Regulating The Use Of Prescription Drug Databases In Health Insurance Underwriting

Kevin L. Eastman, Georgia Southern University, USA
Joseph S. Ruhland, Georgia Southern University, USA
Alan D. Eastman, Indiana University of Pennsylvania, USA

ABSTRACT

This paper examines the use of commercially-available prescription drug profiles in the underwriting of individual and small-group health insurance plans. It explains how these profiles are developed and used by insurers and analyzes their potential advantages and disadvantages to both insurers and consumers. Current and pending legislation and regulations governing the use of these prescription databases are also explained.

Keywords: Regulation; Health Insurance; Databases

INTRODUCTION

Health insurance companies evaluate applicants using information gathered from a variety of sources. The process and information relevant to the underwriting decision differ for individual versus large-group coverage. For large-group insurance, the focus is on the characteristics of the group as a whole, and there is typically no underwriting of the individual members. However, applicants for individual coverage and small-group plans must be evaluated on a case-by-case basis with an emphasis on assessing the loss potential of the particular applicant(s).

Many different factors can be predictive of losses for an individual, including (among others) age, gender, family history, occupation and, perhaps most directly, the applicant's physical condition and medical history. Information on these risk factors can be obtained from many different sources, including: 1) the applicant himself/herself, via the application for insurance, 2) physical exams and/or laboratory tests conducted by the insurer, 3) the applicant's health care providers, subject to legal requirements regarding patient consent to release the information, 4) insurance industry-sponsored databases (such as the Medical Information Bureau or MIB), and 5) commercial data-mining firms that prepare prescription drug profiles for insurers in return for a fee.

While the Medical Information Bureau (MIB) has been in existence for more than 100 years, the data mining technology used to access and search pharmacy records has existed for only about a decade (American Public Media, 2008). Insurers' use of these prescription drug databases first came to light in 2007 when the Federal Trade Commission (FTC) sued the two largest prescription drug data-mining firms for violating federal law related to disclosure of the use and content of the information by insurers (Privacy Rights Clearinghouse, 2010). Since that time, there has been continued debate regarding the use of prescription drug databases in the underwriting of individual health insurance and the appropriate regulatory response. The purposes of this paper are to:

1. describe the manner in which prescription drug databases operate and are used in the health insurance underwriting process
2. explain the associated benefits and concerns
3. summarize current legislation, regulation, and rulings relevant to this issue

PRESCRIPTION DRUG DATABASES

Terhune (2008) reports that two-thirds of all health insurers are using prescription data to make coverage and pricing decisions. While prescription information can be obtained in several ways, many insurers are now purchasing prescription drug histories from commercial firms that use searchable prescription drug databases to develop the profiles. The two largest such firms are Milliman IntelliScript and Ingenix MedPoint, from whom insurers can obtain and verify pharmacy records for more than 200 million Americans (American Public Media, 2008). These firms have developed technology that allows them to access databases containing billions of pharmacy claims, and an increasing number of insurers are using their services. For example, IntelliScript reports that more than 40 health insurance companies have obtained prescription histories[1] , with the total number of queries each year at about one million (Nakashima, 2008). The manner in which the prescription reports are generated by each firm is described below.

Milliman IntelliScript

The process begins when an insurer sends to IntelliScript a request for a prescription history that has been authorized by the applicant in compliance with the Health Insurance Portability and Accountability Act, or HIPAA (the requirements of which are discussed later in this paper). This "authorized request" specifies both the type of information to be disclosed and the parties authorized to disclose and receive the information. The request is then sent by IntelliScript to the data sources with which it has contracted. These data sources consist primarily of pharmacy benefit managers (PBMs), or entities that administer prescription drug programs or provide other prescription services for insurance companies and other parties. IntelliScript organizes the information it receives from its data sources and delivers it online to the insurer. The presentation can be tailored to the insurer's preferences, but generally includes drug names, dosages, fill dates, and physicians' information for up to five years. In addition, IntelliScript color codes the drugs as red (greatest risk), yellow, or green, according to the insurer's instructions (Nakashima, 2008).

