Treatment and Labor Act (EMTALA), 42 U.S.C. § 1395dd(a), (d)(2)(a) (1994) applies to hospital emergency rooms that have treatment agreements under the Medicare program. Summers v. Baptist Med. Ctr., 91 F.3d 1132, 1136 (8th Cir. 1996) (“The operative language of the statute... is that... a hospital ‘must provide for an appropriate medical screening examination within the capability of the hospital’s emergency department... to determine whether or not an emergency medical condition exists’.”). See also the Americans with Disabilities Act of 1990 (ADA), 29 U.S.C. § 794 (1994), (prohibiting discrimination based on race, religion, national origin, age, and gender). But see Rovner, supra note 56 (concluding that MCOs provide the same level of care and quality as FFS). See also FURROW ET AL., supra note 5, at 474-76 (discussing the 1,260 state imposed mandates on health plans).
care systems that deny necessary medical care. Thus, injured parties seeking redress for injuries caused by inadequate MCO decisions must seek either criminal prosecution of the provider or rely on creative applications of criminal statutes in a civil setting.

Injured parties have used traditional common law or existing statutes to bring criminal and civil suits against MCOs. Parties have also used The Racketeer Influenced and Corrupt Organizations Act (RICO)\(^{105}\) and The False Claims Act (FCA),\(^{106}\) which are traditional criminal statutes, to bring both criminal and civil claims.

Throughout the 1990s, prosecutors relied on existing statutes or common law to preserve states' interests against fraud at the hands of health care delivery providers. By criminally charging health care providers for inadequate patient treatment in Medicaid and Medicare situations, prosecutors protected the quality and dignity of life for health plan participants.\(^{107}\) Analysis of these early prosecutions provides an interesting basis for later actions holding managed care providers civilly liable.

One of the first prosecutions brought using common law charges of manslaughter against a health care provider was initiated after two women, Margaret White and Elizabeth Ellis, died in a nursing home.\(^{108}\) The state filed criminal charges against the corporate owner of the home for involuntary manslaughter, among other charges, alleging that the victims died as a result of "criminally negligent and grossly incompetent care."\(^{109}\) The government also alleged that the victims were not provided with the "quality of care which promotes the maintenance and enhancement of the quality of life."\(^{110}\) Although the defendant agreed to a plea bargain in which it was fined $20,000 and ordered to pay $100,000 in court costs, this case became a harbinger of the increasing scrutiny MCOs


\(^{109}\) Id.

\(^{110}\) Id.
would face over the next decade.\footnote{111} Another possible route to criminally prosecute MCOs is RICO.\footnote{112} Even though this statute was initially enacted to battle organized crime,\footnote{113} it has recently been applied in civil suits by individuals and states against health care providers who engage in patterns of illegal activity.\footnote{114} While some cases were disposed of through either dismissal or settlement, civil actions portend a growing trend of holding MCOs accountable for their mistakes and bad acts.\footnote{115} "RICO allows states to send providers a strong message that fraud will not be tolerated – and that it can have consequences beyond simply being compelled to pay restitution – thereby furthering the strong public policy against health care fraud."\footnote{116} A recent civil RICO claim, \textit{Humana v. Forsyth},\footnote{117} affirmed a civil RICO action against a managed care provider.\footnote{118} Accordingly, it is probable that more civil RICO actions will be brought by plaintiffs against managed care providers.\footnote{119} The viability of civil RICO actions against MCOs, however, is still unclear. For plaintiffs to prevail in future civil actions, they will most likely have to show specific instances of fraud and collusion by the MCO as opposed to a broader showing of improper financial terms or unconscionable contract provisions.

Although criminal charges can be brought against an MCO by a prosecutor under existing statutes or RICO, actions under the False Claims Act (FCA) have received the most judicial attention. Federal prosecutors have used the FCA to pursue cases alleging misconduct by

\begin{footnotes}
\footnote{111} See generally Frost and Beck, supra note 22. 
\footnote{112} Supra note 105. 
\footnote{113} Id. at Congressional Statement of Findings and Purposes. 
\footnote{114} Jaff, supra note 105, at 5-9 (discussing Connecticut’s two civil actions under RICO against a health care provider). See also Laura B. Benko, \textit{Managed Care Under Siege}, MODERN HEALTHCARE, July 10, 2000, at 34. 
\footnote{115} Jaff, supra note 105, at 22. 
\footnote{116} Id. at 23. 
\footnote{118} Id. at 313. 
\footnote{120} Supra note 106. See also Schofield, supra note 21, at 122. 
\end{footnotes}
healthcare providers. According to Assistant U.S. Attorney James Sheehan, prosecuting health care providers under the FCA is "easier than you think... [d]octors, hospitals, and plans, all keep data that can point to plans that make it impossible to get appropriate care." Consequently, the FCA has become an important weapon in a prosecutor's arsenal to protect patients from illegal acts by providers such as under-utilization.

