How Medicare Part D, Medicaid, Electronic Prescribing, and ICD-10 Could Improve Public Health (But Only If CMS Lets Them)

Jennifer L. Herbst

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Antitrust and the Future of Nursing

The Board’s opinion is not and cannot be altered by representations that a particular CRNA [Certified Registered Nurse Anesthetist] has received postdoctoral training in such areas or has performed such activities in this or another state. A non-physician may have education, training, and, indeed, expertise in such an area but expertise cannot, in and of itself, supply authority under law to practice medicine.\footnote{Safriet, supra note 97, at 454.}

As a legal matter, the analysis may be trivially correct: education, training, experience, and expertise do not, in themselves, bestow legal authority or lift statutory prohibitions. As a policy matter, however, we might wonder about the bases on which we both assign and limit the authority to meet demand – unmet needs – for health care. However we allocate research resources, tolerate uncertainty, and calibrate substantiation standards, we might say this much when substantiation appears to approach zero: based on competition principles at least, nothing ought to beget nothing, except, perhaps, scrutiny.

\(286\) Safriet, supra note 97, at 454.
CONCLUSION

The United States' health care system is broken. An estimated 1.5 million people are sickened or killed every year due to preventable prescription drug errors.³ As much as half of the $66.8 billion (and growing) spent annually by the Medicare program on outpatient prescription drugs is being misspent.² Most prescription drugs have not been tested for safety and efficacy in our most vulnerable populations - children, pregnant women, the chronically disabled, and elderly - and yet they are the most likely to need and receive prescription drugs covered by government insurance programs.² Between the expansion of Medicaid coverage under the Patient Protection and Affordable Care Act (the primary insurance coverage for over 32 million American children)³ and the 65-plus-year-old Medicare-eligible population growing from 40 million people to 72 million people in the next twenty years,⁴ the federal health care systems' payment of prescription drugs for our most vulnerable populations will only continue to increase.⁵ The Food and Drug Administration (FDA)'s prescription drug review and approval process is unable to detect effectively many risks of prescription drugs until after they have been approved and used by thousands or millions of patients.⁶ It is not much of a stretch to suggest that our Medicare and Medicaid programs are paying for an uncontrolled trial of prescription drugs in vulnerable populations without much prospect for collecting meaningful data to inform future treatment decisions in these populations.

A single, simple step (to the billing system, of all things) could start to remedy these ills: Make patient diagnosis codes a necessary condition for payment of outpatient prescription drugs by Medicare Part D and Medicaid. With the increasing adoption of electronic medical records and electronic prescribing (aided in large part by federal incentive pro-

INTRODUCTION

The United States' health care system is broken. An estimated 1.5 million people are sickened or killed every year due to preventable prescription drug errors.³ As much as half of the $66.8 billion (and growing) spent annually by the Medicare program on outpatient prescription drugs is being misspent.² Most prescription drugs have not been tested for safety and efficacy in our most vulnerable populations - children, pregnant women, the chronically disabled, and elderly - and yet they are the most likely to need and receive prescription drugs covered by government insurance programs.² Between the expansion of Medicaid coverage under the Patient Protection and Affordable Care Act (the primary insurance coverage for over 32 million American children)³ and the 65-plus-year-old Medicare-eligible population growing from 40 million people to 72 million people in the next twenty years,⁴ the federal health care systems' payment of prescription drugs for our most vulnerable populations will only continue to increase.⁵ The Food and Drug Administration (FDA)'s prescription drug review and approval process is unable to detect effectively many risks of prescription drugs until after they have been approved and used by thousands or millions of patients.⁶ It is not much of a stretch to suggest that our Medicare and Medicaid programs are paying for an uncontrolled trial of prescription drugs in vulnerable populations without much prospect for collecting meaningful data to inform future treatment decisions in these populations.

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4. New drugs commonly are tested at most on a few thousand patients, so even the more common side effects may occur only in a handful of cases, and rare but deadly side effects may not emerge at all.

3. More specifically, the clinical studies used for FDA approval are not designed to test safety (instead they are focused primarily on efficacy) and tend to exclude the frail elderly, young children, pregnant women, and patients with comorbidities that could interact with the drugs. Aaron S. Kesselheim, Off-Label Drug Use and Promotions: Balancing Public Health Goals and Commercial Speech, 37 Am. J.L. & Med. 225, 233-38 (2011).
7. Kesselheim, supra note 3, at 233 ("New drugs commonly are tested at most on a few thousand patients, so even the more common side effects may occur only in a handful of cases, and rare but deadly side effects may not emerge at all.")
improved patient safety and better informed long-term management of federal health care dollars for a short-term reduction in federal spending on prescription drugs.

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Introduction

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tested for safety and efficacy in our most vulnerable populations—children, pregnant women, the chronically disabled, and elderly—and yet they are the most likely to need and receive prescription drugs covered by government insurance programs.3 Between the expansion of Medicaid coverage under the Patient Protection and Affordable Care Act (the primary insurance coverage for over 32 million American children)4 and the 65-plus-year-old Medicare-eligible population growing from 40 million people to 72 million people in the next twenty years,4 the federal health care systems’ payment of prescription drugs for our most vulnerable populations will only continue to increase.5 The Food and Drug Administration (FDA)’s prescription drug review and approval process is unable to detect effectively many risks of prescription drugs until after they have been approved and used by thousands or millions of patients.6 It is not much of a stretch to suggest that our Medicare and Medicaid programs are paying for an uncontrolled trial of prescription drugs in vulnerable populations without much prospect for collecting meaningful data to inform future treatment decisions in these populations.

A single, simple step (to the billing system, of all things) could start to remedy these ills: Make patient diagnosis codes a necessary condition for payment of outpatient prescription drugs by Medicare Part D and Medicaid. With the increasing adoption of electronic medical records and electronic prescribing (aided in large part by federal incentive pro-


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4. Distribution of Medicaid enrollees by enrollment group / (last visited Apr. 18, 2014).


6. CONG. BUDGET OFFICE, supra note 2.

7. Kesselheim, supra note 3, at 230 (“New drugs commonly are tested at most on a few thousand patients, so even the more common side effects may occur only in a handful of cases, and rare but deadly side effects may not emerge at all.”).
9. While Medicare Part D sponsors (the contractors charged with administering the Medicare prescription drug benefit on behalf of CMS) are technically supposed to ensure that the drugs paid for by the Medicare Part D program are used properly for "medically-accepted indications," sponsors are not expected to recoup any incorrect payments from pharmacists or patients unless the drug was subject to a sponsor’s prior authorization (contrary to the letter of the Medicare Part D and Medicaid statutes).8

In Part I, I explain the role of diagnostic information in the current legal framework for Medicare and Medicaid reimbursement of outpatient prescription drugs as well as the federal government’s current billing and reimbursement policy in spite of the legal framework. Part II then looks at the potential disadvantages of strict enforcement of the Medicare Part D and Medicaid coverage laws (at least in the short term) due to (A) the disconnect between “medically accepted indications” (the statutory standard for coverage by the Medicare Part D and Medicaid programs) and the actual practice of medicine, (B) the informational uncertainty accompanying the pending transition from the current diagnostic coding system, ICD-9-CM, to its successor, ICD-10-CM, and (C) the systemic incentives for miscoding created by coverage denials based upon the diagnostic information.

As seen in Part III, the significant public health interests potentially served by adding diagnostic codes to outpatient prescriptions—better informed pharmacist review of prescriptions for medication errors, improved drug safety surveillance and comparative effectiveness research based on actual prescribing practices and patient adherence data—will only be realized if the information in the outpatient prescription drug claims database is an accurate reflection of actual medical practice and pharmacy. This information has been historically elusive for health care practitioners, researchers, and policymakers alike and an outpatient prescription drug claims database with diagnostic information would be a tremendously valuable public health research tool. In order to increase the likelihood that the diagnostic information submitted for payment is accurate, prescribers and pharmacists will need to understand diagnostic coding as a part of effective, coordinated patient care as opposed to a mere administrative requirement for payment.

I conclude by suggesting an incremental implementation process in order for CMS and FDA (and, by proxy, patients, health care providers, and taxpayers) to benefit from the outpatient prescription drug use data generated by the federal health care system.

I. The Role of Diagnostic Information in the Current Legal Framework for Reimbursement of Outpatient Prescription Drugs under Medicare and Medicaid

Federal statutes make Medicare Part D and Medicaid outpatient prescription drug coverage contingent on whether a patient’s diagnosis is one of the indications for which the FDA has approved the drug or otherwise supported by peer-reviewed scientific evidence summarized in recognized drug compendia. Congress chose to call this universe of drugs uses “medically accepted indications.”10 In order to determine the eligibility of a particular prescription for Medicare or Medicaid coverage, the claims administrator needs to know the drug name, dosage, quantity, and patient diagnoses.11 At present, outpatient prescriptions lack patient


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10. 42 U.S.C. § 1396a(n)(54) (2012) (indicating that if a state decides to extend Medicaid coverage to outpatient prescription drugs, coverage must comply with the federal requirements for payment for covered outpatient drugs under 42 U.S.C. § 1360e-8, § 1360e-8(k)(6) (defining "medically accepted drug" for Medicaid statute in terms of FDA-approved indications and compendia identified in § 1360e-8(g)(3)(B)(i)); § 1360e-8(g)(3)(C) (indicating that a drug may be excluded from a state’s Medicaid formulary if the use is not a medically accepted indication). See also § 1360e-8(g)(3)(C) (defining "covered outpatient drug" for Medicaid); § 1360e-102(a) (defining "covered Part D drug" and "medically accepted indication"); 42 C.F.R. § 443.100 (2012) (defining "Medicare Part D drug" by referring to Medicaid statute definition of "medically accepted indication" at 42 U.S.C. § 1360e-8(g)(3)(C)).

grants
diagnostic coding to outpatient prescriptions for Medicare Part D and Medicaid beneficiaries could significantly improve pharmacists’ review of prescriptions for errors, the drug safety surveillance efforts of the FDA, and the appropriate allocation of Medicare and Medicaid resources by CMS, but only if CMS is willing to continue its current policy of paying for all outpatient prescriptions not subject to prior authorization (contrary to the letter of the Medicare Part D and Medicaid statutes). 8

