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# Atheoretical Versus Theory-Based Approaches in Promoting Safer ADHD-Medication Prescribing for Adults

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## Walden University

College of Social and Behavioral Sciences

This is to certify that the doctoral dissertation by

Kathleen A. Fairman

has been found to be complete and satisfactory in all respects, and that any and all revisions required by the review committee have been made.

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> > Walden University 2020

Abstract

Atheoretical Versus Theory-Based Approaches in Promoting Safer ADHD-Medication

Prescribing for Adults

by

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MPhil, Walden University, 2019

MA, Arizona State University, 1985

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Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Psychology

Walden University

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#### Abstract

Gaps between treatment guidelines and medical decisions persist despite interventions with physicians, which are mostly atheoretical. The purpose of this retrospective crosssectional study was to compare atheoretical and theory-based logistic regression models of a binary outcome: potentially unsafe prescribing of attention-deficit hyperactivity disorder (ADHD) medications to adults. Social cognitive theory and self-determination theory provided the framework for the study. Predictors were framed as social cognitive theoretical constructs: knowledge (e.g., physician specialty) and environmental influence (e.g., interventions). Atheoretical hypotheses were based on legislation mandating meaningful use of electronic health records and computerized decision support (CDS). Theory-based hypotheses were derived from literature on cognition in medicine and on the controlled motivation construct in self-determination theory. Research questions addressed associations of CDS and meaningful use with the outcome and fit of competing models. The sample included office-based physician visits made by patients aged  $\geq 17$ years with ADHD (n = 810) or potentially unsafe medical conditions (n = 9,101), recorded in a U.S. database in 2014–2016. Findings for the atheoretical model were reduced odds of the outcome with CDS, and nonsignificant improvement in model fit using theory. Supporting the self-determination theory-based hypothesis, odds were increased with meaningful use. This study adds to research suggesting autonomy as a core issue in medicine. Positive social change may result from psychology-based strategies to empower physicians through participation in developing clinically relevant information systems.

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### Dedication

To my students, who inspire me every day, and to Michael, who makes every day brighter.

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In research, as in life, no major project is ever a solo effort. This project was no exception. I thank my family and friends for their support, for meals on days when I was too tired to cook, and for never, even once, uttering the words "at your age" when I first mentioned that I might return to school for a PhD. It is a great blessing to say that you are too many to name, but please know that I appreciate each one of you. Special thanks are owed to James Rucker, for assistance with mathematical formulas and reference verification; to Madeline Rucker, for clerical help; to my cherished friend and long-time research associate, Brenda Motheral, for her sensible counsel and always faithful good cheer; and to my amazing colleagues at the Midwestern University College of Pharmacy-Glendale, for their encouragement and patience throughout this process.

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#### Chapter 1: Introduction to the Study

Evidence-based medicine, broadly defined as the consideration of findings from high-quality research in medical decision-making (Sackett & Rosenberg, 1995), has produced life-saving improvements in medical treatment protocols (Djulbegovic & Guyatt, 2017); is widely supported in concept by physicians and medical associations (Chan et al., 2017; Institute of Medicine [IOM], 2011); and is incorporated in the curricula of most U.S. medical schools (Blanco, Capello, Dorsch, Perry, & Zanetti, 2014). However, inconsistencies between evidence-based treatment guidelines and decisions made in clinical practice have been documented for more than two decades (Cabana et al., 1999; R. Lau et al., 2016). This "evidence to practice gap" has persisted despite many initiatives intended to improve the medical decision-making process (Baker et al., 2015; Jäger et al., 2016; R. Lau et al., 2016, para. 1).

To address this gap, health policy analysts advanced the idea that providing physicians with automated guidance during their encounters with patients would increase adherence to evidence-based practice, thereby improving quality of care and patient safety (Bates & Gawande, 2003; Bates et al., 2003; IOM, 2000, 2001). Meaningful use provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 codified this concept in federal law (Blumenthal & Tavenner, 2010), providing a system of financial incentives and penalties to encourage use of computerized decision support (CDS) and electronic health record (E-HR) technology in medical decision-making (U.S. Centers for Disease Control and Prevention [CDC], 2019a), including the prescribing of medications (U.S. Centers for Medicare & Medicaid Services [CMS], 2012a).

As intended, HITECH Act implementation was soon followed by expanded use of electronic technologies in physician offices nationwide (Hsiao, Hing, & Ashman, 2014). However, the few evaluations of meaningful use performed prior to this study indicated negligible effects on quality of care for a variety of disease states and samples (Afonso, Alfonso, & Morgan, 2017; Grinspan et al., 2017; Jung et al., 2017; Kern, Edwards, Kaushal, & HITEC Investigators, 2015; Levine et al., 2017; Samal, Wright, Healey, Linder, & Bates, 2014; Unruh et al., 2017). Additionally, the expanded use of CDS and E-HRs in medical practice has been associated with new safety problems (Brown et al., 2017; Carling, Kirkehei, Dalsbø, & Paulsen, 2013; Howe, Adams, Hettinger, & Ratwani, 2018) and increased occupational dissatisfaction among physicians (Colligan, Sinsky, Goeders, Schmidt-Bowman, & Tutty, 2016; Friedberg et al., 2013; Shanafelt et al., 2016).

These results may have occurred because psychological theory and evidence, particularly from human factors study of human-device-environment interaction, were not considered in designing CDS or E-HR systems (Ratwani et al., 2016; Savage, Fairbanks, & Ratwani, 2017). More broadly, the core strategy underlying the HITECH Act, paying physicians to meet externally determined metrics, may be inconsistent with psychological theory about the effects of extrinsic financial incentives on human motivation (Himmelstein, Ariely, & Woolhandler, 2014; Kao, 2015). Consistent with these views, one early proponent of electronic technologies in health care recently noted that the exploratory application of behavioral science to CDS began in 2015 or 2016 (Cho & Bates, 2018). Therefore, meaningful use and CDS may be described as atheoretical, meaning they were developed without regard to psychological theory (Prestwich, Kenworthy, & Conner, 2018). This atheoretical approach is typical of health-system interventions on physician behavior (Jäger et al., 2016; R. Lau et al., 2016; L. Liang et al., 2017).

Whether theory-based approaches to changing medical decision-making might produce better outcomes than atheoretical approaches is an important but understudied question. No comparisons of theory-based and atheoretical interventions to promote evidence-based medical practice were identified in the literature review for the current study. To address this gap in the literature, I compared two approaches—theory based and atheoretical—to predicting a non-evidence-based medical decision that negatively affects U.S. population health (see Compton, Han, Blanco, Johnson, & Jones, 2018; Seth, Scholl, Rudd, & Bacon, 2018): the prescribing of attention-deficit hyperactivity disorder (ADHD) medications to adult patients for whom they may be unsafe (see Fairman, Davis, Peckham, & Sclar, 2018). Results may be used to inform health psychology-based interventions to improve medical decision-making, including but not limited to those for ADHD medications, potentially facilitating positive social change.

In this chapter, I introduce the need for theory-based approaches, explain the safety risks associated with some ADHD-medication prescribing decisions, present difficulties in evidence-based practice promotion and potentially unsafe ADHD-medication prescribing as research problems, and describe the purpose of this study. In the remainder of the chapter, I provide an overview of the nature of the study, including

quantitative methods and definitions of key variables, and present research questions, definitions and assumptions, study scope, and study limitations.

#### Background

Theory-based assessments of physician decision-making are uncommon (R. Lau et al., 2016), identified in only two of 178 surveys on barriers to guideline-based medical practice in one systematic 10-year review (Willson, Vernooij, & Gagliardi, 2017), and totals of six studies of clinical practice behaviors and 29 studies of behavioral intentions in a 40-year systematic review of cognitive theory-based research in health care (Godin, Bélanger-Gravel, Eccles, & Grimshaw, 2008). In a 10-year scoping review of guidelineimplementation interventions described as theory based, only 42 studies were found, of which only 10 included a theoretical basis for design or evaluation (L. Liang et al., 2017). Moreover, most guideline-implementation studies that were purportedly theory based did not include a map (link) of specific intervention components to any theoretical construct (L. Liang et al., 2017), a common problem in studies of physician decision-making (R. Lau et al., 2016) and other health behavior-change initiatives (Prestwich et al., 2014; Prestwich, Webb, & Conner, 2015). Related to this problem is a lack of theory-based health care research on objective behavioral measures (Conner & Norman, 2017; Prestwich et al., 2015) or on broad policy interventions with potential population health impact (Conner & Norman, 2017; Prestwich et al., 2018).

These deficits represent inconsistencies between currently available health psychology research and American Psychological Association (APA, 2014) guidelines for the development of preventive interventions. These guidelines recommend a basis in theory, empirical support, consideration of system-wide factors, and advocacy for population-health promotion. Summarizing these needs, theory-based research including objective behavioral measures is needed to study health-related behaviors, including nonevidence-based medical decisions, with potential population health effects (APA, 2014; Conner & Norman, 2017; L. Liang et al., 2017).

One such non-evidence-based medical decision recently identified using an objective behavioral measure (Fairman et al., 2018) is ADHD-medication prescribing that is potentially unsafe according to evidence-based federal guidelines (U.S. Food and Drug Administration [FDA], 2002, 2007a). Specifically, patients with substance use disorder (SUD) who receive a stimulant medication may be put at risk of increased misuse (Compton et al., 2018; FDA, 2007a; McCabe et al., 2019) or of an overdose that leads to emergency care (L. Y. Chen et al., 2016; Fulde & Forster, 2015) or death (Seth et al., 2018). Additionally, those with cardiovascular disease (CVD) who receive either a stimulant or the most commonly used nonstimulant alternative, atomoxetine (Fairman, Peckham, & Sclar, 2017), may be put at risk of a cardiac event, such as a myocardial infarction (heart attack) or cerebrovascular event (stroke; FDA, 2002, 2007a). However, in a national sample of adults who were newly prescribed medications for ADHD, Fairman et al. (2018) found that 11–19% of stimulant-treated patients had SUD, and 16% of patients aged 55–64 years who were prescribed stimulants or atomoxetine had CVD. In accordance with APA (2014) recommendations, a theory-based assessment of this prescribing problem, which represents an important population health issue, was needed

to address the lack of research on psychology-informed promotion of evidence-based prescribing.

#### **Problem Statement**

Two problems were addressed in this study. Each of the two social problems was associated with a research problem. These research problems represented gaps between APA (2014) guidance and available published information.

The first social problem was persistent failure to achieve the goal of promoting evidence-based medical practice (Baker et al., 2015; R. Lau et al., 2016). A related research problem was the paucity of studies in which researchers applied psychological theory to medical decision-making (Godin et al., 2008; Jäger et al., 2016; R. Lau et al., 2016; L. Liang et al., 2017). By mapping potential predictors of medical decisions, including CDS and meaningful use interventions, to theoretical constructs, this research comported with APA (2014) recommendations for use of theory and evidence.

The second social problem was the prescribing of ADHD medications to adults for whom they may be unsafe. As a recently identified issue in the literature on evidencebased medicine (Fairman et al., 2018), potentially unsafe ADHD-medication prescribing was also a research problem because known predictors were limited to a few patient characteristics, such as age or medical conditions (Compton et al., 2018; Fairman et al., 2018; McCabe et al., 2019). Increasing rates of diagnosis and medication treatment for ADHD among U.S. adults (Fairman et al., 2017; Olfson, Blanco, Wang, & Greenhill, 2013) have been accompanied by growth in rates of stimulant misuse, overdose, and death (Seth et al., 2018; U.S. Substance Abuse and Mental Health Services Administration, 2013). Through use of a national sample (CDC, 2015a) to study this problem, this research comported with APA (2014) recommendations for system-wide assessments to promote population health.

#### **Purpose of Study**

The purpose of this quantitative study was to assess the relative strengths of atheoretical and theory-based approaches to promotion of evidence-based medicine by comparing alternative logistic regression models of an objective behavioral measure of potentially unsafe ADHD-medication prescribing: one model based on the rationales underlying two atheoretical interventions (CDS and meaningful use) and the other based on theory-derived predictors. To provide U.S. population-level findings, I chose a sample that was nationally representative (see CDC, 2015a). To provide theory-based research, I mapped hypotheses for predictors of interest, including CDS and meaningful use, to theoretical constructs based on qualitative and quantitative evidence about the psychology of medical practice, and about cognitive and emotional response to CDS and E-HRs (see Holden, 2011; Shanafelt et al., 2016; Slight et al., 2016). Because the term *atheoretical* refers to the way that interventions are developed, not to the way that they are studied (Prestwich et al., 2018), both atheoretical interventions and theory-based predictors were mapped to theoretical constructs in this research.