The core elements of an under-utilization action under the FCA are:

1. the defendant promised the government (or a program beneficiary) that it would provide health care services (or benefits as the case may be);
2. medically necessary treatment was not provided; and
3. the treatment was not furnished as part of either a deliberate plan to make more money and defraud the health benefit program or pervasive reckless conduct.

Moreover under the FCA knowledge is defined as:

'Actual knowledge,' 'deliberate ignorance of the truth or falsity of the information,' or 'reckless disregard of the truth or falsity of the information,' people involved in all aspects of submitting health care claims to the Government can be liable even if they do not actually know of or intend to submit false claims.

While the FCA is a powerful criminal and civil statute, it has certain limitations in combating underutilization. It is argued that the FCA addresses "only false claims and does not reach fraudulent and abusive conduct... [D]amages under the FCA [only] relate to the Government's injury...[while u]nderutilization injures consumers and not the Government... [and] the FCA covers fraud only in federal programs." Despite its shortcomings, application of the FCA has been instrumental in combating health care fraud and, in particular, deterring instances of underutilization by MCOs.

123. Frost and Beck, supra note 22, at 4.
125. Id. at 467.
126. Id.
Even though the FCA has been successfully used by prosecutors to impose liability on providers, courts still find it difficult to define a medical standard of care. This difficulty is also encountered by legislators in drafting criminal statutes to combat improper decisions that deny treatment to plan participants. One case addressing a FCA prosecution in the Medicare/Medicaid context noted that:

It may be easier for a maker of widgets to determine whether its product meets contract specifications than for a hospital to determine whether its service meets 'professionally recognized standards for health care.' In the Court’s view, however, a problem of measurement should not pose a bar to pursuing an FCA claim against a provider of substandard health care services under appropriate circumstances.  

Subsequent cases have held that the government’s case could proceed despite the lack of clarity in this area. One case stated, “[u]ntil this issue works its way through the appellate system it will remain unclear whether the Government’s movement towards increased scrutiny of care facilities through FCA lawsuits is a bona fide exercise of prosecutorial resources or an improper expansion of this powerful Act.”  

In addition to the common law or existing statutes, RICO and FCA, prosecutors can also charge providers with criminal violations such as theft or bribery concerning programs receiving federal funds, false statements relating to health care matters, fraud and swindles, fraud by wire, radio and television, health care fraud, obstruction of criminal investigations of health care offenses, engaging in monetary transactions in property derived from specified unlawful activity and obstruction of justice.
Fraud cases in managed care brought under the above options, even in a Medicaid and Medicare context, provide powerful guidance to those who determine the viability and appropriateness of state action against MCOs. New forms of fraud that involve diversion of capitation fees and result in inadequate medical care can threaten human health to a greater extent than the types of fraud seen in traditional fee-for-service plans. Prosecutions for fraud in underutilization situations, such as those involving subscriber death or injury are instructive for legislators drafting managed care/health plan criminal statutes. Evidence establishing managed care fraud as a result of underutilization include:

[H]igh incidence of complaints by patients, physicians, and payers; barriers to care (inconvenient provider locations and delays in rendering care, authorizing benefits or making specialty referrals); . . . low utilization statistics compared with national norms or with fee-for-service patients; . . . high percentage of successful appeals of benefit denials; . . . and inadequate staffing or training. The proliferation of fraud cases against MCOs illustrates the willingness of prosecutors and courts to hold health care providers criminally accountable for their misconduct. Since state legislatures are drafting statutes that specifically target improper treatment decisions and the denial of medically necessary care, it is necessary to clarify important legal and policy problems surrounding this issue. The remainder of this article will propose criteria for politicians to consider when drafting ameliorative legislation.

Without an objective standard for what constitutes medically necessary or appropriate care, legislation to ensure that patients receive the care for which they have paid will not be effective.

Providers (Spring 2001) (unpublished course outline on file with author).


138. Frost and Beck, supra note 22, at 5.


140. Stauffer, supra note 6.
II. A PROPOSAL TO STANDARDIZE THE DEFINITION OF "MEDICAL NECESSITY"

Defining the phrase "medically necessary" is critical because most decisions are based on an MCOs definition and interpretation of this phrase. Even though the phrase is routinely used in treatment decisions, there is neither an industry definition nor a uniform statutory definition. Several states have responded to concerns that MCOs, taking an overly restrictive statutory interpretation of "medically necessary," could deny some subscribers legitimately appropriate health care. Consequently, the search for a universal definition of "medically necessary" care has become a point of debate among legal scholars, courts and legislatures.

If a criminal statute is enacted to address improper treatment denial decisions based on medical necessity, the state-defined standards of care will be the foundation of MCO prosecutions. While any prosecution would, in part, be based on the failure of an MCO to follow a reasonable process when treating patients, it is imperative to review court opinions addressing medical necessity, along with proposed definitions to obtain a firm understanding of the issue.