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10. 42 U.S.C. § 1396a(n)(54) (2012) (indicating that if a state decides to extend Medicaid coverage to outpatient prescription drugs, coverage must comply with the federal requirements for payment for covered outpatient drugs under 42 U.S.C. § 1396d-8, § 1396r-8(1)(6) (defining “medically accepted indication” for Medicaid statute in terms of FDA-approved indications and compendia identified in § 1396r-8(1)(B)(i)); § 1396r-8(4)(6) (indicating that a drug may be excluded from a state’s Medicaid formulary if the use is not a medically accepted indication). See also § 1396r-8(4)(2) (defining “covered outpatient drug” for Medicaid); § 1396w-102(1) (defining “covered Part D drug” and “medically accepted indication”); 42 C.F.R. § 423.100 (2012) (defining “Medicare Part D drug” by referring to Medicaid statute definition of “medically accepted indication” at 42 U.S.C. § 1396d-8(6)(6)).

diagnostic information (the “information gap” identified in a prior article), making real-time review for coverage eligibility impossible. In order to close this information gap, CMS could require patient diagnosis information, in the form of an International Classification of Diseases (ICD) code, for reimbursement of outpatient prescription drugs under Medicare and Medicaid. My proposal for CMS to require diagnostic information, in the form of an ICD code, for reimbursement of outpatient prescription drug claims merely suggests an extension of the existing billing policy for the small group of outpatient drugs currently covered by Medicare Part B. Generally, Medicare Part B covers “reasonable and necessary” outpatient medical services and items for the “diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” Medicare Part B does not cover most outpatient prescription drugs—it has historically only covered drugs, which are administered by doctors during office or hospital visits. This relatively limited coverage has been extended, though, to include a handful of other specific classes of prescription drugs and biologics that may be purchased at retail pharmacies, including blood clotting factors for hemophilia patients, immunosuppressive therapy after organ transplantation, erythropoietin for dialysis patients, and anti-nausea drugs for those undergoing anticancer chemotherapy. In each of these statutorily defined exceptions to the general Part B rule covering only drugs that “are not usually self-administered by the patient,” Congress limited coverage to use for specific patient diagnoses (i.e., hemophilia, organ failure, kidney disease, cancer). CMS, in turn, has required diagnosis codes on all claims for reimbursement of prescription drugs under Part B, whether furnished by a physician or self-administered by a patient.

The vast majority of outpatient prescription drugs taken by Medicare beneficiaries went uncovered by the program until the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 added a prescription drug benefit to the Medicare program—Medicare Part D. Part D was considered at the time to be “the most significant change to the Medicare program since its inception in 1965.” Unlike the broad “reasonable and necessary” standard for Medicare Part B reimbursement, the legal framework for Medicare Part D limits federal reimbursement of outpatient prescription drugs to “medically accepted indications,” as defined by the Medicaid statute, allowing, but not requiring diagnostic information.


14. U.S. GOV’T ACCOUNTING OFFICE, MEDICARE PRESCRIPTION DRUG ISSUES 3 (1987) (“Outpatient prescription drugs are generally not covered by Medicare Part B, with the exception of drugs that require injection by a physician or nurse.”). 42 U.S.C § 1395k(a)(2)(B) (2012) (providing Medicare Part B coverage for “medical and other health services” rendered in an outpatient setting); § 1395k(a)(2)(A) (defining the term “medical and other health services” to include, in relevant part, “services and supplies (including drugs and biologics which are not usually self-administered by the patient) furnished as an incident to a physician’s professional service, of kinds which are commonly furnished in physicians’ offices and are commonly either rendered without charge or included in the physicians’ bills . . .” (emphasis added)).

15. § 1395k(a)(2)(I).

16. § 1395k(a)(2)(J).

17. § 1395k(a)(2)(O).

18. § 1395k(a)(2)(C).

19. See CTRS FOR MEDICARE & MEDICAID SERVS., MEDICARE CLAIMS PAYMENT POLICY MANUAL § 70 (2003), available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS010511.html (explaining an exception to the general Part B coverage rule that self-administered drugs, including self-administered oral versions of covered injectable cancer drugs, furnished to outpatients for therapeutic purposes are not covered by Medicare unless those drugs must be put directly into an item of durable medical equipment or a prosthetic device); Id. at § 80.1.3 (“A cancer diagnosis code must be reported when billing for [oral cancer drugs using] these HCPCS [Healthcare Common Procedure Coding System] codes. If there is no cancer diagnosis the claim is denied”); CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE BENEFIT POLICY MANUAL § 50.4.1 (2009) [hereinafter MEDICARE BENEFIT POLICY MANUAL], available at http://www.cms.hhs.gov/Manuals/downloads/bpl02c15.pdf (“Use of the drug or biological must be safe and effective and otherwise reasonable and necessary . . . Drugs or biologics approved for marketing by the [FDA] are considered safe and effective for purposes of this requirement when used for indications specified on the labeling.”).

20. Some Medicare patients are able to get additional insurance through Medicaid, in which case Medicaid could cover the outpatient prescription drugs not paid for by Medicare. These patients are known as “dual eligible beneficiaries.” MEDICARE PAYMENT ADVISORY COM’N, REPORT TO THE CONGRESS: NEW APPROACHES IN MEDICARE 71-72 (2004), available at http://www.medpac.gov/publications/congressional_reports/fune04_chl.pdf.


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The vast majority of outpatient prescription drugs taken by Medicare beneficiaries were uncovered by the program until the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 added a prescription drug benefit to the Medicare program—Medicare Part D. Part D was considered at the time to be “the most significant change to the Medicare program since its inception in 1965.” Unlike the broad “reasonable and necessary” standard for Medicare Part B reimbursement, the legal framework for Medicare Part D limits federal reimbursement of outpatient prescription drugs to “medically accepted indication[s],” as defined by the Medicaid statute, allowing, but not


13. Manual, supra note 9, at 10.6

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15. Manual, supra note 9, at 10.6

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19. See CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE CLAIMS PROCESSING MANUAL § 70 (2003), available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912.html (explaining an exception to the general Part B coverage rule that self-administered drugs, including self-administered oral versions of covered injectable cancer drugs, furnished to outpatients for therapeutic purposes are not covered by Medicare unless those drugs must be administered by a doctor or administered by a patient at home or by a patient at work, and other health care settings).

require, states to limit their coverage of outpatient prescription drugs to "medically accepted indications." 20 Medically accepted indications include any specific indication listed on the drug's labeling as approved by the FDA (also known as an "on-label" use) or any use supported by one or more citations found in recognized drug compendia, including the American Hospital Formulary Service Drug Information (AHFS-DI), the United States Pharmacopeia Drug Information (USP-DI), and the DrugDEX Information System. 21 In addition to the on-label and compendia-listed indications, Medicaid also allows reimbursement for any use that is supported by peer-reviewed medical literature, 22 but medical literature alone is not enough to provide Part D coverage unless the drug is "used in an anticancer chemotherapeutic regimen." 23 The uses supported by compendia citations or peer-reviewed medical literature include both on-label uses as well as uses that are not included on the FDA-approved labeling for a drug ("off-label" uses). 24

Despite the statutory language limiting Medicare Part D and Medicaid payment for drugs to "medically accepted indications," there is no single database within the federal health care system in which a patient's outpatient prescription drug use can be cross-referenced with his medical diagnoses. 25 The claims administrators for Medicare Part D, known as Part D Plan (PDP) sponsors, "do not routinely collect diagnosis information because CMS does not require diagnoses as a data element for Part D claims. PDP sponsors do not collect related diagnoses for Part D claims from pharmacies because it is not standard practice for prescribers to provide the diagnoses." 26 As a result, there is no real time, resource-efficient means of determining whether an outpatient prescription is appropriately reimbursed under Medicare Part D or Medicaid.

As a result, current CMS policy is not to enforce the coverage statutes at the time of payment (either the patient's payment for the prescription or the government's payment of the dispensing pharmacist) or to recoup mispaid funds from pharmacists or patients. 27 Instead, the government has generally been paying for outpatient prescriptions, regardless of diagnosis, then trying to recoup inappropriate payments for outpatient prescriptions for uses other than those considered "medically appropriate indications," through False Claims Act suits brought against pharmaceutical companies by the U.S. Department of Justice and state attorneys general. 28 If either the multi-million and billion dollar settle-supported by "clinical evidence in peer reviewed medical literature"), with § 1395w-8(k)(6) (noting the standard for all uses unrelated to cancer, which does not include uses supported by "clinical evidence in peer reviewed medical literature")

23. 42 U.S.C. § 1396d(a)(12) (2012) (defining the Medicaid program's "medical assistance" coverage to include payment for "prescribed drugs"); § 1396a-4(b)(2)(A)(i) (defining the Medicaid program's "covered outpatient drugs" to include all prescription drugs approved by the FDA); § 1396e-8(d)(1)(B)(i) (allowing states to limit coverage of outpatient drugs to "medically accepted indications"); § 1396e-8(k)(6) (defining "medically accepted indication" for Medicaid program). See also § 1395w-102(c); 42 C.F.R. § 423.100 (defining Medicare "Part D drug" by referring to Medicaid statute definition of "medically accepted indication" at 42 U.S.C. § 1396e-8(k)(6) (2012)). At least one federal court has decided that the regulation limiting Part D coverage to "medically accepted indications" is not consistent with Congressional intent. Layzer v. Leavitt, 770 F. Supp. 2d 579, 586 (S.D.N.Y. 2011). But see Kilmer v. Leavitt, 698 F. Supp. 3d 720, 723 (D. Ohio 2009) ("This Court is constrained by the plain language of the [Part D] statutory scheme to conclude that the medically accepted indication clause must be read as a limitation."); Nieves v. Sebelius, 2013 WL 5030386, at *9 (N.D. Cal. 2013) (concluding "it is clear from the plain terms of the statute that a covered Part D drug is one that complies with the medically accepted indication requirement"); Richhoff v. U.S. Sec'y ex rel. Dep't of Health & Human Servs., 2012 WL 6177411, at *4 (D. Ariz. 2012) ("Fasitax" its dosage form is not a 'medically accepted indication' for non-cancer patients and thus is not a covered Part D drug.


25. 1396e-8(g)(1)(B)(i).