#### **Theoretical Framework**

Prescribing is a cognitive activity in which physicians weigh the benefits against the risks of a given medication based on clinical situation, medical knowledge, and influences present in the medical practice environment (Djulbegovic & Elqayam, 2017). The interventions examined in this study included CDS, which was intended to improve the knowledge available to physicians in the decision-making process (see Bates et al., 2003), and meaningful use, which was intended to motivate physicians to use electronic technology (see Buntin, Jain, & Blumenthal, 2010; Heisey-Grove & Patel, 2014). To frame these cognitive and environmental influences in competing statistical models for this study, I chose two theories: social cognitive theory (Bandura, 1989), which served as the general theoretical framework, and self-determination theory (Deci & Ryan, 2008a), which informed hypotheses about incentives in the practice environment, including meaningful use. These theories are described briefly here and in more detail in Chapter 2.

#### **Social Cognitive Theory**

Social cognitive theory depicts decision-making as a function of cognitive processes performed by human actors who actively and reciprocally engage with the environments in which they operate, basing intentions and behaviors on forethought and self-regulation, and influenced by knowledge, social norms, and environmental conditions (Bandura, 1989, 2001; Kelder, Hoelscher, & Perry, 2015). In addition to its appropriateness to describe prescribing as a cognitive activity influenced by environmental factors (Djulbegovic & Elqayam, 2017), the theory facilitates understanding of the transmission of occupational norms in medical training. The professional values inculcated in medical education, which are reflected in medical practice (Colligan et al., 2016), may be described in the theoretical framework as norms developed through training and observational learning (Bandura, 1999) that influence self-regulated cognition and behaviors in occupational settings (Bandura, 2001). In medicine, these norms include a commitment to meeting patients' needs (Colligan et al., 2016; Cooke, Irby, Sullivan, & Ludmerer, 2006) and a personal identity as a biomedical expert who is trained for autonomous, complex decision-making (Accreditation Council for Graduate Medical Education [ACGME], 2019; Berkhout, Helmich, Teunissen, van der Vleutin, & Jaarsma, 2018). Additionally, the theoretical construct of emergent interactive agency (Bandura, 1989), referring to mutual human-environmental influence, facilitates understanding of physicians' adaptations to the introduction of CDS and E-HR systems in the practice environment, sometimes with responses not intended by system developers (Nanji et al., 2014; Slight et al., 2016; Wright et al., 2018).

Knowledge constructs, including characteristics of the patient, such as diagnoses, and of the prescriber, such as specialty, were common to the theory-based and atheoretical models. The environmental-influence constructs differed. Theory-based hypotheses for the use of CDS in the practice environment were derived from research evidence on cognition in medical practice. Hypotheses for the remaining environmentalinfluence predictors were derived from self-determination theory (see Deci & Ryan, 2008a).

#### **Self-Determination Theory**

Self-determination theory is a framework for understanding the ways in which types of motivating factors affect task performance and psychological well-being (Deci & Ryan, 2008a). According to the theory, the more autonomous (i.e., internal to self) a motivating factor is for a given task, the more an individual will persist with the task, execute it well, and derive psychological satisfaction from it. Autonomous motivation results, in varying degrees, either from intrinsic enjoyment of the task, which is fully autonomous, or from extrinsic rewards tied to the performance of tasks that a person would have valued regardless of reward, which is partially autonomous (Deci & Ryan, 2008b; Prestwich et al., 2018). In contrast, incentives linked to tasks that an individual does not value are more likely to be perceived as external to self, leading to a sense of controlled motivation and to diminished task persistence and performance (Deci & Ryan, 2008a). Environmental incentives mapped to these two constructs of self-determination theory, and hypotheses for these incentives, were based on literature describing professional values in medicine. These incentives included meaningful use in both the atheoretical and theory-based models (see Emani et al., 2017; Shanafelt et al., 2016; Weeks, Keeney, Evans, Moore, & Conrad, 2015) and additional incentives, patientderived revenue, and nature of professional relationship with the patient (see Colligan et al., 2016; Friedberg et al., 2013; Tak, Curlin, & Yoon, 2017) in the theory-based model only.

#### **Nature of Study**

This quantitative study was a retrospective and cross-sectional analysis of a sample of U.S. office-based physician visits recorded in the publicly available National Ambulatory Medical Care Survey (NAMCS) archival data set (CDC, 2015a, 2019b). The NAMCS, which is based on a probability, cluster-randomized, stratified, multistage sampling design (CDC, 2015a), is conducted annually by the National Center for Health Statistics (NCHS) and represents services provided by U.S. office-based physicians, excluding those employed in federal facilities (e.g., Indian Health Service, Department of

Veterans Affairs [VA]) or those who do not provide direct patient care (e.g., radiologists, pathologists; CDC, 2019b). Weights provided in the data set are used to adjust for the sampling design and for nonresponse, producing nationally representative estimates. NAMCS data are widely used in research on U.S. health care (CDC, 2019c). During the time period for this study, 2014–2016 NAMCS data were collected for a total of 87,207 visits across all ages and diagnoses (see CDC, 2017, 2018, 2019b).

NAMCS procedures and variables are discussed in detail in Chapter 3. Data for sampled physicians and visits are collected by U.S. Bureau of the Census representatives from medical records using an automated, laptop-based tool and standard definitions (CDC, 2019b). Data relevant to the current study included patient characteristics (e.g., diagnoses, demographics), prescribed medications and therapies, characteristics of the office (e.g., CDS use, meaningful use status) and provider (e.g., specialty, revenue sources), and nature of physician-patient relationship (e.g., whether physician is the primary care provider).

#### **Outcome (Dependent) Variable**

The study outcome (dependent variable), potentially unsafe prescribing of an ADHD medication, was measured as a binomial. Two clinical scenarios were tested. The first scenario (A) represented patients diagnosed with ADHD and prescribed any treatment: a medication, psychotherapy, or both. The binomial outcome in Scenario A was a potentially unsafe medication versus an alternative treatment, including either a safer medication or psychotherapy. The second scenario (B) represented patients who have a medical condition, either CVD or SUD, that would make some ADHD medications potentially unsafe. The binomial outcome in Scenario B was a potentially unsafe prescribed medication versus no potentially unsafe prescription. Only Scenario A was restricted to patients with an ADHD diagnosis, for reasons explained in the descriptions of study assumptions and definitions derived from federal guidance on medication use (see FDA, 2018) and misuse (see Compton et al., 2018). The binomial outcomes, described in Chapter 2 and operationalized in Chapter 3, were based on treatment guidelines current during the study period (see Bolea-Alamañac et al., 2014; Post & Kurlansik, 2012) and on federal prescribing information (see FDA 2002, 2007a).

#### **Predictor (Independent) Variables**

In both scenarios, predictor (independent) variables were mapped to constructs from each of the two theoretical frameworks. Knowledge construct predictors, reflecting both expertise and information needed to perform a behavior (see Kelder et al., 2015), were included and hypothesized to act in the same way in both the atheoretical and theory-based models because they were exogenous (i.e., not affected by the environmental variables of interest during the visit; see Pedhazur, 1982). These variables included characteristics of the patient, including demographics (see Fairman et al., 2017; Grinspan et al., 2017; McCabe et al., 2019; Rigg & Monnat, 2015), medical and psychiatric comorbidities (see Q. Chen et al., 2018; D. D. Jeffery, May, Luckey, Balison, & Klette, 2014; Mao & Findling, 2014; Rigg & Monnat, 2015), and whether the patient had a medical condition associated with a black-box status, which in federal guidance indicates the highest risk level for a medication (see FDA, 2012). Physician characteristics included specialty and urban versus rural location (see Leslie et al., 2012; Rigg & Monnat, 2015).

Environmental construct predictors differed in the atheoretical and theory-based models. Both models included CDS and meaningful use, with competing hypotheses. Additional theory-based predictors were patient-derived revenue and nature of professional relationship with the patient. Hypotheses for these predictors are described below and in more detail in Chapter 3.

#### **Hypotheses for Environmental Predictors**

Hypotheses for CDS and meaningful use in the atheoretical model were based on the rationales described by their proponents. These included provision of easily accessible, evidence-based knowledge (see Bates et al., 2003), incentives to motivate use of that knowledge (see Buntin et al., 2010; Heisey-Grove & Patel, 2014), and prevention of unsafe prescriptions (see Bates & Gawande, 2003), especially those that are highest severity as indicated by black-box warning status (FDA, 2012). Hypothesized associations of CDS with prescribing behavior in the theory-based model were based on the following: (a) literature on cognitive barriers to evidence-based medical practice (see Arts, Voncken, Medlock, Abu-Hanna, & van Weert, 2016; Baatiema et al., 2017; Chan et al., 2017; F. Fischer, Lange, Klose, Greiner, & Kraemer, 2016), (b) a comparison of the cognitive norms for which physicians are trained (see Berkhout et al., 2018; Cooke et al., 2006) with the cognitive demands of CDS and E-HRs (see Ratwani et al., 2016; Ratwani, Reider, & Singh, 2019; Stead, Searle, Fessler, Smith, & Shortliffe, 2011), and (c) evidence about CDS and E-HRs that was available when meaningful use policies were developed (see Linder, Ma, Bates, Middleton, & Stafford, 2007; Romano & Stafford, 2011).

Hypothesized associations of environmental incentives with prescribing behavior in the theory-based model were based on self-determination theory (see Deci & Ryan, 2008a). Meaningful use incentives were hypothesized as a controlled motivator associated with mandated use of a technology that is not valued (see Emani et al., 2017; Shanafelt et al., 2016; Weeks et al., 2015). Patient-derived revenue and nature of professional relationship with the patient were hypothesized as autonomous motivators associated with the valued outcome of maintaining patient relationships (see Anderson, Stowasser, Freeman, & Scott, 2014; Colligan et al., 2016; Friedberg et al., 2013; Sinsky et al., 2013; Tak et al., 2017), compared with other sources of revenue, such as salary. Key to the study hypotheses in the theory-based model was an understanding of positive task performance as the physician is trained to define it: maintaining the therapeutic relationship with, and meeting the needs of, the patient (see Cooke et al., 2006). As discussed in more detail in Chapter 2, the physician's definition of positive task performance for ADHD-medication prescribing may differ from that of evidence-based guidelines or of the FDA.

#### **Statistical Analyses**

Logistic regression analysis of office visits was chosen as the analytic approach to facilitate statistically controlled, quantitative assessments of the theoretical constructs and comparisons of the theory-based and atheoretical models using standard measures of model quality: whether odds ratios were in the predicted direction (see Warner, 2013);

the concordance or "c" statistic, a measure of predictive accuracy (see Austin & Steyerberg, 2012); and model fit (see Pampel, 2000). Differences in model fit, comparing the atheoretical and theoretical models, were tested for statistical significance using the standard  $\chi^2$  difference test based on change in –2 log-likelihood (–2LL), accounting for between-model differences in degrees of freedom (see Pampel, 2000). In accordance with NCHS guidance (CDC, 2019b), all analyses were performed using the IBM SPSS Complex Samples module (V25.0), which adjusts for the design effect (i.e., homogeneity of variance) associated with the multistage sampling process (see Groves et al., 2009). Because of the multistage sampling process, assessment of sample size adequacy was made based on NCHS guidance for post hoc analyses of statistical reliability (see CDC, 2019b; Parker et al., 2017), which is described in Chapter 3.

#### Definitions

The following definitions were used in the development of the rationale, methods, and research questions for this study:

*ADHD medication*: An ADHD medication is a product approved by the FDA to treat ADHD. The definition applies regardless of whether the treated patient has been diagnosed with ADHD because there is no prohibition in the United States against prescribing an approved medication for an unapproved purpose, known as off-label use (FDA, 2018). FDA prescribing guidelines do not describe off-label use of ADHD medications, such as for cognitive enhancement (Compton et al., 2018), as potentially unsafe (Novartis, 2019). *Adult*: According to the American Psychiatric Association (2013), diagnostic criteria for adult ADHD apply to patients who are aged 17 years or older.