The phrase "medical necessity" first captured public attention in 1996 when it was discussed by Dr. Linda Peeno in her testimony before the U.S. Congress. Dr. Peeno stated that as a claims reviewer for an MCO she caused the death of a man by denying him a necessary operation.

141. Griner, supra note 51, at 898.
142. Id. See Campion Quinn, Issues of Medical Necessity: A Medical Director's Guide to Good Faith Adjudication, 3 MANAGED CARE ADMIN. 883 (1997) ("Current corporate definitions of medical necessity are crafted in weak, ambiguous, or circular language."). See also Bazelon Ctr. for Mental Health Law, supra note 103; Margaret Gilhooley, Broken Back: A Patient's Reflections on the Process of Medical Necessity Determinations, 40 VILL. L. REV. 153 (1995) ("The determination of medical necessity appeals to the norm of professional judgment, but the criteria employed are not necessarily based on a professional consensus and may not even be based on public information.") Id. at 162.
143. See generally Linda Bergthold, Medical Necessity: Do We Need It?, 14 HEALTH AFFAIRS 180 (1995).
145. Id.
She now advocates reforming health care by removing some of the broad discretion found in MCO health care plans to determine whether treatment will be provided to plan participants. Dr. Peeno referred to medical necessity decisions as the MCOs "smart bomb" for "cost containment" because these decisions are frequently based on "criteria that is non-standard and rarely developed along accepted clinical methods." MCO advocates, on the other hand, dispute the need for state mandated medical necessity definitions. One senior MCO executive explained:

We're trying to bring some discipline to, let's say doctors... who send out for 25 tests or who do things that are unnecessary. The medical profession has been taught in school that everything is okay. I mean: 'Send out for 1,000 tests. Do it.' You know, with no attention to price control. No attention to the efficient and effective practice of medicine." Former Speaker of the House, U.S. Representative Newt Gingrich, felt a mandated definition would, "bankrupt every insurance company."

Only the passage of time will tell whether these MCO concerns are well-founded or hyperbole. A universal definition of care, if appropriately drafted, would serve only to clarify formally what MCO plans have promised to provide. While a state mandated definition would effectively establish a minimum duty of care, most MCOs have already promised to provide comprehensive and medically necessary health care. Accordingly, the state is merely seeking to define this phrase for the benefit of citizens and health care providers. When articulating a standard of care, the state is making an effort to direct MCOs to follow a reasonable process when making coverage decisions.

The need for a universal definition of medical necessity is even more apparent after reviewing appellate decisions dealing with the issue.

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146. Id.
148. Brubaker, supra note 33, at H12 (quoting Aetna Chairman William Donaldson).
149. STAUFFER, supra note 6 (quoting former House Speaker Newt Gingrich (R-GA), as originally printed in CQ DAILY MONITOR, Aug. 10, 1998).
150. See cases cited supra note 6.
decisions in civil cases are particularly instructive. In cases where no defined standard of care is present, or a dispute exists about the specific medical procedure utilized, courts appear unwilling to impose criminal responsibility on the MCO.

The court in *Luckey v. Baxter Healthcare Corp.* affirmed summary judgment in favor of a health care company that tested plasma for HIV and hepatitis, but failed to perform an additional plasma test that arguably could have been beneficial. The *Luckey* court noted, “[w]hat tests to perform, and when are difficult questions... no one believes (at least, no one should believe) that every possible test, no matter how expensive, should be administered to avoid every conceivable risk, no matter how small. Some form of cost-benefit inquiry must be carried out.”

The FCA suit in *Luckey* ultimately failed because the court concluded that “[a]ll this record reveals is a dispute about whether [the laboratory’s] testing protocols could be improved. An affirmative answer to that question would not suggest that [the laboratory’s] representations to the United States... were false or fraudulent.” Similarly, the court in *United States ex rel. Swafford v. Borgess Medical Center* also granted a defendant’s motion for summary judgment in a False Claims Act action. The complaint in *Borgess* alleged that the claims submitted by the medical center to the government were implicitly false because of “inadequate and pathetic patient care.” However, there were no specifically promulgated regulations regarding the procedures for a doctor’s review of venous ultrasound studies.

In *United States v. Billig*, the Naval-Marine Corps court reversed a physician’s manslaughter conviction. Dr. Billig was charged with causing the death of patients under his care, in part because he failed to

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151. Id.
153. Luckey, 183 F.3d at 732.
154. Id.
155. Id. at 733.
156. Ex rel. Swafford, 98 F. Supp. 2d at 824.
157. Id. at 829.
158. Id. at 827-28.
use a preferred heart surgery procedure.\textsuperscript{160} In reversing the conviction, the court stated, "we decline to substitute our judgment for that of a surgeon choosing a medically acceptable surgical technique."\textsuperscript{161} In a footnote, the court observed:

[o]ur refusal to second guess reasonable medical decisions made by physicians in the course of surgery is closely analogous to our refusal to question judgment calls made by attorneys during the course of providing legal representation. We will not evaluate strategic professional choices from hindsight, but from the perspective of the professional at the time such choices are made, with the presumption that the conduct is reasonable.\textsuperscript{162}

\textit{Luckey, Swafford and Billig} illustrate the reluctance of courts to impose legal culpability in situations of medical uncertainty or good faith mistakes. These cases emphasize the importance of elevating the definition of "medically necessary" and "appropriate care" to a level at which reasonable minds cannot differ when writing criminal statues for improper managed care treatment denial decisions.\textsuperscript{163}

Court cases dealing with medical necessity definitions can be divided into two categories: tort actions and state actions against health care providers for Medicare and Medicaid patients. While the two lines of cases clearly have a different basis for liability, both highlight the difficulty in defining medically necessary and appropriate care and the legal difficulty in reconciling managed care's emphasis on cost-containment.

The court in \textit{McGraw v. Prudential Insurance Company of America},\textsuperscript{164} which involved a tort action, held that, "[a] decision to deny benefits is arbitrary and capricious if it is not a reasonable interpretation of the plan's terms."\textsuperscript{165} The court in \textit{McGraw} dealt with an MCO that "modified

\textsuperscript{160} \textit{Id.} at 751-52.
\textsuperscript{161} \textit{Id.} at 752.
\textsuperscript{162} \textit{Id.} at 752 n.10.
\textsuperscript{163} A federal appellate judge in \textit{Cleland v. Bronson Health Care Group} noted the difficulty of reviewing the propriety of an MCO decision based on the phrase, "medically necessary and appropriate care." 917 F.2d 266, 272 (1990). Judge Boggs wrote, "appropriate is one of the most wonderful weasel words in the dictionary, and a great aid to the resolution of disputed issues in the drafting of legislation. Who, after all, can be found to stand up for 'inappropriate' treatment or actions of any sort." \textit{Id.} at 271.
\textsuperscript{164} 137 F.3d 1253 (10\textsuperscript{th} Cir. 1998).
\textsuperscript{165} \textit{Id.} at 1259.
its definition of medically necessary [to include a requirement that]...treatment provide a measurable and substantial increase in functional ability for a condition having potential for significant improvement."\textsuperscript{166} The MCO defended its contract modification as appropriate because the contract distinguished between medically beneficial and medically necessary.\textsuperscript{167} In a footnote, the court noted, "[if] this criterion [were] carried to its logical conclusion, no [Multiple Sclerosis] patient could qualify for reimbursement of certain medical services, and the contract of insurance would be illusory."\textsuperscript{168} Coverage was also denied because the plaintiff briefly left the hospital, and thus her hospital stay could not be "medically necessary." The court found this denial "shocking," stating "one would assume the opportunity for entertainment [such as an inpatient leaving the confines of the hospital with a family member] would be not only therapeutic, but also desirable in treating this illness (Multiple Sclerosis)."\textsuperscript{169}

In \textit{Franks v. Louisiana Health Services. & Indemnity Co.},\textsuperscript{170} the court ruled in favor of an MCO when a denial of care was fair and reasonable. The plaintiff in the case unsuccessfully protested the inherent conflict of allowing an MCO to make medical necessity decisions. In brief, the plaintiff stated, "[d]efendant is in effect saying that we will sell you this policy of insurance, however, we will not pay unless we want to pay. This is the end result of such a ridiculous and incomprehensible scheme as defendant has placed in its policy."\textsuperscript{171} In dicta, the court made a prophetic observation: "\textit{In the absence of a conflict with a statute or with public policy}, an insurer has the same right as an individual to limit its liability and to impose upon their policy obligations whatever conditions they please."\textsuperscript{172}
At least twenty-three states have attempted to clarify the phrase “appropriate and medically necessary care.”\textsuperscript{173} However, state definitions vary widely, and as a result no clearly articulated standard has emerged.\textsuperscript{174} In the event legislators take up the task of drafting criminal statutes, specific definitions must be crafted. Defining “medical necessity” places MCOs in a difficult position. MCOs deny physician-recommended treatment based on vague definitions of medical necessity but fail to disclose the basis for these standards to the attending physician. “Health insurers need neither a vague description of medical necessity nor a specific list of what should be covered and what should not; insurers need a generally accepted method to determine whether and when a medical technology is to be considered medically necessary.”\textsuperscript{175}

Drafting a definition of “medically necessary” and “appropriate care” is difficult because of the inherent subjectivity of medicine and the frequent lack of a clear solution for many health situations.\textsuperscript{176} Moreover, as the Supreme Court held in \textit{Boyce Motor Lines v. United States},\textsuperscript{177} a “criminal statute must be sufficiently definite to give notice of the required conduct to one who would avoid its penalties.”\textsuperscript{178} One official noted that, “[d]efinitions of ‘medical necessity’ have to be flexible enough to take into account the needs of each patient. One-size-fits-all outcomes make irrelevant the doctor’s knowledge of the individual patient; and that is bad medicine, period.”\textsuperscript{179}