27. Compare 42 U.S.C. § 1395w-102 (a)(4)(A)(i) (defining drugs used for oncology purposes in terms of § 1396e(a)(2)(B), which includes uses
requiring, states to limit their coverage of outpatient prescription drugs to "medically accepted indications."23

"Medically accepted indications" include any specific indication listed on the drug’s labeling as approved by the FDA (also known as an "on-label" use) or any use supported by one or more citations found in recognized drug compendia, including the American Hospital Formulary Service Drug Information (AHFS-DI), the United States Pharmacopoeia-Drug Information (USP-DI), and the DrugDEX Information System.24 In addition to the on-label and compendia-listed indications, Medicaid also requires, states to limit their coverage of outpatient prescription drugs to "medically accepted indication[s]."25 But medical literature alone is not enough to provide Medicaid payment for drugs to "medically accepted indications," there is no single database within the federal health care system in which a patient’s outpatient prescription drug use can be cross-referenced with his medical diagnoses.26 The claims administrators for Medicare Part D, known as Part D Plan (PDP) sponsors, "do not routinely collect diagnosis information because CMS does not require diagnoses as a data element for Part D claims. PDP sponsors do not collect related diagnoses for Part D claims from pharmacies because it is not standard practice for prescribers to provide the diagnoses."27 As a result, there is no real time, resource-efficient means of determining whether an outpatient prescription is appropriately reimbursed under Medicare Part D or Medicaid.

As a result, current CMS policy is not to enforce the coverage statutes at the time of payment (either the patient’s payment for the prescription or the government’s payment of the dispensing pharmacist) or to recoup mispaid funds from pharmacists or patients.28 Instead, the government has generally been paying for outpatient prescriptions, regardless of diagnosis, then trying to recoup inappropriate payments for outpatient prescriptions for uses other than those considered "medically appropriate indications," through False Claims Act suits brought against pharmaceutical companies by the U.S. Department of Justice and state attorneys general.29 If either the multi-million and -billion dollar settle-

23. See 42 U.S.C. § 1396d(a)(12) (2012) (defining the Medicaid program’s "medical assistance" coverage to include payment for "prescribed drugs"); § 1396-8(k)(1)(B)(i) (allowing states to limit coverage of outpatient drugs to "medically accepted indications"); § 1396-8(k)(6) (defining "medically accepted indication" for Medicaid program). See also § 1395w-102(a); 42 C.F.R. § 423.100 (defining Medicare “Part D drug” by referring to Medicaid statute-definition of "medically accepted indication" at 42 U.S.C. § 1396-8(k)(6) (2012)). At least one federal court has decided that the regulation limiting Part D coverage to "medically accepted indications" is not consistent with Congressional intent. Layver v. Leavitt, 779 F. Supp. 2d 579, 586 (S.D.N.Y. 2011). But see Kilmer v. Leavitt, 609 F. Supp. 2d 730, 753 (S.D. Ohio 2009) (“This Court is constrained by the plain language of the [Part D] statutory scheme to conclude that the medically accepted indication clause must be read as a limitation.”); Nievod v. Sebelius, 2013 WL 503039, at *9 (N.D. Cal. 2013) (concluding “it is clear from the plain terms of the statute that a covered Part D drug is one that comports with the medically accepted indication requirement”); Richhoff v. U.S. Sec'y ex rel. Dep’t of Health & Human Servs., 2012 WL 6177411, at *4 (D. Ariz. 2012) (“Fentanyl in lozenge form is not a ‘medically accepted indication’ for non-cancer patients and thus is not a covered Part D drug.”).


25. § 1396-8(k)(1)(B)(i).


27. Compare 42 U.S.C. § 1395w-102 (a)(4)(A)(ii) (defining drugs used for oncology purposes in terms of § 1395w(1)(2)(B), which includes uses reviewed medical literature include both on-label uses as well as uses that are not included on the FDA-approved labeling for a drug (“off-label” uses).30 Despite the statutory language limiting Medicare Part D and Medicaid payment for drugs to "medically accepted indications," there is no single database within the federal health care system in which a patient’s outpatient prescription drug use can be cross-referenced with his medical diagnoses.31 The claims administrators for Medicare Part D, known as Part D Plan (PDP) sponsors, "do not routinely collect diagnosis information because CMS does not require diagnoses as a data element for Part D claims. PDP sponsors do not collect related diagnoses for Part D claims from pharmacies because it is not standard practice for prescribers to provide the diagnoses."32 As a result, there is no real time, resource-efficient means of determining whether an outpatient prescription is appropriately reimbursed under Medicare Part D or Medicaid.

28. § 1395x(t)(2)(B). See also OIG Part D REIMBURSEMENT REPORT, supra note 2, at 3 (“Only one compendium needs to support an off-label use for that use to meet the medically acceptable indications requirement for Medicare Part D reimbursement.”).

29. Reconciling the pharmacy-generated outpatient prescription drug claim databases with the physician-generated office visit claim databases is currently time- and cost-prohibitive on a large scale. See OIG Part D REIMBURSEMENT REPORT, supra note 2.

30. Id. at 5.

31. CMS FOR MEDICARE & MEDICAID SERVS., supra note 9, at § 10.6.1 (“When it was not reasonable to expect a Part D sponsor to require prior authorization to ensure a drug is being used for an accepted medical indication, CMS would not expect the sponsor to recover payments made to pharmacies or attempt to obtain reimbursement from enrollees.” (emphasis added)).

32. In a prior article, I argued that the enforcement of the federal coverage law should be shifted away from the Department of Justice and state attorneys general to a real-time review of prescriptions at the time of payment by the
ment agreements with pharmaceutical companies or the recent memorandum from the Deputy Inspector General for the U.S. Department of Health and Human Services finding "50 percent of Medicare Part D claims of Medicare Part D claims for atypical antipsychotic drugs received by elderly nursing home residents from January 1 through June 30, 2007 were erroneous because the claimed drugs were not provided for medically accepted indications" are any indication of the scope of the overpayment by the federal government for outpatient prescriptions, the practical result of this policy is a significant misspending of billions of taxpayer dollars within the federal health care system.

II. HOW STRICT ENFORCEMENT OF THE COVERAGE LAW WOULD UNDERMINE LONG-TERM PATIENT SAFETY BY INCENTIVIZING MISCODING FOR SHORT-TERM PATIENT BENEFIT

While the recent multi-million and -billion dollar False Claims Act settlements with pharmaceutical companies and the audit findings of erroneously paid Part D claims mentioned above may suggest a significant misallocation of federal health care dollars, they also point to a real likelihood that strict enforcement of the coverage laws at the time of payment would result in widespread coverage denials, perhaps on the scale of millions of prescriptions. Given the socioeconomic situation of the majority of Medicare and Medicaid beneficiaries, coverage denials effectively prevent patient access to the prescribed drugs despite the fact that the health care providers who write the prescriptions have deemed them to be the best treatment for their patients. When confronted with administrative technicalities perceived as arbitrary or harmful to their patients, prescribers and pharmacists may decide to tailor their diagnostic coding practices for payment (and thus, effective treatment) purposes rather than reflecting their patients' actual diagnoses. This section looks at the potential disadvantages of strict enforcement of the Medicare and Medicaid coverage laws due to (A) the disconnect between the statutory definition of "medically appropriate indications" and actual medical practice; (B) the further uncertainty accompanying the transition from one diagnostic coding system to another scheduled for October 1, 2015; and (C) the incentives for miscoding created by coverage denials based upon the diagnostic information.

A. Limitations of Labels and Compendia: An Inherent Disconnect between Medicine and Science

Medicine is a professional practice focused on diagnosing and treating individual patients' diseases or injuries. The traditional goals of medicine include physicians' obligations to 1) prevent and diagnose disease or injury; 2) cure or treat the disease/injury; 3) reduce suffering or, if that is not possible, help patients cope with a disease or injury; 4) educate patients about disease/injury and prognosis; 5) help patients die in peace and with dignity; 6) reassure the "worried well" who do not have a disease/injury. 35

Just as the practice of law requires advising an actual client, the practice of medicine requires an actual patient. Patients are as similar to one another, and as different from one another, as clients are. Medical advice, like legal advice, is individualized. 36 Science, by comparison, is focused "on understanding nature and the universe through human observation, using theories that the human mind can reason from those observations, and reaching conclusions that can be tested through further observations of the universe." 37 Science is interested in creating generalizable knowledge and theories of how nature and the universe work. 38 It need not, and indeed cannot, limit itself to individual, anecdotal information. And there lies the rub — while science is a critically important tool for informing treatment decisions, it cannot account for all of the individual differences that medicine must consider. Yet the term "medically accepted indications" is defined in terms of scientific evidence.


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evidence – specifically the clinical trials underpinning the FDA approval process for prescription drugs and compendia listings.

FDA-approved "on-label" indications are reflective of the patient populations and endpoints studied in clinical trials funded and designed by manufacturers with the FDA’s review and approval. The compendia are "listings[] of drugs . . . which summarized[] evidence on the effectiveness of each drug . . . and provided information regarding clinical indications and proper dosing." The compendia are not overseen or published by any governmental body but instead by various institutions and traditional reference book publishing houses, in different formats, and updated at different intervals. The "evidence" summarized in the compendia need not (and, in many cases, does not) reflect the current or best clinical trials. Further, the generalizable knowledge summarized in the compendia is not available simply because of its persuasive value as scientific evidence. Rather, the evidence is limited to research deemed worth a manufacturer’s (or perhaps the government’s) significant financial investment in the research, and the resulting data is persuasive enough to pass muster with the multiple entities involved in compendia development. While the compendia may be the best compilations of empirical information currently available for purposes of making decisions about appropriate drug use, they are neither representative of how doctors, physician assistants, and nurse practitioners prescribe nor how patients respond outside of a controlled research setting. In adopting the compendia as the standard for “medically accepted indications,” Congress conflated science with medicine. In doing so, it disconnected outpatient prescription drug coverage from actual medical practice and individual patients (who, as discussed in more detail below in Part III, may or may not be represented in the clinical studies informing the FDA and compendia). As Robin Feldman observed, “Science begins with observations and theories that are rationally acceptable and well supported, which is something far less than certain and infallible. Ignoring these qualifications, law tries to translate science into social and legal conclusions without understanding the perils of that translation.” In the context of Medicare Part D and Medicaid outpatient prescription drug coverage, one such peril of that translation is a disconnection between medical practice and the so-called “medically accepted indications.” This disconnection, in turn, provides prescribers and pharmacists reason to question the legitimacy of coverage denials based solely upon lack of FDA or compendia recognition.