Ingenix MedPoint

As with IntelliScript, the data mining at MedPoint begins when an applicant for health insurance authorizes the insurer to retrieve the information in compliance with HIPAA standards. MedPoint maintains servers in the PBM data centers which search the PBM databases for relevant information and then send it to a central server at Ingenix. The central server aggregates the information to create a "prescription profile" for the applicant that includes the drug names, dosages, fill/refill dates, therapeutic class, and physicians' information for up to five years. The profile also includes possible diagnoses and predictive risk assessments.[2] The risk assessment is in the form of a "pharmacy risk score," which quantifies the expected risk for a specified group of people who have taken prescription drugs (Nakashima, 2008). Higher risk scores suggest higher expected medical costs.

THE ADVANTAGES OF USING PRESCRIPTION DRUG DATABASES IN UNDERWRITING

Most of the advantages of using prescription drug databases in underwriting individual health insurance accrue to the insurance company. However, there are arguably benefits to the applicant as well.

Proponents of the use of prescription drug and other electronic databases in insurance underwriting argue that it improves both the efficiency and effectiveness of the underwriting process. With respect to efficiency, both IntelliScript and MedPoint provide nearly instantaneous access to up-to-date prescription records at low cost. Milliman reports that it can check its data sources and return a prescription history to its clients "within seconds"[3],

[1] Milliman, 2010. http://www.milliman.com/expertise/healthcare/products-tools/intelliscript
[2] Ingenix, 2010. http://www.ingenix.com/health-plans/solutions/risk-assessment-health/underwriting-health/medpointprescriptionprofiling/features
[3] Milliman, 2010. http://www.rxhistories.com/faq.html

while Ingenix states that its clients can obtain a medical profile in "just minutes."[4] The prescription profiles are updated as frequently as once a day, thus providing nearly real-time information at a cost of only about $15 per search. In contrast, the more traditional approach – obtaining medical records from the applicant's physician – could take months and cost hundreds of dollars (Nakashima, 2008). In addition, the information contained in prescription drug databases may reduce the need for further medical records or follow-up by the underwriter. For example, an expensive lab test may be unnecessary if the applicant's prescription history has already made it clear that a particular medical condition exists. So, using prescription databases in the underwriting process can both accelerate the decision-making process and reduce insurer costs. These benefits may also accrue to insurance consumers in the form of faster underwriting decisions and reduced premiums.

The use of prescription drug databases may impact the effectiveness of the underwriting process as well as reduce delays and underwriting costs. The goal of the underwriting process is to develop a profitable book of business by accurately assessing the risk posed by applicants and determining an appropriate premium for the level of risk assumed. The information provided by IntelliScript and MedPoint can help improve risk assessment in a number of ways. First, the risk analysis provided by the two firms (IntelliScript's customized color-coded risk profiles and MedPoint's pharmacy risk scores) can assist the insurer in identifying high-risk individuals and predicting ongoing medical expenses. At a minimum, it can lead underwriters to request additional information from the applicant before approving a request for coverage. Second, using prescription profiles in the underwriting process improves an insurer's ability to detect inaccurate health statements or undisclosed doctors or medical conditions. More specifically, an applicant's inaccurate assertion of good health or failure to disclose a significant medical condition may be discovered from a review of the drugs listed in the applicant's prescription profile. Finally, insurers have reported that the use of prescription databases has resulted in more consistent decisions by underwriters with different levels of experience.[5] These improvements in the insurers' ability to assess risk can ultimately result in lower claims costs, more accurate projections of those costs, better alignment of premiums to risk, and greater profitability for insurers. Consumers may also benefit if the insurer's ability to reduce its claims costs by identifying high-risk and/or dishonest applicants translates into lower premiums.

THE DISADVANTAGES OF USING PRESCRIPTION DRUG DATABASES IN UNDERWRITING

Critics of insurers' use of prescription databases in underwriting health insurance often concede that it can speed decisions, reduce insurer costs, and even result in lower premiums to consumers. Nonetheless, they have concerns that generally relate to: 1) a lack of transparency regarding the existence and use of the databases, 2) the possibility of inaccurate or misleading data contained within the databases, 3) privacy issues, and 4) the potential of a negative impact on health care.