The following proposal for a definition of “medical necessity” could be applied in a criminal action, because it balances the needs of both the patient and the MCO:

An insurer should be able to set aside the recommendations of a treating physician only in restricted circumstances. Decisions about coverage should continue to be weighed against clinically

\textsuperscript{173} Stauffer, supra note 6.
\textsuperscript{174} Id.
\textsuperscript{175} Jason Mann, \textit{Selected Topics in Risk Managed in the Faculty of Management at the University of Calgary}, at http://www.ucalgary.ca/MG/inrm/finplan/health/med_necessity/credits.htm (last visited Dec. 18, 2001).
\textsuperscript{176} Morreim, supra note 4, § V(A).
\textsuperscript{177} 342 U.S. 337 (1952).
\textsuperscript{178} Id. at 340.
accepted standards of medical practice. An insurer’s decision should be lawful only if the insurer can prove that the decision rests on valid and reliable evidence that is relevant to the patient’s individual circumstances . . . This . . . requires insurers to act reasonably and weigh the reasonableness of their conduct against professional standards of practice as reflected by valid and reliable evidence.\textsuperscript{180}

Adequately defining “medically necessary” and “appropriate care” to support a criminal statute, however, is inherently difficult. If the definition is too vague, a conviction cannot be sustained. However, a definition must not be too specific because it must account for the nuances of each medical condition and distinct patient histories. A simple standard that places a clearly defined obligation on managed care providers, along with criteria to follow in the event that the MCO disagrees with the attending physician’s recommendations, will allow criminal prosecutions to proceed. In \textit{Boyce}, the Supreme Court acknowledged,

most statutes must deal with untold and unforeseen variations in factual situations . . . Consequently, no more than a reasonable degree of certainty can be demanded. Nor is it unfair to require that one who deliberately goes perilously close to an area of proscribed conduct shall take the risk that he may cross the line.\textsuperscript{181}

Accordingly, while issues of proof and pleadings will be significant hurdles in health care prosecutions, enactment of criminal statutes for improper treatment denial decisions, and the accompanying establishment of a duty of care, is an entirely appropriate area for state intervention. As the court noted in \textit{Wickline v. California},\textsuperscript{182} "an erroneous decision in a prospective review process . . . in practical consequences, results in the withholding of necessary care, potentially leading to a patient’s permanent disability or death."\textsuperscript{183}

\textit{Nothing focuses a subject’s attention upon a legal issue as effectively as the prospect of becoming involved in the criminal justice system – and the chance that the result will be a prison}

\begin{flushright}
180. Rosenbaum, \textit{supra} note 50, at 229.
183. \textit{Id}. at 1634.
\end{flushright}
sentence and immense fines.184

III. CRIMINAL PENALTIES

Criminal statutes proscribing improper treatment denial decisions must contain language that describes the duty owed, the standards by which the conduct is to be judged and the conduct that is prohibited.185 Moreover, such statutes should also embrace the basic tenets of criminal law: preventing harm, ensuring responsibility and deterring future misconduct.186 It is also important that any statute reflect the criminal law principle that “the injury to be vindicated is not the personal wrong suffered by the victim but rather an outrage to the State.”187

But are criminal statutes appropriate in the managed care arena? Criminal statutes targeting improper treatment denial decisions by health care insurers and providers will likely have to respond to several important challenges. First, unconstitutional vagueness poses a problem when “[criminal statutes do] not provide fair notice of the conduct proscribed.”188 Second, a criminal statute may be indefinite because it “confers unlimited discretion on the trier of fact to determine whether an offense was committed.”189 Third, a criminal statute may be improper because mens rea may not be easily established.190

184. Daniel Riesel & James R. Norman, Criminal Enforcement and the Regulation of the Environment, ALI-ABA Course of Study Materials, Environmental Litigation (June 1996). See also Greg Garland, Holiday Spirits: Return to Sender, BALT. SUN, Dec. 24, 1999, at A1 (discussing the enactment of a new criminal act in Maryland making it a felony to ship or distribute wine in the state without a license). One district attorney said, “I think just the threat of felony prosecution has curtailed the activity considerably.” Id. at A6.


186. See Brickey, supra note 39, at 504-06.


189. Id.

190. See id.
providers may also contend that criminal statutes will lead to an increase in the number of uninsured because few providers will want to incur the high costs of complying with additional regulations.\textsuperscript{191}

For guidance on these issues, legislators and courts can look to prosecutions of health care providers based on omissions, fraud, environmental violations, corporate liability and model penal code violations. For example, \textit{Peterson v. Florida},\textsuperscript{192} \textit{Billingslea v. Texas}\textsuperscript{193} and \textit{Arizona v. Brown}\textsuperscript{194} are three cases dealing with elder abuse that underscore the legislative and prosecutorial support for criminal sanctions in cases where failing to provide appropriate care results in harm.