B. Transition from ICD-9-CM to ICD-10-CM: Diagnostic Coding in a State of Flux

In addition to the systemic disconnect between medical practice and “medically accepted indications,” U.S. health care providers are in the midst of a transition from one diagnostic coding system to another. Pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA)’s provisions on “Administrative Simplification,” the U.S. health care system requires providers to use the diagnostic coding system of International Classification of Disease (ICD). Clinical Modification (currently the ICD-9-CM, but the ICD-10-CM will go into effect on October 1, 2015) when submitting electronic claims for diseases, injuries, impairments, other health-related problems, their manifestations, and
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causes of injury, disease, impairment, or other health-related problems. The ICD was initially developed by the World Health Organization (WHO) as a means to classify causes of death. Relying heavily on the WHO’s work, the U.S. Centers for Disease Control and Prevention (CDC) National Center for Health Statistics developed a clinical modification of the classification to include morbidity (or non-fatal disease) purposes, the ICD-9-CM (soon to be the ICD-10-CM). The ICD-10-CM is made up of approximately 70,000 diagnosis codes comprised of three to seven alphanumeric characters, a significant expansion in detail and precision from the approximately 14,500 diagnosis codes comprising the ICD-9-CM. This expansion was meant to address the ICD-9-CM’s inability to accommodate new codes for diagnosis and procedures that have been added to the health care repertoire since its inception in 1979. The ICD-10-CM provides more information detailed on the Way: New Medical-Billing System (HIPAA) Administrative Simplification: Modifications to Medical Data Code Sets, 65 Fed. Reg. 50,913, 50,924-25 (Aug. 17, 2000) (codified at 45 C.F.R. §§ 160, 162). Administrative Simplification: Adoption of a Standard for a Unique Health Plan Identifier; Addition to the National Provider Identifier Requirements; and a Change to the Compliance Date for the International Classification of Diseases, 10th Edition (ICD-10-CM and ICD-10-PCS) Medical Data Code Sets, 77 Fed. Reg. 54,664 (Sept. 5, 2012). Drugs, by contrast, are coded pursuant to “the National Drug Codes maintained and distributed by the U.S. Department of Health and Human Services, in collaboration with drug manufacturers.” Health Insurance Reform: Standards for Electronic Transactions, 65 Fed. Reg. 59,313, 59,324-25 (Aug. 17, 2000) (codified at 45 C.F.R. §§ 160, 162).


HIPAA Administrative Simplification: Modifications to Medical Data Code Set Standards to Adopt ICD-10-CM and ICD-10-PCS, 74 Fed. Reg. 3328, 3330 (Jan. 16, 2009) (to be codified at 45 C.F.R. § 162). See also Anna Wilde Mathews, Walked into a Lamppost? Hurt While Crocheting? Help Is on the Way: New Medical-Billing System Provides Precision; Nine Codes for Maceau Muskog, WALL ST. J. (Sept. 11, 2011) http://online.wsj.com/article/SB10001424052748704050467560047246021108.html (“Today, hospitals and doctors use a system of about 18,000 codes to describe medical services in bills they send to insurers. Apparently, that doesn’t allow for quite enough nuance. A new federally mandated version will expand the number to around 140,000—adding codes that describe precisely what bone was broken, or which artery is receiving a stent. It will also have a code for recording that a patient’s injury occurred in a chicken coop. Indeed, health plans may never again wonder where a patient got hurt. There are codes for injuries in opera houses, art galleries, splash courts and nine locations in and around a mobile home, from the bathroom to the bedroom.”).


Some examples provided by the CDC include a combination code that includes both “a chronic condition [and] a current acute manifestation, as in ICD-9 code 500.81 Diabetes with hyperosmolarity, type I (juvenile type), not stated as uncontrolled . . . a combination code that . . . consists of two acute conditions found together, as in ICD-10 code B65.21 Senec sepsis with septic shock, or a combination code that consists of an acute condition and its external cause, as in I-18 code T58.91 Toxic effect of carbon monoxide from motor vehicle exhaust, accidental (unintentional).” Ctrs. for Disease Control and Prevention, supra note 52, at 3.

OEI Part D REMUNERATION REPORT, supra note 2, at 8-9.
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primary data point for determining appropriate coverage in the context of Medicare Part B reimbursement of prescription drugs.\textsuperscript{22} Extending use of ICD-10-CM to coverage determinations for Part D and Medicaid would be consistent with the existing Part B policy but hardly perfect in its ability to communicate accurately the complexity of individualized medical practice.

While a number of studies have found the transition from ICD-9 to ICD-10 to be fairly smooth in terms of maintaining data quality,\textsuperscript{24} these studies have been limited to inpatient hospital systems (in Australia and Canada) rather than reflective of outpatient coding practices in the United States. The new code *reflects* a significant break from ICD-9-CM,\textsuperscript{23} and the transition to ICD-10-CM will come with a learning curve for prescribers and pharmacists alike. Providers in smaller (primarily outpatient) practice settings have been slower to adapt to the pending transition from ICD-9-CM to ICD-10-CM.\textsuperscript{25} It remains to be seen whether the transition will go smoothly in the U.S., although a preliminary study suggests at least a third of initial ICD-10 coding in the U.S. will be inaccurate.\textsuperscript{26}

57. Sec. e.g., \textit{MEDICARE BENEFIT POLICY MANUAL}, supra note 19, at § 50.6 ("The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 provides coverage of intravenous immune globulin (IVIG) for the treatment of primary immune deficiency diseases (ICD-9 diagnosis codes 779.0, 779.05, 779.10, and 779.5) in the home." (emphasis added)).

58. See Tomi Henderson et al., \textit{Validity of Diagnosis and Procedure Coding in ICD-10 Administrative Data,} 44 MED. CARE 1593, 1593 (2006); Hude-Quan et al., \textit{Assessing Validity of ICD-9-CM and ICD-10 Administrative Data in Recording Clinical Conditions in a Unique Dually Coded Database,} 43 HEALTH SERV. RES. 1424, 1427 (2008).


As the critical data point used to determine whether a particular prescription is for a "medically accepted indication," any additional uncertainty created by the transition to ICD-10-CM will likely increase the perceived gap (if not the actual gap) between medical practice and "medically accepted indications," especially for prescribers and pharmacists working in smaller practices. Even so, the potential public health benefits of including the diagnosis codes on outpatient prescriptions described in Part III below outweigh the limitations of the coding or perceived gap, but only if strict enforcement of the coverage law is suspended until prescribers and pharmacists have gotten accustomed to and accepted the new coding system.

\textbf{C. Incentives for Prescribers and Pharmacists to Misrepresent Patient Diagnoses}

With the disconnect between "medical acceptance" and "scientific acceptance," as well as the uncertainty inherent in the transition from ICD-9-CM to ICD-10-CM, the use of diagnostic information for billing and reimbursement of outpatient prescription drugs (or denials thereof) may create incentives for prescribers and pharmacists to misrepresent patient diagnoses on prescriptions and claims for reimbursement.\textsuperscript{28}

The role of a third-party payor as the gatekeeper to treatment can put health care providers in an ethical dilemma where they are asked to choose between truth-telling (i.e., accurately describing the patient diagnosis and prescribed treatment when submitting bills for services and products) and effectively treating their patients when the effective treatment is not covered by the payer (i.e., when the treatment is truly medically accepted but still not found on the FDA-approved label or in the compendia).\textsuperscript{29} This dilemma exists especially for providers who treat patients living on limited and fixed incomes—the majority of the beneficiaries of Medicare and Medicaid—where out-of-pocket payment is not a viable option for patients.\textsuperscript{30} Strict enforcement of the Medicare Part D

62. Peter Jaret, \textit{Mining Electronic Records for Revealing Health Data,} N.Y. TIMES (Jan. 15, 2013), http://www.nytimes.com/2013/01/15/health/mining-electronic-records-for-revealing-health-data.html ("The information entered into a medical record may be wrong, and diagnostic codes are notoriously unreliable, according to Dr. Tattonetti, partly because they are also used for billing.").

63. Off-label use of drugs unsupported by strong clinical evidence is quite common in oncology and neurosurgery generally, as well as in treating the frail elderly, very young children, high-risk pregnant women, and patients with extremely rare diseases. Kesselheim, supra note 3, at 234-38.

64. Pursuant to the Affordable Care Act's revisions to the Medicaid program, Medicaid eligibility is contingent on an annual income of less than 133% of the federal poverty level—$15,281.70 for an individual or $31,321 for a family of four. See Medicaid Program: Eligibility Changes Under the Affordable Care Act of 2010, 77 Fed. Reg. 17,143, 17,145 (Mar. 23, 2012) (codified at 42 C.F.R. §§ 431, 435, 457); Annual Update of the HHS
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63. Off-label use of drugs unsupported by strong clinical evidence is quite common in oncology and neuropsychiatry generally, as well as in treating the frail elderly, very young children, high-risk pregnant women, and patients with extremely rare diseases. Kesselheim, supra note 3, at 234-38.

64. Pursuant to the Affordable Care Act’s revisions to the Medicaid program, Medicaid eligibility is contingent on an annual income of less than 133% of the federal poverty level — $15,281 for an individual or $31,321 for a family of four. See Medicaid Program: Eligibility Changes Under the Affordable Care Act of 2010, 77 Fed. Reg. 17,143, 17,145 (Mar. 25, 2012) (codified at 42 C.F.R. §§ 431, 435, 457); Annual Update of the HHS
statute (and many states' Medicaid statutes) would significantly limit outpatient prescription drug coverage for the many medically accepted uses with little scientific evidence to support them. As a result, many patients would no longer be able to access their prescribed medications; that is, unless their prescribers or pharmacists decided that the patients' best interests were served by using inaccurate, but otherwise covered, diagnoses on prescriptions and claims. There are a number of characteristics of a strict enforcement policy that would make diagnostic miscoding more justifiable for prescribers and pharmacists concerned about patients' inability to access the most effective treatment.