As noted earlier, insurers' use of prescription drug databases in the underwriting process was largely unknown to the public until 2007, when the Federal Trade Commission (FTC) sued both Milliman and Ingenix for violating certain disclosure provisions of federal law. The lack of transparency meant that applicants who were denied coverage were generally unaware of the existence and use of the records and/or any inaccurate or misleading information contained within them. As such, they had no opportunity to review the data, correct errors, or explain why the implications drawn from the data by insurance company underwriters were incorrect. While these problems have been addressed as a result of the FTC lawsuits (described below), concerns persist regarding consumers' lack of knowledge about the databases and their rights under federal law with respect to them.

A second area of criticism with respect to the use of these databases by insurers relates to the possibility of unfair or incorrect underwriting decisions as a result of inaccurate or misleading information contained within them. As noted above, a lack of transparency means that inaccurate information may go unchallenged. There is also some concern that insurers will obtain the wrong prescription profile for applicants with common names, or may misinterpret an applicant's use of drugs that have multiple uses or are prescribed for "off-label" diagnoses (Terhune, 2008). For example, insurers are often reluctant to cover persons with chronic medical conditions (such as

[4] Ingenix, 2010. http://www.ingenix.com/health-plans/solutions/risk-assessment-health/underwriting-health/medpointprescriptionprofiling/overview

[5] Milliman, 2010. http://www.rxhistories.com/whats_the_value.html

hypertension) and/or mental health problems, both of which can be predictive of higher expected medical costs over the long term. However, medications designed to treat these conditions may also be prescribed "off-label" to deal with other, less significant problems (e.g., migraine headaches, insomnia, etc.). Thus, an insurer's review of an applicant's prescription profile may result in inappropriate denials of coverage.

The database firms contend that the number of errors has been extremely small, given that searches are based on factors other than just the name of the applicant (e.g., date of birth, Social Security number, and address). In 2008, IntelliScript reported that mistakes in matching a query with the correct person occur in fewer than 1 in 10,000 cases, and MedPoint asserted that it had made only two such errors in more than 2 million queries (Terhune, 2008). As for the off-label use of drugs in particular cases, they argue that it is the responsibility of the insurance companies to request additional information from the applicant or to otherwise deal with such situations.

The third major area of concern relates to possible violations of the applicant's right to privacy as a result of unauthorized access to the applicant's prescription drug history. IntelliScript and MedPoint argue that safeguards in their operations minimize this risk. For example, IntelliScript points out that:

1. It develops prescription profiles from its contracted sources only when requested by an insurer that has received authorization from the applicant in compliance with HIPAA requirements.
2. It does not actually maintain a "pharmacy database" on individuals, but rather only keeps records on those individuals for whom an authorized request has been received.
3. Only the specific client authorized to receive the report and the individual that provided that authorization can receive a copy of the report.[6]

Privacy advocates respond that applicants really have no choice as to whether or not to agree to releases of medical information, since failure to sign the consent form would result in certain denial of coverage (Nakashima, 2008; Macios, 2009). In addition, prescription histories are usually referenced only in "the lengthy fine print consumers are instructed to read" when giving consent to review their medical records (Terhune, 2008). As a result, many applicants may actually be unaware that they are agreeing to give insurers access to such information. Finally, some argue that the authorizations themselves are illegal because "a person can't meaningfully give consent to disclose information that doesn't yet exist" (Macios, 2009, 20).

One additional criticism of using searchable databases in underwriting insurance is the potential negative impact on the actual health of individuals. Patients who are concerned about the confidentiality of their medical records may be reluctant to consult with physicians or provide certain types of information to them, or to take certain medications that may otherwise be beneficial (Kornblum, 2008; ACLU, 2008).