In \textit{Peterson}, where a mother's death was caused by the abysmal care provided by her children, a Florida court affirmed a manslaughter conviction based on the defendant's legal duty as a "caregiver."\textsuperscript{195} The court cited the language of Florida statute § 782.07(2), prohibiting conduct that causes the death of an elderly or disabled person by culpable negligence.\textsuperscript{196} The statute reads:

\begin{quote}
[N]eglect of an elderly or disabled person is defined by section 825.102(3) as . . . [a] caregiver's failure or omission to provide an elderly person or disabled adult with the care, supervision, and services necessary to maintain the . . . adult's physical and mental health, including . . . medicine, and medical services that a prudent person would consider essential for the well-being of the elderly person or disabled adult.\textsuperscript{197}
\end{quote}

Most importantly, the \textit{Peterson} court broadly interpreted the definition of a "caregiver" to include "more than just the person or persons who do the actual physical work . . . It also reaches those who \textit{in fact} are

\begin{footnotes}
191. \textsc{Furrow et al.}, \textit{supra} note 5, at 503 (stating, inter alia, that HMO regulatory agencies are currently concerned with the "financial solvency of HMOs"). \textsc{See also Majority Believe Fewer Providers Will Take on Risk}, at http://www.themcic.com/industry/sow-pr2.htm (last visited Dec. 18, 2001)(noting that 60% of health care executives polled in a survey stated that "fewer providers would take on risk this year . . . providers have become disenchanted with managing risk as the losses continue to mount").


195. Peterson, 765 So. 2d at 865.

196. \textit{Id.} at 862.

197. \textit{Id.} (emphasis added).
\end{footnotes}
‘entrusted’ with the responsibility for seeing that an elderly or disabled person is being cared for in a proper and humane manner.”

A defendant found guilty of injuring an elderly person by omission had his conviction reversed by a Texas Court of Appeals in *Billingslea* because no statutory duty of care existed.99 *Billingslea* involved a relative who, while living with the decedent, failed to provide the decedent with any meaningful care despite significant and very obvious health issues.200

The *Billingslea* conviction was reversed because, “the State failed to establish an essential element of the offense, namely, the duty to act, because no such duty existed... Logic dictates that in order for there to be an omission, there must be a corresponding duty to act.”201

The Texas legislature created a duty to act with the amendment of V.T.C.A. Penal Code § 22.04(a). The new statute, which now includes the elderly, reads:

A person commits an offense if he intentionally, knowingly, recklessly, or with criminal negligence, by act or intentionally, knowingly or recklessly by omission, causes a child, elderly individual, or disabled individual: (1) serious bodily injury; (2) serious mental deficiency, impairment or injury; or (3) bodily injury.202

In *Brown*, an Arizona court affirmed a manslaughter conviction against a defendant who ran a boarding home.203 In that case, a 98 year-old died of starvation because of the “pitiful care that was given.”204 The court noted that,

The law recognizes that under some circumstances the omission of a duty owed by one individual to another, where such omission results in the death of the one to whom the duty is owing, will make the other chargeable with manslaughter...This rule of law is always based upon the proposition that the duty neglected must be a legal duty, and not a mere moral obligation.205

198. Id. at 864.
200. Id. at 272.
201. Id. at 274, 276.
204. Id. at 130.
205. See id. at 131 (quoting People v. Beardsley, 113 N.W. 1128, 1129 (Mich.
With respect to criminal statutes targeting improper treatment denial decisions, the Brown court noted situations where criminal liability may be imposed for failing to act,

[F]irst, where a statute imposes a duty to care for another; second, where one stands in a certain status relationship to another; third, where one has assumed a contractual duty to care for another; and fourth, where one has voluntarily assumed the care of another and so secluded the helpless person as to prevent others from rendering aid. 2

Peterson, Billingslea and Brown provide powerful guidance on the viability of criminal statutes focusing on treatment denial decisions or omissions to act. Because MCOs are entrusted with the responsibility of providing comprehensive medical services, it is entirely appropriate for MCOs to bear criminal responsibility if they knowingly, recklessly or negligently engage in conduct that injures a subscriber in violation of either contract or statute.

Environmental prosecutions, like the elder care cases, are tremendously helpful in determining the propriety of prospective criminal statutes against improper treatment denial decisions because of similar legal, social and policy influences. The same issues raised in environmental actions usually are repeated in managed care prosecutions. These arguments posit that criminal penalties of environmental violations are "unfair." In addition, prosecutors in these actions state that there is a "vague sense of uneasiness" about prosecuting "less egregious" environmental misconduct, that environmental law is unique and environmental prosecutions are often politically motivated. 207

"The overriding objective in prosecuting environmental cases is deterrence, and the government has sought to achieve this goal through the use of increasingly strong sanctions... (where) the penalties are not limited to fines." 208 The basic premise behind an environmental crime is that a violation, "ha[s] the potential to cause catastrophic harm to the environment, public health, and local economies' ways of life." 209

1907).