*Atheoretical intervention*: An intervention on health-related behavior or outcomes is considered atheoretical when it is developed "without reference to, or use of, theory" (Prestwich et al., 2018, p. 95).

*Behavior-change technique*: In health care, a behavior-change technique is a method used to attempt to influence the health-related behaviors of individuals or groups, sometimes through manipulation of environmental features to change motivating factors or other influences on behavior (Prestwich et al., 2018).

*Clinical or computerized decision support system*: A clinical or computerized decision support (CDS) system is an electronic device or interface that provides informational support and guidance to clinicians at the point of care, as they make medical decisions or order treatments, including medications (Korb-Savoldelli, Boussadi, Durieux, & Sabatier, 2018).

*Computerized prescription order entry*: Computerized prescription order entry, also known as e-prescribing, is the use of an electronic system or device to generate a prescription, which is transmitted to the entity responsible for executing the order, such as a pharmacy that dispenses medication (Korb-Savoldelli et al., 2018).

*Evidence-based medicine:* Although the concept of evidence-based medicine has evolved over an approximately 50-year period (Djulbegovic & Guyatt, 2017), the currently accepted definition (Blanco et al., 2014) is "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients" based on the integration of clinical observation and expertise with high-quality research evidence (Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996, p. 71).

*Incentives*: Rewards to encourage certain behaviors and discourage alternatives are commonly used in behavior-change techniques (Prestwich et al., 2018). In the HITECH Act of 2009, which was intended to encourage use of electronic technologies in medical decision-making, incentives included payment increases for expanded use of, and payment decreases for failure to use, these technologies (Kibbe, 2010).

*Intention-to-treat*: In this approach to assessment of the effects of an intervention, data are analyzed based on the treatment to which an individual is assigned instead of the treatment received (Prestwich et al., 2018). This approach is distinguished from per protocol analysis, which is limited to those who receive or complete a course of treatment (Ranganathan, Pramesh, & Aggarwal, 2016).

*Intervention mapping*: In the development of behavior-change interventions that are both theory based and evidence based, an intervention mapping approach links constructs from psychological theory to problems, strategies, or interventions, relying on available research evidence (Prestwich et al., 2018).

*Medication-relevant CDS*: Medication-relevant CDS, as operationalized in this study, includes use of computerized prescription order entry and warnings of drug safety issues (see CDC, 2019b).

*Misuse:* Misuse of a prescribed medication is use other than that directed by a physician (Compton et al., 2018). By definition, off-label use as prescribed is not misuse.

*Patient-derived revenue*: As operationalized in this study, this term refers to receipt of income based on patient volume, such as from practice ownership, or satisfaction, such as from patient satisfaction surveys (CDC, 2019b).

*Potentially unsafe prescribing*: This term is used by health care organizations to indicate a medication treatment recommendation that has an elevated potential to result in harm or death (M. M. Jeffery, 2018; Williamson, 2018). For patients with CVD or SUD who are treated with some ADHD medications, potential safety risks occur because of neurochemical side effects (Faraone, 2018; Nissen, 2006).

*Theory-based intervention*: In contrast to an atheoretical intervention on health behavior, which is developed without consideration of psychological theory, a theorybased intervention relies on one or more psychological theories to identify behavioral determinants, target populations, or behavior-change techniques (Prestwich et al., 2018).

*Usability*: The usability of a technological device is defined as the degree to which people using the device in a particular environment or context are able to achieve their goals for use (Ratwani et al., 2016).

#### **Research Questions**

The first two research questions (RQs) addressed the associations of CDS and meaningful use, respectively, with the outcome measure. RQ3 addressed the comparison of the theory-based versus atheoretical models overall.

RQ1: What is the quantitative association of medication-related CDS in the practice environment with potentially unsafe prescribing of ADHD medications,

measured as a binomial, in a logistic regression model that accounts for knowledge construct variables?

 $H_01$ : (theory-based). Medication-related CDS is not significantly associated with potentially unsafe prescribing of ADHD medications.

 $H_{a}1$ : (atheoretical). Medication-related CDS is associated with decreased odds of potentially unsafe prescribing of ADHD medications, particularly for patients who have a medical condition with a black-box warning.

RQ2: What is the quantitative association of meaningful use in the practice environment with potentially unsafe prescribing of ADHD medications, measured as a binomial, in a logistic regression model that accounts for knowledge construct variables?

 $H_02$ : (atheoretical). Meaningful use is associated with decreased odds of potentially unsafe prescribing of ADHD medications.

 $H_a$ 2: (theory-based). Meaningful use is associated with increased odds of potentially unsafe prescribing of ADHD medications.

RQ3: Which model—that based on atheoretical interventions or that based on theory-derived predictors—better explains the binomial measure of potentially unsafe ADHD-medication prescribing, where better explanation is defined as coefficients in the expected direction, predictive accuracy measured with the c-statistic, and model fit measured with the –2LL statistic?

 $H_0$ 3: The atheoretical model better explains potentially unsafe prescribing of ADHD medications.

 $H_a$ 3: The theory-based model better explains potentially unsafe prescribing of ADHD medications.

#### Assumptions

A key assumption of this study was that the prescribing of a medication to a patient for whom it is potentially unsafe, according to federal guidelines (see FDA, 2002, 2007a), is suboptimal. This assumption does not indicate that all such prescriptions are unsafe, as the term *potentially unsafe* confers increased but not absolute risk. The assumption, which was necessary because not every evidence-based suggestion is appropriate for every patient (see Sackett et al., 1996), rests on the increased risk associated with some medications and on the availability of safer alternatives (see Bolea-Alamañac et al., 2014; Post & Kurlansik, 2012).

A second assumption was that intention-to-treat analysis is appropriate to measure the outcomes of CDS as an intervention that represents an expenditure of monetary and human resources. Consistent with an intention-to-treat approach, which has been used to study the association of CDS with quality of care in physician office visits (see M. J. Miller, Burns, Kapusnik-Uner, Carreno, & Matuszewski, 2017), no attempt was made to determine whether the CDS guidance was actually delivered to the physician or whether the physician read it (see Nanji et al., 2014). Instead, the intervention was defined as the presence of a CDS system with a feature intended to warn the physician of drug safety issues. This assumption was necessary because it is not feasible to measure every interaction between a physician and a medical device. Finally, I assumed that the medical risks associated with ADHD-medication use in patients with CVD and SUD occur regardless of whether the patient has ADHD. This assumption was reasonable because these risks are caused by neurochemical side effects, specifically the transmission of dopamine to a brain region associated with addiction and norepinephrine-triggered increases in heart rate and blood pressure (see Faraone, 2018; Nissen, 2006), which would logically be expected to occur regardless of the reason for medication usage. Moreover, the literature review for this study indicated no increase or decrease in ADHD-medication risk associated with off-label prescribing. This assumption was necessary because of increased prescribing of ADHD medications to adults who do not have a formal diagnosis of ADHD (see Olfson et al., 2014; Safer, 2016).

#### **Delimitations and Scope**

The scope of this study was national, representing adults who visited a U.S. office-based practice and received direct patient care from a medical doctor or doctor of osteopathy (see CDC, 2015a). For Scenario A, the scope included adults diagnosed with ADHD. For Scenario B, the scope included adults at risk of potentially unsafe prescribing because they had CVD or SUD (see CDC, 2002, 2007a). The scope of the outcome (dependent) variable was prescribing decisions made by physicians in those visits, not choices made by patients after they left the office (e.g., to overuse medication, give it to a third party, or obtain it elsewhere; see Compton et al., 2018).

The scope of the knowledge-based predictor (independent) variables in this study represented information that was known to the physician and included in the medical record. The scope did not represent information not available to the physician during the visit, or not recorded for another reason. Moreover, the study outcome represented potentially unsafe prescribing, not all types of potentially inappropriate prescribing. No attempt was made to determine whether a patient's symptoms warranted a prescription, which is a medical judgment that may rely on unobservable information. Additionally, because the potential benefits of E-HRs for patient care are widely accepted despite challenges that physicians face in using them (Schiff, Hickman, Volk, Bates, & Wright, 2016), no attempt was made to address the hypothetical question of whether E-HRs represent an improvement over paper record systems.

Finally, I assessed outcomes associated with interventions and environmental features currently present in the medical practice environment, not theory-based interventions that were suggested from the literature review but that have not yet been designed or implemented. As described in Chapter 5, findings of the literature review, coupled with results of the current study, suggested a need for additional theory-based assessments of practice-ownership and physician-employment structures, which were not directly studied in this research. Because the topic of using psychology-based strategies to promote evidence-based practice is relatively unexplored (Godin et al., 2008; R. Lau et al., 2016; L. Liang et al., 2017), the comparison of theory-based with atheoretical approaches in this study should be considered a first step.

#### **Study Limitations**

## **Internal Validity**

One important potential limitation of this study, similar to that of any quantitative research with an objective behavioral outcome measure, was a lack of direct information about psychological mediators, such as physician knowledge, cognition, or emotion, that a researcher might measure in a qualitative study or in a survey in which physician opinion constitutes the outcome. Similarly, results represent intention-to-treat estimated associations of interventions with the outcomes. Whether physicians received or read CDS-delivered guidance is unknown. Although this approach may have resulted in some loss of internal validity in characterizing the reasons for a potentially unsafe prescription, the approach enhanced external validity by making it feasible to study nationally representative data (see CDC, 2015a). In this respect, the methods of this study improved on those of physician surveys that included self-reported measures, which may be unreliable or biased (see Conner & Norman, 2017); that had low response rates without statistical adjustments for nonresponse (see Leslie et al., 2012; Shanafelt et al., 2016; Weeks et al., 2015); or that were based on convenience samples (see Goodman, Surman, Scherer, Salinas, & Brown, 2012).

An additional possibility was confounding by unmeasured factors, such as symptom severity, patient demands, or features of the practice office not included in study measures (see Warner, 2013). Providers who chose to participate in the meaningful use program may have systematically differed from nonparticipants (Grinspan et al., 2017), particularly on attitudinal factors such as agreement with guidelines (Cloutier et al., 2018; F. Fischer et al., 2016) or with their application to individual patient circumstances (Arts et al., 2016). This bias could have affected the associations of CDS and meaningful use with the outcome in this study. Although the measures of model quality used in this research provided information about the degree to which results were affected by this problem, the absence of confounding cannot be guaranteed with this or any nonexperimental design (see Warner, 2013).

An additional potential limitation on internal validity was the possibility of misclassification of exposure because of omissions of relevant data from the medical record (see Madden, Oakoma, Rusinak, Lu, & Soumerai, 2016). Examples include the provision of substance abuse counseling without a recorded diagnosis of SUD and the lack of a code for psychotherapy in visits made to mental health professionals. Although data transformations and sensitivity analyses were used to address these situations, the possibility remains that errors or omissions affected study results.

Potential limitations also arose because of small sample sizes for subgroups, particularly in Scenario A, which included only patients with ADHD. This situation was assessed using standard NCHS tests for statistical reliability estimation (see CDC, 2019b; Parker et al., 2017). Descriptions of quantitative findings include statistical precision of all estimates based on results of these tests.

## **External Validity**

One potential limitation on external validity was caused by an NCHS decision to allow participants in the 2016 NAMCS to submit E-HRs in lieu of on-site data collection, in partial fulfilment of two federal incentive payment systems, including meaningful use (CDC, 2019b). For reasons not fully described by the NCHS, these data, which "presented many processing challenges," were not included in the 2016 data set (CDC, 2019b, p. 2). Because the technological capabilities or practice patterns of physicians who chose E-HR data collection may have systematically differed from those of other participants, I performed sensitivity analyses excluding 2016. Although results suggested that findings were robust to this issue, the possibility remains that findings do not generalize to providers with more sophisticated E-HR systems, or to those who opted against on-site data collection for some other reason. Findings also do not generalize to surgical visits, which were excluded from this research, or to patients who were sent directly from the physician office to emergency care.

Additionally, it is possible that NAMCS participants systematically differed from nonparticipants despite previous research evidence of minimal nonresponse bias in physician surveys with low response rates (see McFarlane, Olmsted, Murphy, & Hill, 2007; Willis, Smith, & Lee, 2013; Ziegenfuss et al., 2012). During the study period, the NAMCS participation rate, defined as the percentage of sampled physicians who contributed at least one patient record, ranged from 29.5–39.3% (CDC, 2017, 2018, 2019b). An extensive validation study, conducted by the NCHS and described in Chapter 3, suggested minimal bias after weighting (Hing, Shimizu, & Talwalkar, 2016). Additionally, comparisons of study results with national data, described in Chapter 4, suggested good external validity. Nonetheless, the possibility of nonresponse bias cannot be completely ruled out.