APPLICABLE LEGISLATION

Fair Credit Reporting Act (FCRA)[7]

The Fair Credit Reporting Act (FCRA) was passed in 1970 to regulate the collection and use of various types of consumer information. Section 602(b) of the FCRA requires "that consumer reporting agencies adopt reasonable procedures for meeting the needs of commerce for consumer credit, personnel, insurance, and other information in a manner which is fair and equitable to the consumer, with regard to the confidentiality, accuracy, relevancy, and proper utilization of such information." Thus, while the title of the act refers only to credit reporting, it is sufficiently broad to include regulation of other types of consumer information as well.

Milliman IntelliScript and Ingenix MedPoint fall within the FCRA's definition of a "consumer reporting agency" because, in return for monetary fees, they regularly engage in the practice of assembling or evaluating information on consumers for the purpose of furnishing consumer reports to third parties.[8] Likewise, the

[6] Milliman, 2010. http://www.rxhistories.com/faq.html
[7] 15 U.S.C. § 1681 et seq.
[8] FCRA, Section 603(f)

prescription drug profiles developed by the firms fall within the FCRA's definition of a "consumer report" because the profiles include information by a consumer reporting agency which is used or collected for the purpose of serving as a factor in establishing the consumer's eligibility for insurance.[9] Medical information includes any information or data in any form or medium that 1) has been created by or derived from a health care provider or the consumer and 2) relates to the past, present, or future physical, mental or behavioral health or condition of an individual, or to the provision (or payment for the provision) of health care to an individual.[10]

Under the FCRA, consumer reporting agencies must provide to the users of consumer reports a notice of their (the users') legal obligations under the FCRA. These obligations include, among others, the following:

1. All users must have (and certify to the consumer reporting agency) a permissible purpose under the FCRA to obtain a consumer report, one such purpose being for the underwriting of insurance as a result of an application from a consumer.
2. All users must notify consumers when "adverse actions" are taken in the underwriting of insurance coverage, where those actions include the denial or cancellation of insurance coverage, an increase in rates, a reduction in benefits, or other adverse or unfavorable changes in the terms of coverage.[11]

In addition, the user must include, in this notice, statements setting forth the applicant's rights to: 1) obtain a free disclosure of his/her file from the consumer reporting agency (if the consumer's request is made within 60 days) and 2) dispute directly with the consumer reporting agency the accuracy or completeness of any information provided to the user. So, insurers who deny or reduce coverage, or increase premiums, based at least in part on information contained in a prescription profile obtained from IntelliScript or MedPoint have an obligation to notify the applicant of that fact and to their rights under the law.

In 2007, the Federal Trade Commission (FTC) investigated both companies for violating the requirement that they provide insurance companies with the "Notice to Users." The FTC did not specify its initial reason for the investigation, but it did confirm that the investigation was not initiated as a result of a consumer complaint or concern about privacy violations (Terhune, 2008). The investigation led the FTC to file complaints against both Milliman and Ingenix in which it alleged "unfair and deceptive acts and practices" as a result of their failure to meet the notice requirement.[12] Both companies agreed to a consent order in order to resolve the allegations. Under the consent orders, Milliman and Ingenix agreed to comply with the requirements of the FCRA to: 1) provide any users or prospective users a Notice to Users, 2) maintain reasonable procedures to limit the furnishing of consumer reports to those with a permissible purpose, 3) follow reasonable procedures to assure maximum possible accuracy of the information contained in the reports and to handle cases in which accuracy is disputed, and 4) comply with rules regarding the disposal of consumer reports. However, the consent order was only for purposes of settlement and did not constitute an admission by either Milliman or Ingenix that they had violated any law.[13] The FTC did not impose any civil penalties at the time of the consent agreement for the firms' past violations of the FCRA. However, it indicated that each future violation of the order could result in a civil penalty of $11,000.[14]