206. See id. at 131-32 (quoting Jones v. United States, F.2d 307, 310 (C.A. D.C. 1962)).


208. See id. at 39-40.

209. Brickey, supra note 39, at 507.
Moreover, "criminal enforcement (of environmental regulations) is needed to protect the integrity of the regulatory scheme, prevent harm to the environment, protect the public health and welfare, and to punish culpable violations."\textsuperscript{210}

The social and political evolution of environmental law is analogous to that of MCO prosecutions. While environmental violations were, "[o]nce viewed as mere economic/regulatory offenses lacking an element of moral delicts... environmental crimes now provoke moral outrage and prompt demands for severe sanctions and strict enforcement,"\textsuperscript{211} Like environmental violations, MCO conduct also provokes moral outrage as well as demands for reform.\textsuperscript{212}

Commonwealth v. Feinberg,\textsuperscript{213} a case cited by advocates of environmental criminal penalties, is also instructive.\textsuperscript{214} The defendant, a store owner, was convicted of manslaughter for selling a potentially lethal strain of alcohol to patrons. The Pennsylvania Supreme Court agreed with the opinion of the lower court that the store owner was "grossly negligent and demonstrated a wanton and reckless disregard for the welfare of those whom he might reasonably have expected to use the product for drinking purposes."\textsuperscript{215} Thus, when managed care organizations provide a level of health care they either know or should reasonably know will cause harm, culpability should follow.

A managed care plan provider may be criminally liable as a corporation for the illegal conduct of its employees if the employees are acting within the scope of their authority and their conduct benefits the corporation.\textsuperscript{216}

\begin{itemize}
  \item \textsuperscript{210} Id. at 509.
  \item \textsuperscript{211} Id. at 489.
  \item \textsuperscript{212} Democrats Introduce Patients' Bill of Rights, supra note 40, at *1. Senator Tom Daschle (D-SD) told the story of David Garvey of Illinois, whose wife was diagnosed with aplastic anemia while on vacation in Hawaii and died after her health maintenance organization insisted that she travel to Chicago for treatment. Sen. Daschle said, "I am outraged by what happened to the Garveys and believe we need legislation to protect patients against medically inappropriate decisions by health plans that too often put the financial bottom line before patients' health care needs." Id. See also Glodt, supra note 7, at 642.
  \item \textsuperscript{213} 253 A.2d 636 (Pa. 1969).
  \item \textsuperscript{214} Humphreys, supra note 29, at 336.
  \item \textsuperscript{215} Feinberg, 253 A.2d at 642 (quoting the lower court's opinion).
  \item \textsuperscript{216} See Joel M. Androphy et al., General Corporate Criminal Liability, 60 Tex. J. Bus. L. 121 (citing United States v. Gold, 743 F.2d 800 (11th Cir. 1984); United States v. MacDonald & Watson Waste Oil Co., 933 F.2d 35 (1st Cir. 1991).}
\end{itemize}
Moreover, criminal liability may be imposed on anyone in the corporation, including executive officers and directors.\textsuperscript{217}

In \textit{United States v. Park},\textsuperscript{218} a CEO of a grocery chain contested his criminal conviction for violating the Food and Drug Act on the grounds that he had delegated responsibility for the conduct that was subsequently held to be illegal.\textsuperscript{219} The Supreme Court held that the probative inquiry was not whether the defendant participated in the illegal conduct but rather, whether he had a "responsible relationship" to the conduct.\textsuperscript{220} The Supreme Court stated that, "the Act imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur."\textsuperscript{221}

Similar to environmental actions, criminal prosecutions for Food and Drug Act violations are also instructive. A Federal Court of Appeals affirmed a conviction of a child psychiatrist for failing to maintain required records of an experimental drug.\textsuperscript{222} Furthermore, a manufacturer of a catheter was convicted of, \textit{inter alia}, concealing adverse patient information from the FDA.\textsuperscript{223} The environmental and FDA criminal cases are relevant to prospective criminal statutes for treatment denial decisions because they are indicative of the legal support for statutes enacted to protect the health, safety and welfare of citizens.