#### Significance of the Study

The medical literature has implicated the incorporation of electronic technologies into the practice environment as a major or partial contributor to numerous outcomes that have the potential for negative impact on the health care system and the health of individuals: disengagement from patients (J. Levinson, Price, & Saini, 2017), professional burnout (Shanafelt et al., 2016), departure from the practice of medicine (Sinsky et al., 2017; Wright & Katz, 2018), and potential or actual medical harms (Howe et al., 2018; Schiff et al., 2015; Korb-Savoldelli et al., 2018). These concerns are supported by a substantial body of research evidence. The current study investigation of whether theory-based interventions on medical decision-making might represent an improvement over current approaches has the potential to benefit physicians and the health care system. More broadly, positive social change could result from encouraging a multidisciplinary approach to the study of medical decision-making and evidence-based practice promotion (see Djulbegovic & Guyatt, 2017) by engaging the unique capabilities of professionals working in the fields of psychology, health policy, and medicine (see Holden, Binkheder, Patel, & Viernes, 2018; Ray et al., 2019). Study findings suggested several potential roles for health psychologists in these endeavors, which are described in Chapter 5.

Additionally, the medical decision examined in this research, potentially unsafe ADHD-medication prescribing, may be understudied relative to its population-health implications. Although psychostimulants other than cocaine caused only 12% of U.S. drug-overdose deaths in 2016, the rate of increase from 2015 to 2016 in overdose deaths

from these substances (33%) was triple that of prescribed opioids (11%; Seth et al., 2018). Recognizing these risks, the CDC recently added stimulants to its drug surveillance protocols (Kariisa, Scholl, Wilson, Seth, & Hoots, 2019). By providing information about predictors of potentially unsafe ADHD-medication prescribing, this study may inform efforts to mitigate the problem, thereby benefiting patients treated in U.S. medical practice.

## **Summary**

In this quantitative study, I compared theory-based with atheoretical approaches to explaining a non-evidence-based medical decision with potentially substantial effects on population health. The theory-based approach reflected physician training, professional norms, and cognitive demands of CDS and E-HRs, as recorded in a large body of qualitative and quantitative research. The theory-based approach also reflected an assessment of whether physicians value E-HRs and the guidance provided by CDS, an important determinant of the effects of meaningful use incentives, according to selfdetermination theory. All statistical models accounted for physician specialty and patient characteristics that may affect ADHD-medication prescribing decisions.

In Chapter 2, I describe the study's theoretical frameworks in more detail and assess potential linkages between those frameworks and medical decision-making. The remainder of Chapter 2 addresses research relevant to three key constructs of social cognitive theory: knowledge, cognition, and environmental influence. The review of knowledge covers the specific treatment choices made during an ADHD-medication prescribing decision and the limitations on information available during the decisionmaking process. The review of cognition includes a description of medical training and professional norms. At the intersection of cognition and the environment are evidencebased decision-making and barriers to it. Environmental factors reviewed include CDS, meaningful use, and other incentives. The chapter concludes with summaries of gaps in the literature and of theory-based and atheoretical perspectives on environmental influences affecting medical practice.

#### Chapter 2: Literature Review

Despite widespread support for principles of evidence-based medicine among U.S. physicians (Blanco et al., 2014; Chan et al., 2017), treatments prescribed in routine practice commonly differ from those recommended in evidence-based guidelines (Baker et al., 2015; R. Lau et al., 2016). The widespread adoption of E-HRs in U.S. medical practices that resulted from implementation of the HITECH Act (Gabriel & Swain, 2014), although intended to improve patient health by aligning routine care with research evidence (Bates et al., 2003), produced unintended consequences (Brown et al., 2017; Colligan et al., 2016; Ratwani et al., 2019; Shanafelt et al., 2016). These outcomes have been attributed by some observers to failure to consider psychological theory or evidence, particularly from human-factors research (Ratwani et al., 2016; Savage et al., 2017), in developing E-HR systems. Similar concerns have been expressed about the psychological effects of strategies that pay physicians to perform according to externally determined metrics (Himmelstein et al., 2014; Kao, 2015), such as meaningful use incentives.

As atheoretical behavior-change interventions (Cho & Bates, 2018), CDS and the HITECH Act were typical of policies intended to improve medical decision-making (Jäger et al., 2016; R. Lau et al., 2016; L. Liang et al., 2017). Whether use of a theoretical basis in designing these interventions might represent an improvement over current approaches is an understudied question. As a preliminary step in addressing that question, this quantitative study was conducted to compare atheoretical and theory-based models of potentially unsafe ADHD-medication prescribing (see Fairman et al., 2018). Study results may effect positive social change both for physicians who are affected by interventions on their medical decisions and for adults who are prescribed ADHD medications.

The order of sections in this chapter was based on three core tenets of the study's primary theoretical framework, social cognitive theory: knowledge, cognition, and environmental influence (see Bandura, 1989, 1999; Kelder et al., 2015). After explaining the literature search strategy, theoretical framework, and evidence regarding the study dependent variable (DV, outcome) measure, I discuss knowledge available to physicians about ADHD medications and safety issues. Then I consider cognition: how physicians are trained to make decisions and the occupational values and norms that influence their decision-making. I discuss evidence-based medical practice as an interaction of cognition and environment, describing barriers to evidence-based practice and evaluating whether the provision of knowledge, the core function of CDS, might reasonably be expected to mitigate those barriers. I then discuss two key environmental influences on the medical practice environment, CDS and meaningful use provisions, explaining the rationale for these policies and describing physician experiences with them. Because study hypotheses about CDS were based in part on evidence available at the time the HITECH Act was developed, I distinguish early (pre-2012) from postimplementation experiences. The chapter concludes with summaries of the literature on CDS and meaningful use, set within the current study's theoretical frameworks, and of gaps in the literature addressed by this research.

## **Literature Search Strategy**

As shown in Figure 1, the systematic strategy used to search the literature encompassed the following topics and sources: (a) theoretical frameworks (PsycARTICLES); (b) medical information about ADHD, ADHD medications, and outcomes of CDS and E-HRs (PubMed); (c) physician cognition and decision-making (PsycARTICLES, PsycINFO, Academic Search Complete); (d) key policy documents and position white papers (Google); and (e) purposive searching for works by key opinion leaders (varied sources).

(a)	(b)	(c)	(d,e)
PsycARTICLES for Theoretical Framework	PubMed for Medical Research	PsycARTICLES, PsycINFO, and Academic Search	Google for Key Policy Documents
Subject terms physicians or prescribers with behavioral economics, extrinsic rewards, Deci, or financial rewards in text	ADHD and substance abuse ADHD and practice guidelines and adult	Complete for Decision- Making Psychology Subject terms prescribing, therapeutic process, and physicians	Meaningful use or computerized decision support or CDS with Centers for Medicare & Medicaid Services, Congressional Budget Office, Office of Inspector General, or Institute of Medicine
Deci or Bandura as authors Subject terms physicians and occupational stress	CDS, EHR (E-HR), or CPOE and meaningful use with opioids, benzodiazepines, methylphenidate, amphetamine, and controlled substances	Subject terms inappropriate medication or prescribing and physician-patient relationship or patient expectations Subject terms physicians and prescribing with attitudes in text	Federal prescribing guidance for ADHD medications <b>Purposive Searching for</b>
Subject terms physicians and occupational satisfaction or job satisfaction	CDS with knowledge base content, prescribing, and drug-disease interaction	Subject term physician and attitudes and electronic health records in text (U.S. studies only)	Key Opinion and Research Leaders Reference sections of
Subject terms physicians and occupational stress and drug- seeking	CDS, EHR (E-HR), or meaningful use with National Ambulatory Medical Care Survey	Subject prescribing (drugs) with theory or Bandura or Deci in full text Subject terms guidelines and evidence-based medicine	governmental documents for underlying evidence supporting "meaningful use" initiative
Subject terms physicians, treatment, and autonomy	Meaningful use with clinical outcomes or quality of care	with barriers, enablers, implementation, or acceptance Subject terms medical students and medical decision making; medical education and curriculum and medical	By author for two highly active investigators (Ratwani, Schiff) American Medical Association
	Pay for performance Evidence-based medicine interventions	decisions or educational objectives Subject terms prescribing and physicians and evidence- based in text	website for proposed E-HR modification policies Websites of accrediting bodies for
	Evidence-based prescribing	Subject terms drug abuse or drug misuse and adulthood, predictors in text	medical education and training Searches of reference sections, review articles

*Figure 1*. Literature search strategy. ADHD = attention-deficit hyperactivity disorder; CDS = computerized decision support; CPOE = computerized prescription order entry; E-HR = electronic health record.

Most searches were limited to 2010 or later. Exceptions included the following:

(a) searches on the rationales for CDS and meaningful use policies, which covered

approximately 10 years prior to HITECH Act passage (see U.S. Congressional Budget

Office [CBO], 2008); (b) information about adult ADHD and inappropriate use of stimulants, which covered primarily the past 3 years because research attention to these topics is recent (see Compton et al. 2018; Fields, Johnson, & Hassig, 2017; Kooij et al., 2019; McCabe et al., 2019); and (c) theoretical texts. Literature regarding features of E-HR technologies was limited to the United States to reflect state of practice for U.S. settings.

#### **Theoretical Frameworks**

Prescribing is a cognitive activity that is intended to be information based and rational but may be context dependent and constrained by environmental influences (Djulbegovic & Elqayam, 2017). A theoretical framework for prescribing decisions should encompass (a) informational inputs, (b) the way those inputs are processed cognitively, and (c) environmental influences on the cognitive process. The theories chosen were social cognitive theory and self-determination theory.

## **Social Cognitive Theory**

Social cognitive theory is grounded in a core assumption that human action is characterized by emergent interactive agency, neither completely independent of, nor completely determined by, environmental influence (Bandura, 1989). The framework presents individuals as constantly engaging with their environments, both acting on them and being acted upon by them, in a process of triadic reciprocal causation that encompasses mutual interactions among individual (emotional or cognitive), behavioral, and environmental events. Although the theory acknowledges environmental constraints that may be "thrust upon people whether they like it or not," the theory also suggests that humans respond to these constraints with personal agency in an ongoing process of adaptation (Bandura, 1999, p. 23). Humans engage in forethought about various courses of action; form intentions, which are plans and strategies; act in a way that is expected to provide satisfaction; and monitor the outcomes of those actions, adjusting future cognition and behavior accordingly (Bandura, 1989; Bandura & Locke, 2003).

Outcome expectations, knowledge, and the environment. According to social cognitive theory, human actions are based on outcome expectations, a theoretical construct that refers to the anticipated effects of decisions (Bandura, 1989; Kelder et al., 2015). These expectations are derived from a cognitive process that accounts for knowledge, which includes both the expertise and the information necessary to perform a behavior, and environmental influences. In prescribing, relevant knowledge includes proficiency in medical practice derived from medical training (Mowery, 2015) and information about the patient, such as symptoms, clinical complexity, or other factors that affect the potential benefits or risks of the prescription (Anderson et al., 2014; Gupta & Cahill, 2016; Pérez de los Cobos, Siñol, Pérez, & Trujols, 2014). Environmental influences, which are facilitators and barriers to various actions (Kelder et al., 2015), may in the medical practice office include tools that provide information, such as CDS (Cho & Bates, 2018); input from other providers or from patients (Donohue et al., 2018; Sirota, Round, Samaranayaka, & Kostopoulou, 2017); or financial or nonfinancial rewards for specific behaviors (Heisey-Grove & Patel, 2014; Tak et al., 2017).