The failure to impose a fine or other penalty for the violations was criticized by some privacy advocates. For example, the World Privacy Forum objected to the consent agreement for that reason and because it did not require Milliman and Ingenix to provide actual notice or other remedies to consumers. Its executive director sent a letter to the FTC which advocated a penalty equal to fifty percent of the firms' gross revenues from those activities that violated the law. The FTC defended its decision not to impose fines or other penalties by noting that Milliman and Ingenix "provided the reports only to insurance companies that both had a permissible purpose to receive the reports and obtained consent from consumers prior to requesting the reports."[15] In addition, it noted that direct

[9] FCRA, Section 603(d)(1)
[10] FCRA, Section 603(i)
[11] FCRA, Section 603(k)
[12] FTC Complaints, 0623189 and 0623190.
[13] FTC Consent Orders, File Nos. 0623189 (Milliman) and 0623190 (Ingenix)
[14] FTC, 2010. http://www.ftc.gov/opa/2007/09/ingenixmilliman.shtm
[15] FTC, 2010. http://www.ftc.gov/os/caselist/0623189/080212letter.pdf

notice to consumers is not required under the FCRA; rather, the obligation is to provide notice to the users of the reports (the insurance companies) of their FCRA obligations. Nonetheless, the FTC's decision not to fine Milliman and Ingenix is considered by some as an indication that it is acceptable to ignore the law.

Health Insurance Portability and Accountability Act (HIPAA)[16]

Title II of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) contains the Privacy Rule, which regulates the use and disclosure of protected health information (PHI) held by covered entities. Protected health information is defined as individually identifiable health information, including demographic data which relates to: 1) the individual's past, present or future physical or mental health or condition, 2) the provision of health care to the individual, or 3) the past, present, or future payment for the provision of health care to the individual (Office of Civil Rights, 2003). Covered entities include health plans, health care providers and health care clearinghouses[17].

The object of the Privacy Rule is "to define and limit the circumstances in which an individual's protected health information may be used or disclosed by covered entities." Unless the individual provides written authorization waiving his privacy rights, covered entities may use or disclose protected health information only: 1) to the individual, 2) for treatment, payment or health care operations, 3) incident to an otherwise permitted use or disclosure, 4) if the individual is informed in advance and has an opportunity to agree to or prohibit or restrict the use or disclosure, 5) for specified public health activities, and 6) as a limited data set for the purposes of research, public health or health care operations. Under these rules, a pharmacy benefits manager, a pharmacy, and a health insurance plan may share information required for adjudication of claims for a covered member without prior consent.

Firms such as Milliman Intelliscript and Ingenix fall outside the definitions of a covered entity and, as described earlier, are regulated under the Fair Credit Reporting Act (FCRA). As a non-covered entity, however, these firms were not necessarily absolved from protecting the privacy of protected health information. Until early 2009, "business associates" who contract with covered entities to use protected health information to perform some service (e.g., Intelliscript and Ingenix) had to comply with privacy rules to the extent required by their contracts with covered entities. Further, federal regulators were powerless to hold business associates accountable for breach of contract dealing with privacy and were limited in their ability to discipline the covered entity based on the actions of their business associates. However, the American Recovery and Reinvestment Act (i.e. the stimulus act) passed in 2009 materially changes the level of care business associates must provide. The act calls for business associates to follow most all of the HIPAA regulations as they pertain to data security regardless of whether existing contracts call for less. Further, the same criminal and civil penalties may be levied against business associates as can be levied against the covered entities themselves.[18] Consistent with these regulations, Milliman Intelliscript and Ingenix each stress the need for a HIPAA-compliant individual authorization before any data is requested from PBMs.[19,20]

Patient Protection and Affordable Care Act[21]

As part of the health care reform bill passed in 2010, companies selling individual and small group policies may only vary their pricing with respect to: 1) family vs. individual coverage, 2) rating area (geographic), 3) age, and 4) tobacco use[22]. In addition, issuers offering group or individual coverage may not establish rules for eligibility