First, the most likely immediate outcome of miscoding (as seen from the prescriber or pharmacist's perspective) would be better, or at least sustained, patient health — a favorable outcome. Decisions resulting in favorable outcomes are more likely to be judged as good than those with poor outcomes (such as a decline in patient health due to lack of treatment).64 Second, the people most likely to be harmed by accurately reporting diagnoses under a strictly enforced Medicare Part D coverage law (again, from the prescriber and pharmacist's perspective) will be the patients denied treatment — identifiable victims. Identifiable victims are more likely to create an empathic response on the part of prescribers and patients denied treatment — identifiable victims. Identifiable victims are more likely to create an empathic response on the part of prescribers and pharmacists than the "statistical victims" of miscoding — the taxpayers or beneficiaries of other governmental programs denied funding due to rising health care costs.65 Third, coverage denials, especially where a

65. When evaluating decisions, a "bad outcome" (the visible result of a decision) as a result of a particular decision, such as a decline in health, is often attributed to "bad decision making." See Jonathan Baron & John C. Hershey, Outcome Bias in Decision Evaluation, 54 J. PERSONALITY and SOC. PSYCHOL. 569, 569-70 (1988). Similarly, to the extent that good outcomes are perceived as the result of good decision making and a good health outcome is understood to be dependent on a particular treatment, a decision to ensure access to the treatment will likely be considered "good." Id. at 569. See also Francesca Gino et al., Namelessly Harmless Blamelessness: When Seemingly Inoffensive Characteristics Influence Judgment of Unethical Behavior, 111 ORIG. BEHAV. & HUM. DECISION PROCESSES 63, 96 (2010) (noting people tend to judge behavior as more unethical when the behavior leads to a negative rather than positive outcome).

66. The most important factor in the disparate treatment between identifiable and statistical victims appears to be the perception that a high proportion of the identifiable victims can be saved," compared to the uncertainty of "saving" the unknown number of adversely affected taxpayers or beneficiaries of other government programs denied funding. Karen E. Jenni & George Lowenstein, Explaining the "Identifiable Victims" Effect, 14 J. RISK & UNCERTAINTY 235, 254 (1997). See also Gino et al., supra note 65, at 96 (noting that people tend to judge behavior as more unethical when
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tailor diagnoses for payment purposes rather than treatment purposes or at least make justification of miscoding easier for individual prescribers or pharmacists. Systemic miscoding would, in turn, significantly undermine the public safety benefits potentially gained through the more thorough pharmacist review of outpatient prescriptions for medication errors and increased drug safety surveillance efforts described in Part III.

III. HOW INCREMENTAL IMPLEMENTATION OF THE LAW WOULD SUPPORT BOTH PATIENT SAFETY AND BETTER MANAGEMENT OF FEDERAL HEALTH CARE FUNDS

Instead of relying, as suggested by CMS Administrator Donald Berwick, primarily on price authorization strategies for drugs that are at high risk for prescription without a medically accepted indication (or the nearly impossible retrospective review), I propose that CMS require submission of ICD-10-CM codes for reimbursement of outpatient prescription drug claims, but limit the current use of those codes for pharmacist prescription review, not coverage denials. In doing so, CMS would encourage more thorough, real-time pharmacist review of prescriptions for patient safety purposes as well as truthful reporting of diagnostic and prescribing habits for future pharmacosurveillance and comparative effectiveness research.71

A. Role of Diagnosis in Pharmacists’ Standard of Care

With the increasingly commercial nature of drug store chains and grocery store pharmacy counters in the second half of the twentieth century, pharmacists are often misunderstood to be glorified sales clerks who merely count pills, but that understanding is simply not accurate.72

70. ORG PART D REIMBURSEMENT REPORT, supra note 2, at 9.

71. By reframing the goal of accurate diagnostic coding from a mere billing necessity to a critical step in preventing medication errors (a negative outcome that can be avoided), this subtle change may significantly influence truthful prescribing and pharmacist report behavior. Francesca Gino & Joshua D. Margolis, Bridging Ethics Into Focus: How Regulatory Focus and Risk Preferences Influence (Un)ethical Behavior, 115 ORIG. BEHAV. & HUM. DECISION PROCESSES 145, 154 (2013).

72. Anonymous v. CVS Corp., 728 N.Y.S.2d 333, 337 (N.Y. Sup. Ct. 2001) ("Unlike in a traditional commercial transaction, pharmacists are required to collect otherwise confidential medical information, and are obliged to review that information before each prescription is dispensed.") (citations omitted)). Horner v. Spadolino, 1 S.W.3d 519, 524 (Mo. Ct. App. 1999) ("We agree that a physician typically is in a superior position to judge the propriety of a particular patient’s drug regimen, but this should not relieve the pharmacist to the role of being merely an order filler."); Jones v. Irvin, 602 F. Supp. 399, 400 (S.D. Ill. 1985) (citations omitted) (noting "a pharmacist is not strictly liable under a products liability theory since he is not a retailer").

Historically, the practice of pharmacy was limited to the making (through a practice called compounding) and dispensing of drugs with prescribers solely responsible for advising patients on their appropriate use.73 More recently, pharmacists have become, and continue to be, recognized as highly educated, licensed professionals entrusted with evaluating confidential patient information in order to dispense medications with both great treatment potential and great (even fatal) risk if misused.74

The practice of pharmacy, like the practices of medicine, nursing, and law, is primarily governed by state law and includes not only dispensing drugs and custom compounding medications for patients contraindicated for commercially prepared products, but also consulting (with both patients and prescribers) about the contents, therapeutic values, interactions, and uses of any prescription drug; the review and monitoring of a patient’s drug therapy regimen; assisting the patient in managing his or her drug therapy; and communicating with the patient’s prescribing health care provider in the event that the pharmacist or patient has a question about a treatment regimen.75 Indeed, the increase in


74. Happel v. Wal-Mart Stores, Inc., 706 N.E.2d 1118, 1123 (Ill. 2000) (quoting Kirby v. Gen. Paving Co., 229 N.E.2d 777, 779 (Ill. App. Ct. 1967)) ["A duty to warn exists where there is unequal knowledge, actual or constructive [of a dangerous condition], and the defendant[,] possessed of such knowledge, knows or should know that harm might or could occur if no warning is given."] (citing Houck, 188 N.E. 274 (N.Y. 1933)) ("While the role of a pharmacist may not equal that of a physician treating a patient, surely access and the right to collect private medical information on one’s customers does not make a pharmacist merely ‘the dispenser of a commercial product.’"); Morgan v. Wal-Mart Stores, Inc., 30 S.W.3d 455, 469 (Tex. Ct. App. 2000) ["The pharmacist’s role has changed in the last few decades from a mere dispenser of medication to a trusted professional who plays a vital role in patient treatment."] (citing Morgan Pharmacy, 308 A.2d 1247, 1251 (Pa. Super. Ct. 1980) (rejecting the argument that a pharmacy is strictly a warehouse of drugs and that a pharmacist should unquestionably obey the written orders of physicians).

75. The following state statutes define "practice of pharmacy," "practice of the profession of pharmacy," and/or the scope of the practice of pharmacy.

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ing reliance on prescription drugs, and increasing number of prescription drugs available for use has led many pharmacists to play a greater role in coordinating drug therapy for patients than ever before. In addition to the state laws regulating the practice of pharmacy, Federal law has relied heavily on pharmacists' professional standards in structuring the federal health care delivery system (specifically in the laws governing both Medicaid and Medicare) and regulation of drugs (in the context of the federal Food, Drug and Cosmetic Act (FDCA)).


76. The entire prescription drug regulatory system dating back to the Food, Drug and Cosmetic Act of 1938 depends squarely on pharmacists and pharmacists' professional standards. As explained below, adding diagnosis codes to prescriptions would not affect the existing boundaries between the practices of medicine, nursing, and pharmacy, but would likely increase the level of care expected of pharmacists.

1. The Duty to Warn Patients about Risks Generally Associated with Prescription Drugs Would Remain with Prescribers, Not Pharmacists

State courts have traditionally, and quite consistently, held that a pharmacist has no general duty to warn a customer of the risk of harm that might be encountered from drugs which are accurately dispensed upon a valid and legal prescription, unless (1) the prescription itself


79. As part of the Controlled Substances Act, "a pharmacist may not fill a written order from a practitioner, appearing on its face to be a prescription [for a controlled substance], if he knows the practitioner issued it in excess of the usual course of medical treatment." United States v. Hayes, 555 F.2d 258, 260 (5th Cir. 1977) (construing 21 C.F.R. § 1306.04(a)). See also 21 U.S.C. § 832(c)(2) (2012) (noting a "valid prescription" is "a prescription that is issued for a legitimate medical purpose in the usual course of professional practice ....")

78. For example, it was a piece of federal legislation (OBRA-90)'s artificing conditions for state receipt of Medicaid funds that prompted widespread adoption of prospective drug utilization review software by pharmacists nationwide. See Thomas R. Fields et al., Current Status of Prospective Drug Utilization Review, 10 J. OF MANAGED CARE PHARMACY 433 (2004); see also United States v. Joe Gab Kim, 449 F.3d 933, 937 (9th Cir. 2006) (sentencing a pharmacist to five months incarceration, three years supervised release, and a $15,000 fine for selling pseudoephedrine in violation of federal Controlled Substances Act and state law); United States v. Mifflin, 430 F.3d 1357, 1364 (11th Cir. 2005) (sentencing defendant to ten months' imprisonment and a $10,000 fine for dispensing drugs without a valid prescription in violation of FDCA).

80. For instance, pharmacy is named in the felony statute for dispensing prescription drugs to a minor, 231 U.S.C. § 794. Formerly, 231 U.S.C. § 794 (requiring a pharmacist to keep a true record of drugs dispensed to a minor).
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Despite the myriad state and federal laws governing the pharmacist–patient relationship, pharmacists have never had a general duty to warn patients about the risks associated with prescription drugs; this duty to warn has traditionally fallen instead into the realm of medicine (and more recently nursing) than pharmacy. Like all professionals, though, pharmacists are responsible for exercising due care in the course of their practice. As explained below, adding diagnosis codes to prescriptions would not affect the existing boundaries between the practices of medicine, nursing, and pharmacy, but would likely increase the level of care expected of pharmacists.

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and Controlled Substances Act). To the extent that state laws governing the practice of pharmacy are not as rigorous as the federal expectations, the federal statutes have created both regulatory and statutory consequences for pharmacists who fall short of the federal standards.