**Application of social cognitive theory to study topic**. As noted in Chapter 1, cognitive theories have seldom been applied to the study of medical decision-making

(Godin et al., 2008). Nonetheless, as will be shown throughout this chapter, four constructs of social cognitive theory are helpful in explaining physician behavioral response, this study's outcome (DV), to E-HR-delivered CDS, the independent variable (IV, predictor) in RQ1. The first two constructs are occupational self-regulation (Bandura, 2001) and moral agency (Bandura, 1999). These constructs represent the ways that human beings regulate their behavior in accordance with occupational norms, forming what Bandura (2001) described as a "personal identity" (p. 15) around work. Application of these constructs to this study derived from an inconsistency between the ways that physicians are trained to think, as a part of their occupational identity, and the changes to the practice environment brought about by CDS and E-HRs (see Berkhout et al., 2018; Colligan et al., 2016; Friedberg et al., 2013; Shanafelt et al., 2016).

The third construct is self-efficacy, referring to the degree to which humans perceive themselves as capable of executing certain behaviors (Bandura & Locke, 2003). Self-efficacy for medical practice is developed in physicians through a rigorous training process (Mowery, 2015) that is discussed in the section on medical training. Application of this construct to this study derived from an inconsistency between the tasks for which physicians are trained to have self-efficacy (see Berkhout et al., 2018) and the cognitive demands introduced by CDS and E-HRs (see Ratwani et al., 2016).

The fourth construct is emergent interactive agency (Bandura, 1989). The literature review for this study indicated inconsistencies between the expectations of E-HR system proponents (see Bates et al., 2003; Blumenthal & Tavenner, 2010) and the sometimes unexpected ways in which physicians have responded to these systems (see Nanji et al., 2014; Slight et al., 2016; Wright et al., 2018). In theoretical terms, physicians adapted to E-HR-related environmental changes with the human agency described by Bandura.

**Potential limitation of theory to explain prescribing**. Social cognitive theory does not alone indicate whether a given environmental influence is a facilitator or barrier. Rather, social cognitive theory provides a structure of constructs to which various environmental features may be mapped (i.e., linked) in a theory-based model (see Prestwich et al., 2018). A potential limitation of social cognitive theory for a model of prescribing decisions, the outcome (DV) in this study, is that it does not address competition among the various types of environmental incentives that may influence the outcome expectations of physicians. Different incentives—such as financial rewards for using CDS (Heisey-Grove & Patel, 2014), satisfied patients (Tak et al., 2017), or revenue derived from volume of patient business (Kao, 2015)—could produce different choices. Therefore, theory-based hypotheses about prescribing must address not only whether incentives affect behavior, but also the expected direction of influence. Selfdetermination theory helps resolve this dilemma by pointing to the importance of type of motivation in determining the effects of incentives on psychological well-being and task performance (Deci & Ryan, 2008a).

## **Self-Determination Theory**

Self-determination theory is built on a foundational assumption that human beings have universal needs for competence, autonomy, and relatedness with others (Deci & Ryan, 2008a). Motivators that meet these needs will improve task persistency, task

performance, and psychological health. A key consideration in determining these outcomes is whether motivation is autonomous or controlled.

Autonomous motivation, which improves task performance and psychological health, is associated with rewards that are intrinsic, that is, inherent to an activity, such as enjoyment of a task (Deci & Ryan, 2008b). In contrast, controlled motivation, which damages task performance and psychological health, is associated with rewards that are extrinsic, that is, both tangible (e.g., money, grades in school) and contingent on criteria determined by others. However, the theory does not suggest a simple motivational dichotomy. Instead, subtypes of motivation lie on a continuum from more to less selfdetermined, based on the degree to which a reward structure is consistent with an individual's values (Deci & Ryan, 2008b; Prestwich et al., 2018).

Autonomous motivation may result not only from intrinsic rewards, but also from extrinsic reward systems that reflect values with which an individual identifies as a core aspect of self, a subtype of autonomous motivation known as integrated motivation, or from rewards that reflect a valued outcome, a subtype known as identified motivation (Deci & Ryan, 2008b; Prestwich et al., 2018). In work contexts, environmental inputs that are viewed as informational, meaning they foster a perception of "choice and personal initiative," increase the sense of self-determination and thereby autonomous motivation (Deci & Ryan, 1985; Deci, Connell, & Ryan, 1989, p. 580). In contrast, work-environment inputs that signify externally determined pressure, such as threats of penalties or behavioral surveillance, foster a sense of controlled motivation (Deci & Ryan, 2008b).

Consistent with the concept of a motivation continuum, occupational or scholastic rewards linked to level of task performance, such as exceeding standards achieved by peers, may have neutral or positive effects on motivation and performance (Cameron, Banko, & Pierce, 2001; Deci, Koestner, & Ryan, 1999). Only rewards that communicate "task triviality" produce negative outcomes (Eisenberger, Pierce, & Cameron, 1999, p. 677). In a study conducted in one corporation, allowing workers opportunities for choice and initiative was associated with improved occupational satisfaction if basic working conditions (e.g., pay, benefits) were satisfactory (Deci et al., 1989). Despite these applications to work settings, no studies in which researchers applied self-determination theory to the promotion of evidence-based practice were identified in the current literature review, although the theory has been applied to suggest that extrinsically determined financial incentives may diminish intrinsic motivation for medical practice (Himmelstein et al., 2014; Kao, 2014).

Considered together, these findings suggest that the more an individual identifies with the values and outcomes associated with a reward system, the more that system is likely to meet the needs for competence and autonomy. The key question in determining type of motivation is not so much whether rewards exist, but the degree to which those rewards represent values with which the "true or integrated self" would have identified regardless of the reward (Deci & Ryan, 2008b, p. 16). Applying this question to the current study topic, the theory suggests that prescribing-behavior response, the study outcome (DV), to the extrinsic rewards offered in meaningful use incentives, the study predictor (IV) in RQ2, would depend on physician assessments of the value of meaningful use. For physicians to see meaningful use as valuable would require that the standards they use to assess their task performance match those implicit in the technology promoted by meaningful use. This question is addressed in this chapter with assessments of how physicians are trained for decision-making, which is the primary task in the medical practice environment, and with evidence about their experiences in performing that task using the electronic tools promoted by the HITECH Act. Before turning to those topics, I describe literature on the specific task that is this study's outcome measure (DV): the decision of whether to prescribe a potentially unsafe ADHD medication to an adult.

#### **Adult ADHD Symptoms and Treatments**

ADHD is a chronic condition characterized by symptoms that fall into two broad domains: (a) inattention (e.g., forgetfulness, carelessness) and (b) hyperactivity or impulsivity (e.g., fidgeting, impatience; Kooij et al., 2019). Among those aged 17 years or older, a formal diagnosis of ADHD requires at least five symptoms, which may present in a combined type across both domains, of which "several" must have been present before aged 12 years (American Psychiatric Association, 2013, p. 33). Symptoms should impair functioning in more than one setting, such as both home and work, and should not be better explained by a different diagnosis, such as a mood disorder or psychosis.

Although classified in treatment guidelines as neurodevelopmental and genetically inheritable, ADHD is associated with few consistent neurobiological characteristics or symptoms (Kooij et al., 2019; Mahone & Denckla, 2017). Complicating diagnosis, ADHD symptoms often overlap with those of other disorders (Asherson, Buitelaar, Faraone, & Rohde, 2016). For example, ADHD shares with anxiety disorders, symptoms of restlessness and mind-wandering; with depression, symptoms of irritability, diminished concentration, and lowered self-esteem; and with bipolar disorder, symptoms of restlessness, mood lability, and lack of mental focus. One guideline describes ADHD as "an umbrella term for a range of different but related pathophysiological entities" (Bolea-Alamañac et al., 2014, p. 183) for which no reliable physiological test exists (Kooij et al., 2019). In patients with SUD, the diagnostic process is even more complicated because symptoms of both disorders, such as poor impulse control, overlap (Fatseas, Debrabant, & Auriacombe, 2012; Mao & Findling, 2014) and because patients may feign symptoms to obtain stimulants (Clemow & Walker, 2014).

#### **Treatment Options for Dependent Variable: ADHD Medications and Therapies**

Medications currently approved by the FDA to treat ADHD are summarized in Table 1. These options informed the outcome (DV) measure in this study, potentially unsafe versus safer treatments. As shown in the table, all ADHD medications work by increasing the availability in the brain of one or both of two neurotransmitters, dopamine and norepinephrine, that are thought to play key roles in ADHD symptoms (Bolea-Alamañac et al., 2014). The two types of potentially unsafe prescribing, the outcome (DV) in this study, arise from side effects of these neurotransmitters. As explained in Chapter 1, these neurotransmitter-related side effects would be expected to occur regardless of whether the patient has been diagnosed with ADHD, although only anecdotal evidence about off-label use is available (Lakhan & Kirchgessner, 2012).

# Table 1

Medications Approved	for Attention-Deficit Hyperactivity Disorder

Name	Mechanism of action	Treatment considerations
Amphetamines	<ul> <li>Increases availability of dopamine and norepinephrine by blocking reuptake and decreasing breakdown in neuronal synapses<sup>a</sup></li> <li>Increases release of dopamine from neurons<sup>a</sup></li> </ul>	<ul> <li>Black-box warning for abuse and dependence<sup>b</sup></li> <li>Extended-release formulations may have reduced abuse potential<sup>c</sup></li> <li>Should not be used in serious CVD<sup>b</sup></li> </ul>
Atomoxetine	• Increases norepinephrine availability by blocking reuptake <sup>c</sup>	<ul> <li>No known abuse potential<sup>d</sup></li> <li>Preferred for those with abuse risk<sup>c,d,e</sup></li> <li>May be somewhat less effective than stimulants (mixed evidence)<sup>c,f</sup></li> <li>Slower onset of action than stimulants<sup>c</sup></li> <li>Should not be used in serious CVD<sup>d</sup></li> </ul>
Clonidine as brand Kapvay <sup>g,h</sup>	• Agonist (stimulating) effect at $\alpha_{\text{-}2A}$ adrenergic receptors <sup>i</sup>	<ul> <li>No known abuse potential<sup>h</sup></li> <li>Use with caution: hypotension, bradycardia, heart block, severe CVD, or kidney failure<sup>h</sup></li> </ul>
Guanfacine as brand Intuniv <sup>gj</sup>	• Agonist (stimulating) effect at $\alpha$ -2A adrenergic receptors <sup>g</sup>	<ul> <li>No known abuse potential<sup>j</sup></li> <li>Use with caution: hypotension, bradycardia, syncope<sup>j</sup></li> <li>No other known cardiovascular considerations<sup>j</sup></li> </ul>
Lisdexamfetamine <sup>k</sup>	• Increases availability of dopamine and norepinephrine by blocking reuptake, decreasing breakdown in neuronal synapses, and increasing release <sup>k</sup>	<ul> <li>Black-box warning for abuse and dependence<sup>k</sup></li> <li>Prodrug formulation thought to make it less abusable than other stimulants<sup>c,f</sup></li> <li>Should not be used in serious CVD<sup>k</sup></li> <li>Unlike other ADHD medications, has a dual indication for binge-eating disorder<sup>k</sup></li> </ul>
Methylphenidate <sup>l</sup>	<ul> <li>Increases availability of dopamine and norepinephrine by blocking reuptake<sup>a</sup></li> <li>Activates α-2 adrenergic receptors<sup>a</sup></li> </ul>	<ul> <li>Black-box warning for abuse and dependence<sup>1</sup></li> <li>Extended-release formulations may have reduced abuse potential<sup>c</sup></li> <li>Should not be used in serious CVD<sup>1</sup></li> </ul>

*Note.* ADHD = attention-deficit hyperactivity disorder; CVD = cardiovascular disease; FDA = Food and Drug Administration.

<sup>a</sup>Faraone (2018). <sup>b</sup>Teva Pharmaceuticals (2017); FDA (2007a). <sup>c</sup>Bolea-Alamañac et al. (2014). <sup>d</sup>FDA (2002). <sup>e</sup>Post and Kurlansik (2012). <sup>f</sup>Kooij et al. (2019). <sup>g</sup>For clonidine and guanfacine, brand names are shown because these formulations are approved for ADHD, and other brands are for hypertension (Jain, Hiremath, Michael, Ryan, & McMahon, 1985). <sup>h</sup>FDA (2010). <sup>i</sup>Bidwell, Dew, and Kollins (2010). <sup>j</sup>FDA (2013). <sup>k</sup>FDA (2007b). <sup>l</sup>Novartis (2019).