A final concern in developing criminal statutes is the proper level of mens rea required to support a conviction. Should the statute merely require knowledge of the action or knowledge of the wrongfulness of the action?\textsuperscript{224} The Model Penal Code can serve as the foundation for this analysis. In section 2.02: General Requirements of Culpability, the Model Penal Code defines purposely, knowingly, recklessly and negligently.\textsuperscript{225}

\begin{itemize}
  \item \textsuperscript{217} Androphy, \textit{supra} note 212, at 121.
  \item \textsuperscript{218} 421 U.S. 658 (1975).
  \item \textsuperscript{220} \textit{Park}, 421 U.S. at 672.
  \item \textsuperscript{221} \textit{Id}.
  \item \textsuperscript{222} \textit{United States v. Garfinkel}, 29 F.3d 451 (8th Cir. 1994).
  \item \textsuperscript{223} \textit{United States v. C.R. Bard, Inc.}, 848 F. Supp. 287 (D. Mass. 1994).
  \item \textsuperscript{224} \textit{See} United States v. Johnson \& Towers, Inc. 741 F.2d 662, 664 (3rd Cir. 1984); \textit{United States v. Hayes Int'l Corp.}, 786 F.2d 1499, 1502 (11th Cir. 1986); Gaynor, \textit{supra} note 203, at 58.
  \item \textsuperscript{225} \textit{MODEL PENAL CODE} § 2.02 (1962).
\end{itemize}
The definitions of purposely, knowingly, recklessly, negligently and causal relationship are as follows:

(a) **Purposely.** A person acts purposely with respect to a material element of an offense when: (i) if the element involves the nature of his conduct or a result thereof, it is his conscious object to engage in conduct of that nature or to cause such a result; and (ii) if the element involves the attendant circumstances, he is aware of the existence of such circumstances or he believes or hopes that they exist.

(b) **Knowingly.** A person acts knowingly with respect to a material element of an offense when: (i) if the element involves the nature of his conduct or the attendant circumstances, he is aware that his conduct is of that nature or that such circumstances exist; and (ii) if the element involves a result of his conduct, he is aware that it is practically certain that his conduct will cause such a result.

(c) **Recklessly.** A person acts recklessly with respect to a material element of an offense when he consciously disregards a substantial and unjustifiable risk that the material element exists or will result from his conduct. The risk must be of such a nature and degree that, considering the nature and purpose of the actor's conduct and the circumstances known to him, its disregard involves a gross deviation from the standard of conduct that a law-abiding person would observe in the actor's situation.

(d) **Negligently.** A person acts negligently with respect to a material element of an offense when he should be aware of a substantial and unjustifiable risk that the material element exists or will result from his conduct. The risk must be of such a nature and degree that the actor's failure to perceive it, considering the nature and purpose of his conduct and the circumstances known to him, involves a gross deviation from the standard of care that a reasonable person would observe in the actor's situation.

Section 2.03: **Causal Relationship Between Conduct and Result** Conduct is the cause of a result when:

(a) it is an antecedent but for which the result in question would not have occurred; and

(b) the relationship between the conduct and the result satisfies any additional causal requirements imposed
by the Code or by the law defining the offense.  

While there are obvious hurdles with any MCO prosecution for wrongful treatment denial decisions resulting in patient harm, there are also prosecutorial weapons. "The stigma of an indictment, let alone a conviction, should weigh heavily in the minds of corporate officials." Moreover, the prosecution may access and seize the records of MCOs. "The Supreme Court has consistently held the Fifth Amendment privilege is limited to its historic function of protecting only the natural individual from compulsory incrimination through their own testimony or personal [private] records." 

While MCO prosecutions could appear to be the second-guessing of surgical decisions, criminal actions against MCOs should remain focused on egregious instances of treatment denial decisions. Any MCO prosecution, because of the subjective nature of health care, will be difficult. Regardless of those difficulties, public safety, deterrence and regulation of health care must guide legislators.

"A single death is a tragedy, a million deaths is a statistic."  

CONCLUSION

Clearly ERISA affords MCOs certain protection from civil litigation. Just as clearly, MCOs have a profound impact on the health and well being of the populace, arguably a greater impact than environmental polluters. Current consumer protections, which include tort actions and certain state legislation, are inadequate. Therefore, it is critical that tools be developed to hold MCOs properly accountable. One such tool is criminal prosecution. Although prosecutors could use certain existing statutory and common law crimes to pursue managed care abuses, the difficulty associated with defining medical necessity and establishing a duty of care (in non-Medicare/Medicaid cases) dictates that the

226. MODEL PENAL CODE §§ 2.02(2), 2.03(1) (1962).
228. Id. at 1124-25.
229. Id. at 1125 (quoting United States v. White, 322 U.S. 694, 701 (1944)).
appropriate course is to create specific statutes proscribing treatment denial decisions.

Legislators should focus on providing as much notice as possible by drafting consistent, uniform standards of medically necessary care. This will establish the MCO duty and avoid a patchwork of varying, and possibly confusing, treatment standards. Moreover, legislators must also determine the level of mens rea required to support a criminal conviction. The inquiry into criminal statutes and administrative actions should be considered with respect to, not only their lawfulness, but also to their utility and value. Based on FDA, elder care and environmental prosecutions, the enactment of health care criminal statutes that establish a standard of medically necessary care and accompanying MCO obligations will not only survive legal challenges, but will be the socially, legally and morally correct path to take.

Finally, legislators must consider the political reality of criminal statutes and the possibility that they may lose some managed care plans in their state. As long as there are profits to be made in health care, MCOs will continue to exist and modify their conduct accordingly.