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81. See Downing v. Hyland Pharmacy, 194 P.3d 944, 946 (Utah 2008) (quoting Schaefer v. Stewart’s Plaza Pharmacy, 79 P.3d 922, 929 (Utah 2003)) (“So long as a pharmacist’s ability to distribute prescription drugs is limited by the highly restricted, FDA-regulated drug distribution system in this country, and a pharmacist cannot supply a patient with prescription
contains "patent, clear, or obvious errors" or (2) the pharmacist has knowledge of patient-specific information that would indicate that a particular patient has a higher risk profile for a particular drug. 83 Pharmacists and pharmacies have been exempted from a duty to warn due to the learned intermediary doctrine. 83 As articulated by courts, the

Pharmacies and pharmacists have been exempted from a duty to warn due to the learned intermediary doctrine in the context of prescription drug manufacturers. 84 Attributed by courts, the intermediary doctrine prevents pharmacists from interfering with the doctor-patient relationship because it "prevents pharmacists from constantly second-guessing a prescribing doctor's judgment simply in order to avoid his or her own liability to the customer." 85

Even where courts have decided that the learned intermediary doctrine protects pharmacists from a duty to warn, the decisions have been qualified because the foreseeability of injury to an individual consumer "varies greatly depending on the medical history and condition of the individual - facts which we cannot reasonably expect the pharmacist to know." 86 But when in fact a pharmacist is aware of a patient's individual allergies or diagnoses, the learned intermediary doctrine does not foreclose a pharmacist's potential for liability because the pharmacist has knowledge of a customer-specific risk. 87 At a minimum, pharmacists have a duty to warn physicians and patients when a prescription drug is contraindicated for a specific patient or when a patient is concurrently taking two drugs which are known to cause serious adverse effects in some patients when taken together, but there remains a disagreement

Happel v. Wal-Mart Stores, Inc., 764 N.E.2d 1118, 1129 (Ill. 2002) ("For the reasons set forth above, we hold that a narrow duty to warn exists where, as in the instant case, a pharmacy has patient-specific information about drug allergies, and knows that the drug being prescribed is contraindicated for the individual patient. In such instances, a pharmacy has a duty to warn either the prescribing physician or the patient of the potential danger."); Lasley v. Shackle's Country Club Pharmacy, Inc., 880 P.2d 1129, 1132-34 (Ariz. Ct. App. 1994) (imposing a duty for failing to warn the customer when filling two prescriptions that adversely interacted with one another); Klasch v. Walgreens Co., 264 P.3d 1155, 1159 (Nev. 2011) ("What a pharmacy sometimes knows, however, without investigation, and the manufacturer will not know and even a treating physician may not know, is susceptibility of particular customers of the pharmacy to the side effects of a drug that it sells them - susceptibility because of other drugs that the pharmacy knows the customer is taking, or a pre-existing physical or mental condition (again known to it) that makes the drug contraindicated for the customer - and then it must warn either the customer or his physician. But not otherwise."").

Keff v. Lorentz, 2012 WL 3235938, at ¶ 17 (D.C. Super. Ct. 2012) (noting pharmacists likely had a duty to warn because patient was "at risk of a specific, defined, and foreseeable harm of which the pharmacist knew or should have known," specifically the concurrent use of two drugs known to cause serious adverse events when taken together).
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85. Lasley, 558 N.E.2d at 762 (citing Eldridge, 485 N.E.2d 551).

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87. Keffe v. Lorentz, 2012 WL 3235398, at *17 (D.C. Super. Ct. 2012) (noting pharmacists likely had a duty to warn because patient was “at risk of a specific, defined, and foreseeable harm of which the pharmacists knew or should have known,” specifically the concurrent use of two drugs known to cause serious adverse events when taken together).
between jurisdictions whether pharmacists have a duty to warn physicians or patients when a dose is in excess of the manufacturer's recommendation (and FDA approval) has been prescribed. While contraindications are seen as straightforward warnings that do not require a pharmacist to make an independent medical judgment, dosage decisions appear to cross the line from the practice of pharmacy into the practice of medicine. 88

88. See Horner v. Spaltito, 1 S.W.3d 519, 523 (Mo. Ct. App. 1999) (finding that the pharmacist is “in the best position” to contact the patient’s physician to discuss any potential problems with the patient’s prescription); Riff v. Morgan Pharmacy, 508 A.2d 1347, 1350 (Pa. Super. Ct. 1986) (“Pharmacists and a pharmacist testified that a pharmacist who receives a prescription which has inadequate instructions as to maximum dosage has a duty to either ascertain if the patient is aware of the limitation concerning the use of the medication or to contact the prescribing physician to call the inadequacy of the prescription to the doctor’s attention. Experts testified further that under the facts of this case a reasonably prudent pharmacist would have taken steps to correct the error of the prescribing physician.”). See also McKee v. Am. Home Prod. Corp., 782 F.2d 1043, 1053 (Wash. 1989) (“We agree pharmacists should have a duty to be alert for patent errors in a prescription, for example obvious initial dosages, inadequacies in the instructions, known contraindications, or incompatible prescriptions, and to take corrective measures.”). But see Fakhouri, 618 N.E.2d at 519 (denying request to impose upon pharmacists a duty to contact the prescribing physician to advise of such a dosage error when the pharmacist is not aware of such a dosage error). See also Eldridge v. Eli Lilly & Co., 485 N.E.3d 551, 553 (Ill. App. Ct. 1985) (“A prescription which is excessive for one patient may be entirely reasonable for the treatment of another. To fulfill the duty which the plaintiff urges us to impose would require the pharmacist to learn the customer’s condition and monitor his drug use. To accomplish this, the pharmacist would have to interject himself into the doctor-patient relationship and practice medicine without a license.”). See also Brumaghim v. Eckel, 94 A.3d 1391, 1393 (N.Y. Sup. Ct. 2012) (“Imposing a duty upon a pharmacist to contact the prescribing physician whenever there has been a change in dosage— without a medically acceptable range— of a particular patient’s medication would, in essence, require the pharmacist to question the physician’s judgment regarding the appropriateness of each customer’s prescription. Sound policies exist for not imposing such a duty.”); McKee, 782 F.2d at 1051 (“Neither manufacturer nor pharmacist has the medical education or knowledge of the medical history of the patient which would justify a judicial imposition of a duty to intrude into the physician-patient relationship.”). But see Riff, 508 A.2d at 1353 (“Expert testimony established that the ‘responsible pharmacist’ has an affirmative duty to read the prescription and to be aware of patent inadequacies in the instructions as to maximum safe dosage of known toxic drugs and medicines.”).
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88. See Horner v. Spaltito, 1 S.W.3d 519, 523 (Mo. Ct. App. 1999) (finding that the pharmacist is “in the best position” to contact the patient’s physician to discuss any potential problems with the patient’s prescription); Riff v. Morgan Pharmacy, 508 A.2d 1347, 1350 (Pa. Super. Ct. 1986) (“Pharmacists and a pharmacist testified that a pharmacist who receives a prescription which has inadequate instructions as to maximum dosage has a duty to either ascertain if the patient is aware of the limitation concerning the use of the medication or to contact the prescribing physician to call the inadequacy of the prescription to the doctor’s attention. Experts testified further that under the facts of this case a reasonably prudent pharmacist would have taken steps to correct the error of the prescribing physician.”). See also McKee v. Am. Home Prod., Corp., 783 F.2d 1045, 1053 (Wash. 1986) (“We agree pharmacists should have a duty to be alert for patent errors in a prescription, for example obvious initial dosages, inadequacies in the instructions, known contraindications, or incompatible prescriptions, and to take corrective measures.”). But see Fakhouri, 618 N.E.2d at 519 (denying request to impose upon pharmacists a duty to warn their customers of prescribed dosages of medication in excess of the manufacturer’s recommended limits).

89. A contraindication is a serious limitation on a drug’s use, necessarily implying grave consequences if it is ignored. As one court has noted, a contraindication refers to “a circumstance under which the drug must never be given.” Happel, 766 N.E.2d at 1128 (quoting Hand v. Krakowski, 453 N.Y.S.2d 121, 123 (N.Y. App. Div. 1983)) (“It requires no medical judgment simply to notify a physician of a patient of such a contraindication.”) Happel, 766 N.E.2d at 1128.

90. See Eldridge v. Eli Lilly & Co., 485 N.E.2d 551, 553 (III. App. Ct. 1985) (“A prescription which is excessive for one patient may be entirely reasonable for the treatment of another. To fulfill the duty which the plaintiff urges us to impose would require the pharmacist to learn the customer’s condition and monitor his drug usage. To accomplish this, the pharmacist would have to interject himself into the doctor-patient relationship and practice medicine without a license.”). See also Brumaghim v. Echel, 94 A.D.3d 1391, 1393 (N.Y. Sup. Ct. 2012) (“Imposing a duty upon a pharmacist to contact the prescribing physician whenever there has been a change in dosage – without the Supreme Court’s approval – would, in essence, require the pharmacist to second-guess the physician’s judgment regarding the propriateness of each customer’s prescription. Sound policy reasons exist for not imposing such a duty.”); McKee, 782 F.2d at 1051 (“Neither manufacturer nor pharmacist has the medical education or knowledge of the medical history of the patient which would justify a judicial imposition of a duty to intrude into the physician-patient relationship.”). But see Riff, 508 A.2d at 1253 (“Expert testimony established that the ‘reasonable pharmacist’ has an affirmative duty to read the prescription and to be aware of patent inadequacies in the instructions as to maximum safe dosage of known toxic drugs and medicines.”).

91. Eldridge, 485 N.E.2d at 553 (“A pharmacist owes a duty of ordinary care in practicing his profession, but such care requires the highest degree of prudence, thoughtfulness and diligence, and it is proportioned to the danger involved.” (emphasis added)). See generally Marchitelli, supra note 82, at § 2[2].

92. Despite the increased adoption of electronic prescribing as part of their role in “interpreting” and “evaluating” prescriptions pharmacists still encounter sloppy writing and inappropriate directions, which can lead to adverse drug events. Randall Stron, Chicken Scratches v. Electronic Prescriptions, N.Y. TIMES (Apr. 28, 2012), http://www.nytimes.com/2012/04/28/business/e-prescriptions-reduce-errors-but-their-adoption-is-slow.html?_r=0. Additionally, prescription errors are a known reality in our health care system. See Riff, 508 A.2d at 1253 (“Fallibility is a condition of the human existence. Doctors, like other mortals, will from time to time err through ignorance or inattention. An error in the practice of medicine can be fatal; and so it is reasonable that the medical community including physicians, pharmacists, anesthesiologists, nurses and support staff have established professional standards which require vigilance not only with respect to primary functions, but also regarding the acts and omissions of the other professionals and support personnel in the health care team. Each has an affirmative duty to be, to a limited extent, his brother’s keeper.”).