**Types of potentially unsafe prescribing measured in study DV**. The first safety concern with ADHD medications arises because stimulant-produced increases in dopamine availability in the central nervous system take place not only in target brain regions, such as the prefrontal cortex, but also in the nucleus accumbens, a brain region commonly implicated in addictive behaviors (Faraone, 2018). For this reason, stimulants are controlled substances (Clemow & Walker, 2014). All FDA product labels for stimulants (FDA, 2007a; Novartis, 2019) contain black-box warnings, so named because they appear surrounded by a prominent black rectangle to indicate "serious or lifethreatening risks" (FDA, 2012, p. 1), for SUD. These risks are considered greater for immediate- than extended-release formulations (Bolea-Alamañac et al., 2014; Fields et al., 2017), although even an extended-release action may be bypassed by parenteral abuse, such as crushing or dissolving a tablet to sniff or inject the active ingredient (Morton & Stockton, 2000; Novartis, 2019). One stimulant product with reduced abuse potential (Kooij et al., 2019) is lisdexamfetamine, which is a prodrug (FDA, 2007b), meaning it does not become pharmacologically active until after it is digested and metabolized (Advokat, Comaty, & Julien, 2014).

The second safety concern arises because increases in norepinephrine availability resulting from use of either stimulants or atomoxetine increase blood pressure and heart rate (Kooij et al., 2019). Although small and clinically unimportant on average, at a population level, these changes are potentially clinically significant for patients at elevated risk of cardiovascular events, such as those with CVD (E. F. Liang et al., 2018; Martinez-Raga, Ferreros, Knecht, Alvaro, & Carabal, 2017), particularly among the

estimated 5–15% of treated patients who experience unusually large increases in heart rate or blood pressure (Hammerness, Karampahtsis, Babalola, & Alexander, 2015). Accordingly, product labels for stimulants warn that because serious cardiovascular events, including sudden death, heart attack, and stroke, have been reported in adults taking "recommended doses" of these medications, they should be avoided in those with "known structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, and other serious heart problems" (Novartis, 2019, p. 3). The warning for atomoxetine is similar (FDA, 2002).

**Evidence-based recommendations for patients with risk factors**. The operationalized outcome (DV) measures in this study, which are described in Chapter 3, reflected evidence-based guidelines for treatment options in patients with CVD or SUD. These guidelines suggest that for patients with medical conditions that would make one ADHD treatment potentially unsafe, similarly effective alternatives are available, including safer medications and behavioral therapies. These alternatives are presented below for each type of risk.

*SUD*. Although the topic of ADHD-medication treatment for patients with SUD is somewhat controversial (Carpentier & Levin, 2017; Pérez de los Cobos et al., 2014; Faraone, 2018), treatment guidelines available during the study period were consistent with FDA prescribing guidance in recommending against use of stimulants in patients at risk of medication abuse (FDA, 2007a, 2007b). Three guidelines in effect during or immediately after the current study period all recommended atomoxetine for these patients (Bolea-Alamañac et al., 2014; Fields et al., 2017; Post & Kurlansik, 2012). One also mentioned the nonstimulants clonidine and guanfacine as treatment options without specifically recommending them for patients with SUD (Bolea-Alamañac et al., 2014). Evidence on potential use of the stimulant prodrug, lisdexamfetamine, for patients with SUD was emerging during the study period (Bolea-Alamañac et al., 2014) and was eventually incorporated into one recent European guideline (Kooij et al., 2019) but not into FDA (2007b) prescribing information.

*CVD*. Guidance about CVD risks was somewhat equivocal during the study period. Like FDA-approved product labels (FDA, 2002, 2007a), one guideline published during the first year of the current study period (Bolea-Alamañac et al., 2014) recommended a thorough history and physical examination, cardiovascular testing if initial screenings indicate potential disease, and monitoring during treatment for symptoms of cardiac problems. However, guidance from the American Academy of Family Physicians did not recommend CVD risk assessment (Post & Kurlansik, 2012). Medication options for patients with CVD include guanfacine (Bolea-Alamañac et al., 2014) and clonidine, but neither should be used in patients with certain serious cardiovascular or kidney conditions (FDA, 2010, 2013).

*Either CVD or SUD*. An additional treatment option for patients with CVD or SUD is cognitive behavioral therapy, such as mindfulness or skills training (Jensen, Amdisen, Jørgensen, & Arnfred, 2016; Knouse, Teller, & Brooks, 2017). Although behavioral treatments are generally recommended for use with medication, rather than as a substitute for it (Bolea-Alamañac et al., 2014; Fields et al., 2017; Post & Kurlansik, 2012), the authors of one recent guideline noted that for patients who do not "desire or tolerate" medication, behavioral therapy may be optimal (Kooij et al., 2019, p. 25). Published results for behavioral strategies are consistent with these recommendations, suggesting positive outcomes (Arnold, Hodgkins, Caci, Kahle, & Young, 2015), with treatment effect sizes comparable to those of amphetamines (Castells, Blanco-Silvente, & Cunill, 2018; Knouse et al., 2017; Lopez et al., 2018).

# **ADHD-Medication Knowledge Gaps and Safety Problems**

A few studies have suggested that prescriptions for ADHD medications do not consistently comport with evidence-based safety guidelines, perhaps because of gaps in knowledge. One survey, conducted with a Web-based convenience sample of physicians, suggested a lack of confidence in diagnosing and treating ADHD, with 8% of primary care physicians and 27-28% of psychiatrists rating themselves as "extremely confident" in these activities (Goodman et al., 2012). In vignette-based knowledge tests, rates of recognition of SUD were generally high at 76% of primary care physicians and 82% of psychiatrists. However, only 33% of primary care physicians and 44% of psychiatrists recognized the need for a cardiovascular assessment or treatment change when a patient develops symptoms suggesting CVD. Confidence in managing a patient with CVD was generally low, at 5% of primary care physicians and 13% of psychiatrists. Another selfreport survey, based on a national probability sample of psychiatrists with a response rate of 40%, measured cardiac assessments prior to stimulant prescribing for pediatric ADHD (Leslie et al., 2012). Although nearly all respondents reported obtaining a medical history (96%), and most (71%) obtained vital signs, 26% reported no physical examination, by themselves or by another physician, prior to writing the prescription.

A limitation of both physician surveys was their reliance on self-reported behavior. Stronger evidence was provided by two studies of objective behavioral measures. Gerhard et al. (2010) examined the association of cardiovascular risk with prescribing choice, using a retrospective analysis of a claims (medical and pharmacy billing) database, in a large (n = 8,752) sample of commercially insured patients aged 21– 64 years diagnosed with ADHD in 2006 or 2007. The investigators found that stimulant prescriptions were filled by 41% of patients with and 53% of those without CVD, suggesting some risk awareness. However, this effect was observed only in younger adults, not in those aged 46–64 years, and was not observed for atomoxetine.

Fairman et al. (2018) used the same database but a different design, examining prevalence of SUD, CVD, and serious CVD—defined as pacemaker-controlled arrhythmia, cardiomegaly, cardiomyopathy, cerebrovascular disease, congestive heart failure, myocardial infarction, or a heart valve disorder—in patients aged 18–64 years (n= 91,588) newly treated for ADHD with either atomoxetine or a stimulant in 2014–2015. These investigators found that in the one year prior to the first prescription, the prevalence of SUD in the subgroup of stimulant-treated patients was 11–19%, depending on how SUD was defined. Although rates of CVD were generally low for the sample overall, only 6% for all CVD and 2% for serious CVD, these rates increased with older age, reaching 16% for any CVD and 7% for serious CVD among those aged 55–64 years.

An important limitation of the studies by Fairman et al. (2018) and by Gerhard et al. (2010) is that neither included the growing population of patients prescribed ADHD medications without an ADHD diagnosis (Olfson et al., 2013; Safer, 2016). Mitigating

this limitation, similar findings were produced by an analysis of National Survey on Drug Use and Health (NSDUH) household-interview data for 2015–2016 (Compton et al., 2018). In the NSDUH, 5% of adult respondents who reported heart disease indicated past-year use of prescribed stimulants; and use rates were high among persons with SUD: 18% among those with alcohol use disorder; 26% and 34% with misuse of prescribed opioids and sedatives, respectively; and 33-34% with use of cocaine or heroin. In addition to these rates, which indicated any prescribed stimulant use, rates of misuse, expressed as a proportion of all prescribed stimulant use, were considerably elevated in adults with SUD, ranging from 58–66% among those with use disorders for alcohol, prescribed opioids or sedatives, or cannabis. NSDUH findings also suggested that the likelihood of obtaining medication from a physician, rather than from a family member or friend, increased with degree of misuse (ranging from 7% of those with 1-2 days of pastmonth misuse to 25% with  $\geq$  7 past-month misuse days) and was highest (38%) in those with SUD. These findings, together with those of the database studies, suggest that patients for whom an ADHD medication is potentially unsafe are nonetheless commonly able to obtain that medication from a physician.

Because physicians are trained to seek and use scientific evidence in making medical decisions (Berkhout et al., 2018), a key question in ADHD-medication prescribing is the degree to which the consequences of potentially unsafe prescribing are reported in the research literature. Like the evidence-based guidelines described previously, the research literature contains more definitive information for SUD than for CVD. Specifically, public health alerts documented a 3.5-fold increase in the number of U.S. emergency visits made by adults aged 18 years or older for nonmedical use of ADHD medications from 2005 to 2010 (U.S. Substance Abuse and Mental Health Services Administration, 2013), and a 32% increase in the rate of overdose from stimulants excluding cocaine for those aged 24 years or older from 2015 to 2016 (Seth et al., 2018). The medical literature also reported challenges in medical management of stimulant overdose because no antidote agent exists (Fulde & Forster, 2015; Spiller et al., 2013). Despite the availability of this knowledge, its salience may have been offset by competing risk information. Some researchers have suggested that attention to opioid misuse has diverted public health focus away from the also-substantial risks of abusing stimulants and sedatives (McCabe et al., 2019). For this reason, awareness of SUDassociated ADHD-medication risks may have been limited during the study period.

For CVD-associated ADHD-medication risks, the base of published research evidence is even more limited. Based on studies demonstrating no increased populationlevel cardiovascular event risk from ADHD-medication treatment of adults (Martinez-Raga et al., 2017), the medications are generally perceived as safe (Kooij et al., 2019; Kratochvil, 2012). However, this population-level base of evidence provides limited information about event rates in higher-risk patients (Jackson, 2016; Mick, McManus, & Goldberg, 2013). The only study of that question identified in this study's literature review was conducted in a sample of children who developed a new heart rhythm disorder during treatment with methylphenidate (Shin, Roughead, Park, & Pratt, 2016). Consistent with warnings against use in patients with CVD (Jackson, 2016), a temporal association between arrhythmia onset and treatment initiation (incidence rate ratio [IRR] = 1.61 for the first 2 months of use), was particularly pronounced in children with congenital CVD (IRR = 3.49).

Several patterns in use of stimulants by adults—rapidly growing prevalence, ageassociated elevations in cardiovascular risk, and evidence that fatalities had occurred in patients with CVD not identified until autopsy—led the Drug Safety and Risk Management Advisory Committee of the FDA to recommend black-box warning status for cardiovascular event risks on stimulant product labels (Nissen, 2006). However, the FDA overrode the recommendation. Other than a black-box warning for cardiovascular events in amphetamine overdose (Teva Pharmaceuticals, 2017), these risks are currently given only a standard warning, not the more salient black-box caution. Despite this decision, a recent draft of proposed FDA (2019) guidance for pharmaceutical manufacturers would, if implemented, require studies of cardiac safety during the stimulant drug-development process, to include evaluations of heart-rhythm changes and dose-response assessments of heart rate and blood pressure.

#### Summary: Uncertainty in the Prescribing of ADHD Medications to Adults

As a disorder that shares symptoms with other prevalent psychiatric conditions, ADHD is difficult to diagnose and treat, especially in patients with SUD. Moreover, concerns about medication-associated risks, although based in evidence, may not be fully understood. Heightening these challenges, use of ADHD medications by adults has increased rapidly in the past 20 years (Fairman et al., 2017; Olfson et al., 2013). From the perspective of the treating physician, these patterns may represent an important source of uncertainty about which evidence-based prescribing guidance is available but not readily synthesized—exactly the circumstance that CDS is intended to address (Bates et al., 2003). However, the degree to which CDS can improve decision-making may depend on its alignment, as an environmental strategy, with the way that physicians are trained to think and make decisions. This topic is discussed in the next section.