[16] Public Law 104-191.
[17] Health care clearinghouses are entities that process nonstandard information they receive from another entity into a standard (i.e., standard format or data content), or vice versa. (Office for Civil Rights, 2003, p. 5)
[18] Secs. 13401 and 13404 of the American Recovery and Investment Act of 2009 http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h1enr.pdf
[19] Milliman, 2010. http://www.rxhistories.com/faq.html
[20] Ingenix, 2010. http://www.ingenix.com/Products/Payers/UnderwritingActuarial/Underwriting/ActuarialSolutions/MedPointPrescriptionProfiling
[21] Public Law 111-148.
[22] Sec. 2701 [42 U.S.C. 300gg]. Fair Health Insurance Premiums, pg. 46 http://docs.house.gov/energycommerce/ppacacon.pdf

(including continued eligibility) of any individual to enroll under the terms of the plan or coverage based on any of the following health status-related factors in relation to the individual or dependent of the individual: 1) health status, 2) medical condition (including both physical and mental illnesses), 3) claims experience, 4) receipt of health care, 5) medical history, 6) genetic information, 7) evidence of insurability (including conditions arising out of acts of domestic violence), 8) disability, and 9) any other health status-related factor determined appropriate by the Secretary."[23]

These two sections of the law may call into question the continued relevance of the prescription drug history reports. We feel that they will remain relevant for two reasons. First, although most of the components of the law were recently held to be constitutional by the U.S. Supreme Court, the threat of repeal remains depending on the outcome of the election in November, 2012. In addition, this section of the law has an effective date of 1/1/2014, which leaves a significant period of time for which the reports will still be used in the individual and small group underwriting process. Secondly, while insurers may not use the information in the reports to make individualized coverage and/or pricing decisions, the information will remain important to insurers for pricing purposes. Insurers will still need to accurately estimate total expected claims so as to calculate an average premium which will apply to everyone within the broader underwriting categories. Further, augmenting the "behind-the-scenes" individual underwriting with prescription drug history will better allow insurers to assess individuals' expected deviation from the mean. This allows insurers to estimate the probability of healthier individuals leaving the plan and altering the average expected claims cost for the plans' participants.

CONCLUSION

Over the past decade, the aggregation and reporting of historical pharmacy claims data by third party firms has evolved to become a crucial tool for individual and small group health insurance underwriters. However, their use has caused controversy. While supporters of this data's use tout the increased efficiency, effectiveness and consistency in underwriting decisions, detractors point to the clandestine nature of these data, privacy issues, misinterpretation of data, and the potential negative impact on health care.

Along with the use of the data, the regulatory scrutiny to which the data aggregators are subject has evolved as well. The Fair Credit Reporting Act, HIPAA, and the Patient Protection and Affordable Care Act have influenced the behavior and relevance of the aggregators from a federal perspective. While the health care reform bill will effectively disallow the use of individual factors, such as historical pharmacy claims for individual pricing and offer decisions, they will still have relevance in the aggregate and thus will be of continued interest to regulators and consumer advocacy groups.

AUTHOR INFORMATION

Kevin Eastman is a Professor of Finance at Georgia Southern University. He earned his Ph.D. in Managerial Science and Applied Economics at the Wharton School of Business of the University of Pennsylvania. His research areas of interest include insurance regulation, no-fault auto insurance, insurance market performance, and business ethics. E-mail: keastman@georgiasouthern.edu. Corresponding author.

Joe Ruhland is Assistant Professor of Finance at Georgia Southern University. Joe received his Ph.D. in Risk Management and Insurance from the University of Georgia, after significant corporate experience as an employee benefits consultant. His research areas of interest include asymmetric information, political risk and corporate governance. E-mail: jruhland@georgiasouthern.edu

Alan Eastman is a Professor of Finance at Indiana University of Pennsylvania. Alan earned a doctorate in Risk Management and Insurance from Florida State University, with prior business experience in public accounting and small business management. His teaching and research interests include financial management, investments, insurance and insurance regulation. E-mail: aeastman@iup.edu

[23] Sec. 2705 [42 U.S.C. 300gg-4]. Prohibiting Discrimination Against Individual Participants and Beneficiaries Based on Health Status, pg. 47 http://docs.house.gov/energycommerce/ppacacon.pdf

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