93. 42 U.S.C. § 1395d-8(g)(2)(A)(i) (2012). Physicians may not be aware of all contraindications associated with the drugs they prescribe. See, e.g., Happel, 766 N.E.2d at 1121 (Ill. 2002) (noting the physician did not know that Toradol was contraindicated for patients with allergies to aspirin). But, at present, pharmacists may similarly be unaware of all of a patient’s conditions. See Fuld, et al., supra note 80 (recognizing that drug-disease contraindications may only be identified “when disease information is available or using surrogate indicators”).
use diagnostic information (at this point provided entirely by patients, unless they are taking one of the few outpatient drugs reimbursed by Medicare Part B) to warn them about contraindications for specific patients. Even so, at least one long-term (twenty-month) study has found that nearly 50 percent of drug problem interventions by pharmacists were problems that required the pharmacist's independent professional judgment as opposed to problems flagged by drug utilization review software. Once the validity and appropriateness of the prescription are established, the pharmacist is then expected to (3) dispense the correct medication in the dosage and quantity prescribed, (4) offer each patient or designated caregiver counseling on safe and appropriate use of the medication as prescribed (an offer which may be refused by the patient or caregiver), and (5) maintain records with patient information to facilitate future counseling. While these standards are technically a matter of state law, the state laws governing them have been heavily influenced by the federal Medicaid funds conditioned on states' adoption of the standards pursuant to the Omnibus Budget Reconciliation Act of 1990 (OBRA-90). Inclusion of diagnosis information as part of the Medicare and Medicaid programs would better inform four of these five practices (i.e., all but the correct dispensation of the product) and, as a result, likely heighten the standard of care pursuant to each of these practices. As observed by one court, the burden of warning a single physician or patient may be small, but in the aggregate (especially with the increasing number of insured patients due to the Supreme Court's decision upholding the Affordable Care Act) the increased resources necessary to satisfy the augmented duty to warn created by the addition of diagnostic information to all outpatient prescriptions may be significant. The burden on pharmacists may be heightened, too, where patient care for comorbid conditions remains fragmented among specialists and no one prescriber is aware of all of a patient's diagnoses or medications. To the extent, though, that the practice of pharmacy "should increase the overall quality of health care," inclusion of

94. See, e.g., Keffer v. Lorenz, 2012 WL 2235388, at *2 (D.C. Super. Ct. 2012) ("CVS's pharmacy personnel used a computerized prescription system (the CVS system) that informed them of Mr. Keffer's prescription history, that he had been prescribed both Cymbalta and Vyvanse, and that he was filling both medications simultaneously. In addition, the CVS system notified CVS's personnel that they should not fill the two prescriptions without first contacting Mr. Keffer's physicians to confirm that they wanted him to take both medications at the same time."); Happey, 766 N.E.2d at 1121 (noting a "drug interaction" warning would have flashed across the [pharmacist's] screen, halting the prescription process for customers" for whom the drug was contraindicated until the pharmacist had consulted with the patient's physician); Morgan, 30 S.W.3d at 469 (encouraging the use of computer systems to assist pharmacists in "preventing the sale of potentially fatal drugs"); Knoche, 264 F.3d at 1157 (Walgreens maintains a 'patient profile' for each of its customers, which its pharmacists use to identify any potential allergic reactions, harmful interactions with other medications, or adverse side effects that a customer may have to a particular medication.").

95. Publix et al., supra note 80, at 437 (“Approximately one half of the documented medication problems would not have been detected by computer-generated alerts available at that time. This suggests that [because Drug Utilization Review] systems can assist pharmacists but cannot identify all of the problems that must be addressed to ensure appropriate drug use.").


99. Happey, 766 N.E.2d at 1124 ("The burden on defendant of imposing this duty [to warn] is minimal. All that is required is that the pharmacist telephone the physician and inform him or her of the contraindication. Alternatively, the pharmacist could provide the same information to the patient. Since this burden of warning about a contraindication is extremely small, this factor also favors the imposition of a duty here.").


101. See Lesley v. West, 518 N.E.2d 756, 763 (Ill. App. Ct. 1988) (explaining that the burden of conveying the warnings pharmacies receive from drug manufacturers to its customers would be very burdensome because it may well mean that pharmacists must bear the additional costs of reproducing the material they receive); McKee v. Am. Home Prod. Corp., 782 F.2d 1045, 1053 (Wash. 1986) (noting that requiring pharmacists to warn patients of risks of off-label use "would result in the pharmacist second guessing numerous prescriptions to avoid liability. This would not only place an undue burden on pharmacists, but would likely create antagonistic relations between pharmacists and physicians.").


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100. The Robert Wood Johnson Foundation estimates that the health care system will have thirty million newly insured patients once the Patient Protection and Affordable Care Act is fully implemented. See CATHERINE DOWER & EDWARD O'NEIL, ROBERT WOOD JOHNSON FOUND., PRIMARY CARE WORKFORCE IN THE UNITED STATES REPORT 2 (2011), available at http://www.rwjf.org/content/dam/iam/farm/reports/issue_briefs/2011/rwjf70613.pdf.

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diagnostic information on prescriptions seems a logical next step, especially with the added potential that the claims database would provide for even greater drug safety surveillance and comparative effectiveness research.

B. Potential Role of Outpatient Prescription Drug Database in Informing FDA Drug Safety Surveillance

Use of patient-specific information gathered in the context of health care treatment relationships for purposes other than patient treatment is always accompanied by privacy concerns – prescription drug information is no exception. To the extent that individual patient privacy concerns have been weighed against the informational needs of a functional federal health care system (including a drug safety surveillance system), the balance is found in the HIPAA Privacy Rule and the Food and Drug Administration Amendments Act of 2007 (FDAAA). Reflecting the significant public health interest in drug safety surveillance, the HIPAA and FDAAA standards expressly allow pharmacists and pharmacies to disclose otherwise-protected health information to the FDA to report adverse events or engage in post-marketing surveillance without patient consent.

104. Marc A. Rodwin, Rorting Out Institutional Corruption to Manage Inappropriate Off-Label Drug Use, 41 J. L. Med. & Ethics 654, 659 (2013) ("Data from tracked off-label prescriptions would help to set priorities for about drug therapy to physicians, and – where appropriate – warn the public. Physicians should be required to indicate on each prescription the purpose for which the drug is prescribed.").

105. For an excellent summary of these concerns, as well as the state and federal privacy law that governs protection of prescription health information, see generally Christopher R. Smith, Protecting Patient Privacy in Prescription Health Information, 36 Vt. L. Rev. 931 (2012). In addition to the privacy concerns, there are also cost and quality of care concerns that may accompany data breaches that compromise Medicare and Medicaid beneficiary numbers. Julie K. Taitman et al., Protecting Patient Privacy and Data Security, 368 New Eng. J. Med. 977, 977 (2013).


108. Barbara J. Evans, Seven Pillars of a New Evidentiary Paradigm: The Food, Drug, and Cosmetic Act Enters the Genomic Era, 85 Notre Dame L. Rev. 419, 452 (2010) ("In effect, Congress determined that the public is not outweighed by individuals’ interest in keeping their data out of it.").

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C. Potential Role of Outpatient Prescription Drug Database for Comparative Effectiveness Research and Coverage Decisions

Prescribers are able to recommend any FDA-approved drug for any use they deem in their patients' best interests. Often these recommendations differ from the intended use(s) studied in the clinical trials and, in many specialties and diseases, become the standard of care. Likewise, previously accepted treatments are occasionally called into question by new research or evolving scientific thought, and CMS has tried to respond effectively to emerging evidence. Instead of denying coverage outright for these newer or newly questioned technologies, CMS has occasionally used a "Coverage with Evidence Development" (CED) program to "provide Medicare coverage while further evidence is developed." CMS generally relies on clinical evidence to determine whether particular items or services should be considered "reasonable and necessary" for purposes of Medicare Part B coverage. For prescription drugs covered under Part B, CMS looks to evidence beyond that considered for "medically accepted indications," including medical literature and other indices of accepted standards of care. Even with the expanded universe of evidence available for Part B coverage, information may still be significantly limited for both very new and older products, making well-informed coverage determinations impossible. In particular, clinical evidence for new technologies subject to the FDA pre-market approval process (all new prescription drugs) may be limited to a single intended use, and clinical evidence may not provide much information on a product's "real world benefit in typical patient care settings." Additionally, recent studies on the informational bias in peer-reviewed literature call into question the current body of evidence supporting many, if not most, of the products on the market.

Within the Department of Health and Human Services, the Agency for Healthcare Research and Quality (AHRQ) is charged with "conducting and supporting research with respect to the outcomes, effectiveness, and appropriateness of health care services and procedures in order to identify the manner in which diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically" consistent with the needs and priorities of the Medicare program. Indeed, "[AHRQ] believes that the principal function of CED is to generate new evidence on the benefit or harm of an item or service among the Medicare beneficiary population based on rigorous scientific inquiry." The Medicare patient population, which includes the elderly, chronically disabled, and patients with end stage renal disease who are treated with dialysis, is often excluded from clinical trials conducted to evaluate products for FDA pre-market approval.

Similarly, many of the patients historically covered by Medicaid—children, pregnant women, people with disabilities, and the elderly—are also often excluded from clinical trials for both ethical and practical reasons. Inclusion of diagnosis codes in the Medicare and Medicaid claims databases would significantly increase the amount of prescription drug use data available for drug safety surveillance in these otherwise underrepresented patient populations, many of whom are more physically, socially, and economically vulnerable than those studied in clinical trials.

In an attempt to address the underrepresentation of these patient populations in clinical trials, Medicare Parts A and B claims databases...
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117. See Kesselheim, supra note 3, at 238 ("Scientifically unsupported offlabel use may also be reasonable and appropriate in circumstances where collection of rigorous evidence is impossible.").

118. See Draft Guidance, supra note 116.

119. CMS originally grounded its authority for this policy in Sections 1862(a)(1)(A) and 1862(a)(1)(E) of the Social Security Act (42 U.S.C. § 1395y(a)(1)), but more recently decided that the policy was not consistent with Section 1862(a)(1)(A). Id.


121. MEDICARE BENEFIT POLICY MANUAL, supra note 10, at § 40.4.2 ("FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare [Part B] if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice." (emphasis added)).


123. Id.

124. See, e.g., Andrew P. Prayle et al., Compliance with Mandatory Reporting of Clinical Trial Results on Clinical Trials.gov: Cross-Sectional Study, 344 BMJ 7373 (2012); Sylvain Mathieu et al., Comparison of Registered & Published Primary Outcomes in Randomized Controlled Trials, 302 JAMA 977 (2009).