#### Medical Education and Occupational Identity

Medical education, and the occupational norms and values resulting from it, reflect three core themes that have remained consistent since 1910, the date of a pivotal curriculum-development document, the *Flexner report* (Cooke et al., 2006; Schrewe, 2013). The foremost theme is professional autonomy. In 1915, Flexner noted that the primary characteristic of a profession, such as medicine or law, was a "free, resourceful, and unhampered intelligence applied to problems and seeking to understand and master them" (Flexner, 1915, para. 7). This theme repeats throughout training, which lasts for 7 to 11 years after college graduation (Mowery, 2015). A core objective of medical-school education is the promotion of lifelong, self-regulated patterns of learning that will translate across clinical circumstances (Berkhout et al., 2018). The foremost goal described by the accrediting body for postgraduate training is that physicians should be able to make high-quality decisions about patient care with "autonomy and independence" (ACGME, 2019, para. 5). Final training outcomes include a licensing examination that assesses capability for "unsupervised" practice (U.S. Medical Licensing Examination [MLE], 2019, para. 1) and assessment of entrustable professional activities, which are tasks to be performed without direct supervision (ten Cate, 2013).

The second and third goals of medical education, biomedical expertise (Schrewe, 2013) and devotion to patients (Cooke et al., 2006), are linked. In the vision espoused by Flexner, expertise, to be acquired in programs characterized by rigorous empiricism (Schrewe, 2013), was intended to be applied to the well-being of patients and the public (Flexner, 1915). Consistent with this goal, an editorial published in a high-impact medical journal to commemorate the *Flexner* centennial noted that medical education should inculcate "a crucial set of professional values and qualities, at the heart of which is the willingness to put the needs of the patient first" (Cooke et al., 2006, p. 1341). Accordingly, the second accreditation goal is that a demanding training program should enable physicians to "take life-saving actions" for patients (ACGME, 2019, para. 6).

The centrality and persistence of these values suggests that, consistent with Bandura's (2001) concept of personal identity in occupational settings, medical training consists of much more than developing biomedical knowledge. It is intended to be a process in which physicians develop professionally normative patterns of thought, confidence in information seeking and decision-making (Berkhout et al., 2018), and devotion to patient care (Cooke et al., 2006) that reflect what Bandura (1999) described as moral agency. Additionally, physicians are trained for, and therefore would be expected to have self-efficacy for, a self-directed cognitive flexibility that Bandura (2001) described as occupational self-regulation. These training outcomes are reflected in the ways that physicians make decisions, discussed next.

## **Occupational Identity and Cognition in the Medical Practice Environment**

Information about the occupational identity and cognitive processes that physicians use in medical decision-making comes from two bodies of evidence, the first on physician occupational satisfaction and the second on predictors of medical decisions, including prescribing. As shown in the literature presented in this section, these two bodies of evidence are linked because, as social cognitive theory would suggest, humans act in ways that they believe will provide them with satisfaction (Bandura & Locke, 2003). Specific applications of these predictors to the theory-based model are summarized at the end of this section.

The physician-patient relationship and patient preference. Consistent with the training emphasis on applying biomedical knowledge to promote the well-being of patients (Cooke et al., 2006), physicians characterize good patient relationships as an indicator of high-quality care, place value on meeting the needs of individual patients (Friedberg et al., 2013), and derive satisfaction from patient relationships (Colligan et al., 2016; Tak et al., 2017) and from resolving intellectually challenging clinical problems to benefit patients (Colligan et al., 2016). Conversely, physicians experience loss and dissatisfaction from organizational changes, such as increases in administrative tasks and reductions in time allotted for visits, that diminish opportunities for patient care (Colligan et al., 2016; Friedberg et al., 2013; Sinsky et al., 2013). Corresponding to these values, extensive evidence suggests that patient preferences influence prescribing decisions (Becker & Midoun, 2016; Dempsey, Businger, Whaley, Gagne, & Linder, 2014; Hawkins et al., 2017; Moloney, 2017; Sirdifield et al., 2013; Wallis, Andrews, &

Henderson, 2017). In several studies, physicians cited patient expectations and concerns about loss of patient relationships as key determinants of potentially inappropriate prescribing (Anderson et al., 2014; Sirdifield et al., 2013; Wallis et al., 2017).

The role of the patient-physician relationship in prescribing decisions encompasses both clinical and business considerations. Because physicians view alleviation of patient suffering as a critically important aspect of their role as clinical providers, they may write prescriptions for medication they believe will alleviate physical or emotional distress (e.g., insomnia, anxiety, pain), even knowing that the root cause of the problem is biologically unclear or represents a difficult life circumstance rather than a biomedical issue (Moloney, 2017; Sirdifield et al., 2013). For the same reason, they may choose to give patients "the benefit of the doubt" even when misuse is suspected (M. A. Fischer et al., 2017, p. 7). At the same time, physicians may acquiesce to clearly inappropriate requests because they know that a patient who is denied medication may provide a negative rating on a satisfaction survey, potentially reducing physician compensation (Zgierska, Miller, & Rabago, 2014), or may choose another physician, who will prescribe the requested medication (Moloney, 2017; Sirdifield et al., 2013).

**Professionalism**. Related to desires to make decisions that benefit individual patients, and consistent with the occupational norms of autonomy and self-directed learning, are considerations of professionalism. These include autonomous decision-making (Friedberg et al., 2013; Wright & Katz, 2018); work content and provision of high-quality care consistent with professional expertise (Colligan et al., 2016; Friedberg et al., 2013; Shanafelt et al. 2016); and the perception of medicine as a calling (Tak et al.,

2017). In a mixed-methods study of a geographically diverse sample of U.S. physicians, odds of occupational satisfaction were approximately tripled by opportunities to provide high-quality care and to initiate quality-improvement efforts (Friedberg et al., 2013).

**Personal experience and cognitive salience**. Consistent with a training environment that encourages physicians to develop and rely on their own biomedical expertise in making decisions (Berkhout et al., 2018; Stead et al., 2011), physicians commonly rely on personal experience, including familiarity with histories of individual patients, medications, and salient events (Bell, Steinsbekk, & Granas, 2015; Doctor et al., 2018; Ebbert et al., 2018). For example, in a small-sample (N = 26), single-institution study, psychiatrists who were asked about the most important sources of information in prescribing decisions commonly gave "more than average" ratings to the patient's (96%) and physician's (85%) experiences with the medication, although the patient's diagnosis and symptoms were foremost (100%; Rajendran, Sajbel, & Hartman, 2012, p. 274). Similarly, Hawkins et al. (2017) found that among primary care physicians in the VA, a commonly cited reason for benzodiazepine-opioid coprescription was that the patient was already successfully taking the combination without adverse effects. Conversely, adverse experience may play a role in the decision not to prescribe a medication. For example, knowledge of a patient's overdose reduced opioid prescribing by 10% in one randomized trial (Doctor et al., 2018), and was associated with a 31% increase in prescription drug monitoring program enrollment in a survey (Ebbert et al., 2018).

As these findings suggest, physicians do not consistently use formal guidance in making treatment decisions, sometimes comparing informational resources with their own experience to determine their quality (Cook, Sorensen, Hersh, Berger, & Wilkinson, 2013). In the survey of psychiatrists, which found that 85% placed high value on their own experiences, only 61% and 39%, respectively, gave practice guidelines and FDA criteria a "more than average" importance ranking (Rajendran et al., 2012). Physicians may also consider perceived social norms in making decisions (Donohue et al., 2018; Ponnet, Wouters, Van Hal, Heirman, & Walrave, 2014).

#### Medical Decision-Making: Summary and Implications for a Theory-Based Model

The findings of studies on medical decision-making suggest that, consistent with their medical training, physicians place high value on patient needs and preferences. They define professionalism as autonomy to perform tasks that reflect the high level of expertise and complexity for which they were trained. Rather than relying solely on published knowledge in making decisions, they are likely also to consider professional norms, their personal experiences, and salient events.

These findings had several implications for the theory-based model presented and operationalized in Chapter 3. First, consistent with an understanding of the clinical and business importance of physician-patient relationships, the theory-based model included predictors (IVs) for the nature of those relationships and the derivation of revenue from patient volume or satisfaction. Second, the understanding that autonomous decisionmaking to promote high-quality care is a core professional value, coupled with the findings of research on the outcomes of E-HRs presented later in this chapter, informed the hypotheses in the theory-based model by highlighting the contrast between occupational norms and the new demands placed on the medical practice environment by meaningful use and CDS. Third, the understanding of the role of experience in medical decision-making informed the inclusion of a predictor (IV) for new versus continuing use of ADHD medication.

In the next section, I consider response to evidence-based guidelines as an interaction between this cognitive decision-making process and the environment in which medical decisions are made. I focus on barriers to evidence-based practice. Some, but not all, of these barriers were cited as part of the rationale for the introduction of CDS into medical practice (Bates et al., 2003; Stead et al., 2011).

## **Barriers to Evidence-Based Medical Practice**

As originally conceptualized in the 1970s and 1980s and formally defined for the first time in 1991 (Djulbegovic & Guyatt, 2017; Guyatt, 1991), the term *evidence-based medicine* referred to the replacement of conventional wisdom with findings of randomized controlled trials (Sackett, 2010) to be used as a starting point in medical decision-making (Djulbegovic & Guyatt, 2017). The term was later expanded to clarify the roles of clinical judgment (Sackett et al., 1996) and patient preference (Djulbegovic & Guyatt, 2017). Ideally, evidence-based medicine is not an automated, thought-free conformity to clinical rules; it is meant to reflect a synthesis of high-quality evidence with clinical observation and professional assessment (Djulbegovic & Guyatt, 2017; Sackett & Rosenberg, 1995).

One core tenet of evidence-based medicine supported the rationale for the HITECH ACT. Specifically, recognition of the need for unbiased evaluations of the totality of evidence (Djulbegovic & Guyatt, 2017), gave rise to the Cochrane

Collaboration, a framework for systematic review and meta-analysis (Cochrane Community, 2019). In turn, awareness of the volume of this base of evidence led to the concept of point-of-care information delivery strategies, in which physicians could be provided with evidence-based guidance as they were making decisions (Djulbegovic & Guyatt, 2017). Such automated support was viewed by key stakeholders as crucial to improving health care quality and safety (IOM, 2000, 2001).

# Evidence for and Against Use of CDS in Evidence-Based Decision-Making

Some commonly described cognitive or environmental barriers to evidence-based practice are consistent with the stakeholder view of automated support as essential. These include lack of awareness of the guideline or of deviations from it and constraints on time or on other resources (Baatiema et al., 2017; Chan et al., 2017; F. Fischer et al., 2016). Another commonly reported barrier, patient resistance to guideline-based practice (Arts et al., 2016; Dempsey et al., 2014; Matthys et al., 2014), potentially could be mitigated with timely algorithms. In the survey of VA providers on benzodiazepine-opioid coprescribing, the most commonly cited need was structured guidance that providers could use in interacting with patients who refused discontinuation (Hawkins et al., 2017).

In contrast, other barriers to evidence-based practice may represent reactions to the guidance itself. These include disagreement with guideline recommendations (Chan et al., 2017; Cloutier et al., 2018; F. Fischer et al., 2016; Matthys et al., 2014) and the related concern that recommendations based on population-level evidence may not apply to the complex needs of individual patients (Arts et al., 2016). In routine practice, physicians see a heterogenous patient population whose characteristics may not be wellrepresented by the homogeneous samples used in randomized controlled trials (Makady et al., 2017). Trials of ADHD medications commonly exclude patients with comorbid cardiovascular or psychiatric disorders (see Castells et al., 2018; Huss et al., 2014; Philipsen et al., 2014). In contrast to these sample characteristics, real-world prevalence estimates for psychiatric comorbidities among adults with ADHD are high: 11–35% for SUD; 19–53% for depression or dysthymia, and 34–47% for anxiety disorders (Q. Chen et al., 2018; Fairman et al., 2018; Katzman, Bilkey, Chokka, Fallu, & Klassen, 2017; Kooij et al., 2019; Mao & Findling, 2014). This discrepancy may make it difficult for clinicians to apply ADHD-guideline recommendations to treatment decisions.