125. 42 U.S.C. § 1320a-12 (2012). Medicare coverage determinations may then be made pursuant to the research conducted by the Agency. See § 1395y(a)(1)(E) (cross-referencing the research conducted pursuant to 42 U.S.C. § 1320a-12).


127. Id.
are already available and have been used for research purposes, 126 and private insurers are working to create a claims database covering a broader cross-section of the population. 127 Increased use of electronic medical records, especially those that meet the meaningful use standards issued under HITECH, 128 may provide robust databases for some research, 129 but they are inherently provider-based datasets that may not

126. The Dartmouth Atlas Project has used Medicare claims data to provide comprehensive information and analysis about the national, regional, and local markets, as well as individual hospitals and their affiliated physicians. FAQ, DARTMOUTH ATLAS OF HEALTH CARE, http://www.dartmouthatlas.org/tools/faq/ (last visited Apr. 19, 2014) ("The Centers for Medicare and Medicaid Services (CMS), the federal agency that collects data for every person and provider using Medicare health insurance, makes available a uniform national claims database for research purposes."). See also John Carnavos, Access to Wides on Medicare Data, WALL ST. J., Dec. 8, 2011, at A1 ("In an abrupt policy change, the Department of Health and Human Services will make its huge Medicare claims database more broadly available to the public, to help consumers and employers make better-informed decisions about medical care. In particular, the federal agency will relax its restrictions on the release of information about individual doctors who participate in Medicare, the $24 trillion federal program for the elderly and disabled, reversing a three-decade policy that doing so would violate physicians’ privacy rights.").

127. See Anna Wilde Mathews, Health Insurers Will Give Claims Data to Institute, WALL ST. J. (Sept. 19, 2011), available at http://www.cnbc.com/trade/2011/09/19/health-insurers-will-give-claims-data-to-institute.html ("Researchers have sometimes struggled to perform such studies on the commercially insured population. They often turn to Medicare data, which reflect a mostly elderly population, as the federal government’s unique payment model. The Health Care Cost Institute will start with claims from UnitedHealth Group Inc., Aetna Inc., Humana Inc. and the nonprofit Kaiser Permanente, and the carriers are also providing initial funding to set it up.").

128. David C. Glassen & David W. Bates, Finding the Meaning in Meaningful Use, 369 NEW ENG. J. MED. 855, 860 (2013) ("The meaningful-use criteria require the collection of specific quality measures: in particular, 15 patient and 6 outpatient quality measures that will have to be collected and reported to meet these criteria. The stage 2 criteria for quality measures will raise the bar further, although they are still in a draft stage. Broadly, the hope is that stage 2 will encourage providers to begin improving process, whereas stage 3 will result in improved outcomes.").

129. See also Peter Sleis, Mining Electronic Records for Revealing Health Data, N.Y. TIMES, Jan. 14, 2013, http://www.nytimes.com/2013/01/15/health/mining-electronic-records-for-revealing-health-data.html ("The monitoring and analysis of electronic medical records, some scientists say, have the potential to make every patient a participant in a vast, ongoing clinical trial, pinpointing treatments and side effects that would be hard to discern from anecdotal case reports or expensive clinical trials.").

132. Steven H. Feldman, Compartmental: How the Brightest, Best-Trained, and Most Caring People Can Make Judgments That Are Completely and Utterly Wrong 18 (2000) ("Dermatologists prescribe patients medications but don’t get to see what patients do with the medicines . . . . It turns out many patients don’t use their topical medications as directed, and over the long run, their use of medication steadily drops. But dermatologists didn’t know this.").

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134. See David Brudno et al., Implications of Real-World Adherence on Cost-Effectiveness Analysis in Multiple Sclerosis, 16 J. MED. ECON. 547, 547 (2013) ("[E]conomic analyses of [multiple sclerosis] therapies should incorporate real-world adherence rates where available, rather than relying exclusively on trial-based efficacy estimates when considering the economic value of treatment alternatives, and that highly efficacious therapies with low adherence may yield real-world efficacy that is substantially lower than that observed in closely monitored clinical trials."). Ruby Grymonpre et al., Validity of a Prescription Claims Database to Estimate Medication Adherence in Older Persons, 44 MED. CARE 471, 476 (2006) (finding strong correlation between prescription drug claim database information and actual patient adherence for discrete prescriptions to be taken regularly).

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135. See, e.g., Theodore Fincs, Limitations of Randomized Clinical Trials to Recognize Possible Advantages of Combination Therapies in Rheumatic Diseases, 23 SEMINARS IN ARTHRITIS & RHEUMATISM 2, 3 (1993).
to evaluate the comparative effectiveness of drugs within a treatment class.\textsuperscript{139}

Comparative effectiveness research (CER) is "research that compares the clinical outcomes, effectiveness and appropriateness of items, services, and procedures that are used to prevent, diagnose, or treat diseases, disorders, and other health conditions."\textsuperscript{136} Unlike most clinical trials, which are conducted to determine the safety and efficacy of a single drug, CER can provide information on the relative risks and benefits of multiple treatment options. There remains much debate on whether CER should be considering the costs of treatment options or used for drug coverage determinations in the United States.\textsuperscript{138} but there is widespread acceptance that the U.S. health care system can only benefit from a better understanding of which treatment options work best for which patients.\textsuperscript{137} While the current Medicare and Medicaid outpatient prescription drug claims databases may be able to provide longitudinal data on drug use generally, the inclusion of ICD-10-CM codes would imbue the claims databases with the potential for deeper refinement in defining and understanding diseases and conditions, eventually leading to more customized medical management programs.\textsuperscript{139}

Given the underrepresentation of much of the Medicare and Medicaid patient population and informational bias in the existing universe of clinical evidence and the potential of a robust, accurately coded claims database to capture real-world prescription drug use information, which can in turn provide evidence of long-term efficacy and safety of drugs (or lack thereof), CMS should continue to provide Medicare and Medicaid prescription drug coverage while further evidence is developed consistent with the agency's existing CED program for Part B coverage. In doing so, a revised Medicare Part D and Medicaid billing policy (as made possible through electronic prescribing and ICD-10-CM coding) could play a critical role in better informing and reforming health care of those who have been traditionally underrepresented in the clinical evidence.

**Conclusion**

On first glance, adding ICD-10-CM diagnosis codes to outpatient prescriptions appears to be an obvious "win-win" situation for fiscal stability and public health – real-time coverage determinations for purposes of controlling federal health care costs and meaningful data collection to improve public health. CMS would be able to better police its Medicare Part D and Medicaid spending, and pharmacists, FDA, and researchers would have meaningful information for prescription review, drug safety surveillance, and comparative effectiveness research. But strict enforcement of Medicare Part D and Medicaid coverage laws in the short-term could undermine all of these policy goals. While most health care providers desperately try to comply with all relevant laws and regulations, they are also driven by their vocation to treat their patients effectively. Given the immediate nature of health and illness and the often abstract and distant nature of laws and regulations, combined with the sheer fact that at some point we will all be patients, it would be wise to underestimate the likelihood (and fervent wish of many) that health care providers may take steps to effectively treat a patient despite the laws and regulations that stand in the way. One such step may be miscoding a diagnosis to get a needed prescription paid. Where coverage denials are perceived as arbitrary and out-of-pocket payment for prescription drugs is not a viable option, the "right" choice between accurately reporting diagnoses or effectively treating a patient can get blurred. When national health care policies are impacted, I
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CONCLUSION

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136. See generally Len S. Schneider et al., Effectiveness of Atypical Antipsychotic Drugs in Patients with Alzheimer’s Disease, 355 NEW ENG. J. MED. 1255, 1256 (2006) (studying the number of patients with at least a minimal improvement on a standardized symptom rating scale during a timeframe of initial treatment to the discontinuation of treatment).


138. Many other countries have already decided to include costs in their comparative effectiveness programs. Keckley & Frink, supra note 137, at 56 (“At least sixteen developed systems in the world feature a comparative effectiveness program to define effective care. Comparative effectiveness programs in Britain, Australia, Canada, Germany, and others align provider payments with adherence to recommendations of comparative effectiveness programs, but each program is unique in design and application.”).

suggest erring on the side of accurate information at the cost of immediate, strict enforcement of the letter of the law to bolster better evidence-based decisions in the future. Fortunately (at least in this context), administrative agencies are afforded tremendous discretion in their enforcement policies, especially when enforcement involves a complicated balancing of a number of factors that are peculiarly within the agency’s expertise.\textsuperscript{141} Given the complexity of the legal framework here, the informational limits of scientific evidence and diagnostic coding, the vulnerability of the patient populations insured under Medicare and Medicaid, and the opportunities to improve both individual patient safety and public health tied up in this enforcement policy, it seems unlikely that any federal court would compel CMS to apply the strict letter of the coverage laws.

Accordingly, in order to better control federal health care costs and improve public health in the long-term (possible only through collection and use of accurate information), CMS should make inclusion of an ICD-10-CM diagnosis code a condition of payment for all Medicare Part D and Medicaid claims for outpatient prescription drugs but suspend strict enforcement of the coverage laws unless there is widespread concern in the medical community that a particular treatment is always ineffective or harmful. The alternatives are unsatisfying: either a continuation of the status quo – essentially unchecked federal spending on prescription drugs that further threatens the fiscal stability of the Medicare and Medicaid programs, exacerbated by poorly understood prescription drug use in vulnerable populations – or worse.

While the inclusion of ICD-10-CM codes on outpatient prescriptions may be a simple proposal with significant potential for improving public health and patient safety, it is neither an easy nor inexpensive one. It would be a tremendous disservice to patients, taxpayers, health care providers, researchers, and policymakers alike to implement the proposal solely as a means of reducing federal health care spending on off-label prescriptions. With strict enforcement of the coverage laws and the accompanying systemic incentives to miscode created by widespread coverage denials, we could easily end up with the worst of all options – a significant investment of time and money in a claims database corrupted by inaccurate information that neither meaningfully polices federal health care spending nor provides sufficiently robust data for improved practice of pharmacy, drug safety surveillance, or comparative effectiveness research. Let us hope it does not come to that.

\textsuperscript{141} See generally Heckler v. Chaney, 470 U.S. 821, 831 (1985) ("An agency’s decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency’s absolute discretion.")