# **Evidence-Based Prescribing: Summary and Implications for a Theory-Based Model**

Evidence-based prescribing may be viewed as the outcome of an interaction between the cognitive processes of physicians and environmental influences, such as available knowledge and time. Specifically, physicians may engage in non-evidencebased prescribing because of lack of information, need for assistance in managing patient expectations, or lack of awareness that their behaviors depart from evidence-based guidelines—problems that could potentially be addressed by CDS-delivered knowledge. Less easily addressed by the provision of knowledge are disagreement with guideline content or challenges in applying guidelines to individual patients. Physicians who have been trained to value high-quality care may be reluctant to accept CDS-delivered guidance, and meaningful use incentives to use that guidance, unless these tools appear to result in better patient outcomes. For this reason, the question of quality-of-care outcomes associated with E-HR technology and with meaningful use, and physicians' opinions of those outcomes, were important in determining the hypotheses in the theory-based model. These questions are considered in the next two sections. After a review of the rationales for CDS and meaningful use, the chapter turns to experience with E-HRs and CDS before and after HITECH Act implementation, then to attitudes of physicians toward meaningful use.

### **CDS and Meaningful Use**

The idea of applying electronic technologies to medical decision-making to make "the practice of evidence-based medicine a reality" (Bates et al., 2003, p. 523) emerged in about the year 2000 (IOM, 2000, 2001). Proponents suggested that the concept was analogous to "mass customization" procedures used in other industries, which leverage high-technology tools to provide personalized services to a large base of consumers (Bates & Gawande, 2003, p. 2526). Several core assumptions undergirded the approach.

One was that use of electronic technology was essential because of increasing complexity in care delivery, such as the need to adjust dosages for kidney impairment or customize treatment for genetic variation (Bates & Gawande, 2003; Stead et al., 2011). Systems would, proponents suggested, help providers by anticipating and meeting needs that "have not been consciously realized," for certain medical orders (Bates et al., 2003, p. 525) and allow physicians to spend more time in patient care, "empowered by ... a network of brains and computers" (Stead et al., 2011, p. 430). Despite this notion of empowerment, arguments for increased use of electronic technologies were also based in part on an assumption that forcing functions, which are system features that constrain

available treatment choices, would improve patient safety by making unsafe decisions impossible (Emanuel et al., 2008). For example, when physicians at one hospital found a way to work around an E-HR function intended to reduce non-evidence-based use of growth hormone, hospital administrators identified them from system log-ins and engaged them in "targeted discussions" about their choices (Bates et al., 2003, p. 526).

Another assumption was that certification of E-HR systems through a central federal office, coupled with assistance provided to physicians by regional technical assistance centers, would facilitate interoperability, which is information exchange to enable rapid access to a comprehensive health history across all sites of care (Buntin et al., 2010). More broadly, the information exchange that would come from widespread adoption of E-HRs was viewed as a way to change "the mind-set of the [physician] workforce" by increasing its focus on the measurement and management of quality (Buntin et al., 2010, p. 1216).

# **Evidence About E-HRs and CDS Prior to HITECH Act Implementation**

Advocacy for widespread use of E-HR and CDS in medical decision-making was somewhat supported by evidence available at the time. Consistent with the notion that physicians could not be expected to keep up with the volume of available research evidence without automated assistance, more than 480,000 Medline-indexed articles were published in the year 2000 (see U.S. National Library of Medicine, 2019). Moreover, many early studies of adoption of CDS or E-HRs documented potential or realized improvements in quality, safety, or efficiency (CBO, 2008). Despite these findings, the base of evidence about CDS and E-HRs in office-based prescribing was limited, partly because most studies had been conducted in inpatient hospital settings (CBO, 2008). Moreover, as of August 2012, no studies of CDS-guided prescribing had examined technology-related adverse effects as primary outcomes, and few trials measured these risks (Bright et al., 2012; Carling et al., 2013).

Additionally, reported outcomes were mixed and mostly minimal, especially in office-based care (Bright et al., 2012; CBO, 2008). In a systematic review by Garg et al. (2005), 11 of 16 studies of CDS-assisted prescribing suggested improvements, but of studies that measured patient outcomes, none showed improvements. In other systematic reviews, Wolfstadt et al. (2008) found reductions in adverse drug events in five of 10 studies of CDS; Lainer, Mann, and Sönnichsen (2013) found that unsafe prescribing was reduced in three of six randomized trials of CDS published through March 2011; and Shojania et al. (2010) found in a meta-analysis of 21 comparisons that computerized reminders were associated with a median 3.3 percentage-point improvement in prescribing behaviors. In one systematic review and meta-analysis of randomized controlled trials published from 1999–2012, which assessed CDS systems linked to patient-specific medical data, Moja et al. (2014) found inconsistent effects. Of three outpatient studies included in that review, one reported process-of-care improvements but a "failed clinical outcome" (Holbrook et al., 2011, p. 1742); one reported no improvements in four of six outcomes (McCowan et al., 2001); and one, conducted in a specialty clinic, found improvement (Robbins et al., 2012).

Studies of E-HRs or CDS based on NAMCS data produced similarly mixed findings (Linder et al. 2007; Romano & Stafford, 2011; Samal, Linder, Lipsitz, & Hicks,

2011). Outcomes, estimated in these studies using multivariate analyses adjusted for patient and provider characteristics, included no change in 14 of 17 quality indicators (Linder et al., 2007) and no improvement in any of 12 indicators of prescribing quality (Romano & Stafford, 2011). One NAMCS study did find a modest but clinically and statistically significant improvement in blood pressure control with CDS reminders (79%) compared with no reminders (74%; Samal et al., 2011). Together with the smallersample studies, these NAMCS findings suggested that in physician-office settings, CDS would be expected to have no significant association with the safety of prescribing decisions. This evidence, along with literature on E-HR-related cognitive demands presented later in this chapter, informed the hypotheses for RQ1.

# E-HR Cost Estimates as a Foundation for the HITECH Act

Despite equivocal evidence about effects of E-HRs and CDS on quality of medical care, mathematical models published beginning in 2003 suggested the possibility of large savings to the health care system from increased use of electronic technologies (CBO, 2008), including one estimate of \$81 billion annually from improved efficiency, safety, and chronic disease management (Hillestad et al., 2005). However, these projections of large cost savings were based on questionable evidence, according to a CBO (2008) analysis. For example, authors of the \$81 billion estimate excluded from their calculations all studies with unfavorable results for E-HRs, stating that they "chose to interpret" negative findings "as likely being attributable to ineffective or not-yeteffective implementation" (Hillestad et al., 2005, p. 1105). Reflecting a more comprehensive assessment, a meta-analysis of randomized controlled trials of CDS published through January 2011 found "modest evidence" of a "trend toward" lower costs in 22 studies conducted in inpatient or outpatient settings and mixed evidence about cost-effectiveness in outpatient care (Bright et al., 2012, p. 32).

Still, the possibility of savings, and the perception that implementation costs were a barrier to adoption, led to the idea of paying physicians to use E-HRs in medical decision-making (Terry, 2013). One study of 14 small primary care practices suggested start-up costs, including equipment and staff time, averaging \$44,000 (R. H. Miller, West, Brown, Sim, & Ganchoff, 2005). This estimate was the basis for meaningful use provisions of the HITECH Act (Terry, 2013), discussed next.

# Meaningful Use Program Overview

Meaningful use regulations developed under the HITECH Act had their roots in the 2004 establishment of the Office of the National Coordinator (ONC) of Health Information Technology (CBO, 2008), which certified E-HR systems as required by the law and continues to play a key role in the program (Cohen et al., 2018). Overarching goals were similar to those previously described for CDS and E-HRs: improvements in medical decisions and patient outcomes, increased efficiency, and changing the way that physicians think about quality of care (Buntin et al., 2010; Terry, 2013). A phased approach (Table 2) was used to minimize provider burden while encouraging progress in an escalator concept (Blumenthal & Tavenner, 2010). Each meaningful use phase, known as a stage, included menu objectives, from which physician offices could choose, and core objectives, which were mandatory except when inapplicable (e.g., physician writes fewer than 100 prescriptions annually; Wright, Feblowitz, Samal, McCoy, & Sittig, 2014). Menu objectives are not discussed here because they were unrelated to prescribing

(e.g., public health surveillance; CMS, 2012a).

Table 2

Key Dates for Meaningful Use Program Rules and Implementation

Event	Date	Requirements
Rule for E-HR certification issued <sup>a</sup>	June 2010	ONC-certified system required to receive payments
Final Stage 1 rules published <sup>b</sup>	July 2010	<ul> <li>15 core objectives</li> <li>5 of 10 menu objectives</li> <li>Report ≥ 1 population health measure using E-HR</li> </ul>
First opportunity to file for Stage 1 achievement <sup>b,c</sup>	April 2011	• Based on 90 or more consecutive days of use
Stage 2 start date <sup>d</sup>	January 2014	<ul><li>17 core objectives</li><li>3 of 6 menu objectives</li></ul>
Final Stage 3 rules and modified Stage 2 requirements published <sup>e</sup>	October 2015	<ul> <li>Modified Stage 2 requirements, retaining core objectives</li> <li>Stage 3 optional in 2017, mandatory in 2018</li> </ul>

*Note*. E-HR = electronic health record; ONC = Office of the National Coordinator.

<sup>a</sup>Blumenthal and Tavenner (2010). <sup>b</sup>Halamka (2010). <sup>c</sup>Kibbe (2010). <sup>d</sup>CMS (2012b). <sup>e</sup>CMS (2015).

Prescription-related core objectives at stage 1, achieved by 12% of Medicare providers as of May 2012 (Wright et al., 2013), included ordering of at least one medication electronically for more than 30% of patients; electronically recorded lists of diagnoses, medications, and drug allergies for more than 80% of patients; electronic transmission of more than 40% of medication orders; and ability to perform druginteraction checks (D. R. Levinson, 2017). In practice, physician offices typically exceeded these metrics because once the computer infrastructure for a measure was built, it was relatively easy to apply it to more than the minimum number of prescriptions (Wright et al., 2014). For example, at stage 1, 63% of physicians ordered more than 70% of prescriptions by computer, 62% transmitted more than 70% of prescriptions electronically, and 89% had electronic lists of diagnoses and medication allergies for more than 90% of patients (Wright et al., 2014). Stage 2, implemented on the start date for the current study, required use of increased E-HR functionality, such as CDS checks for drug-drug and drug-allergy interactions (CMS, 2012a, 2012b).

Financial incentives for meaningful use were substantial, depending on speed of implementation: up to \$63,750 in Medicaid, with various achievement dates permissible, and up to \$44,000 in Medicare for providers achieving stage 1 by 2011 or 2012 (see Kibbe, 2010). Slower implementation yielded lower payments (e.g., up to \$24,000 in Medicare for implementation by 2014). Additionally, penalties were imposed for failure to engage in meaningful use, including Medicare payment reductions of 1% in 2015 and 2% in 2016 (Kibbe, 2010; Monica, 2017).

Together, these findings suggest that physician offices that achieved meaningful use experienced substantial changes in the practice environment. Because only 9 months elapsed between publication of final program rules (July 2010) and the earliest filing date (April 2011), these changes may have been implemented quickly for offices that applied early in the program. In the next section, macrolevel outcomes of meaningful use implementation are presented, followed by a discussion of linkages between these outcomes and physician opinions of the value of meaningful use.

### **Physician Experiences With Meaningful Use**

Implementation of the HITECH Act in 2011 was followed by growth, as intended, in the extent and sophistication of E-HR use nationwide. Prevalence of E-HR use by U.S.

physicians increased from an estimated 35% in 2007 to 57% in 2011 and 72% in 2012 (Hsiao & Hing, 2014). Among small practices, use prevalence for key E-HR medication-related metrics increased from 2007–2010 to 2012–2013: from 29% to 51% for inclusion of medication lists, from 25% to 70% for electronic transmission of prescriptions to pharmacies, and from 17% to 46% for drug-interaction checks (Rittenhouse et al., 2017). By April 2014, 70% of U.S. physicians were using an E-HR to prescribe, and 96% of pharmacies were able to accept electronic prescriptions (Gabriel & Swain, 2014).

**Benefits of meaningful use**. Early reports identified several benefits of the expanded use of electronic technologies brought about by meaningful use achievement. These included increased adherence to health care process behaviors included in meaningful use metrics (e.g., smoking-cessation interventions; Ancker et al., 2015), improved within-facility access to information (Jamoom, Patel, King, & Furukawa, 2013), easier remote access to patient records (King, Patel, Jamoom, & Furukawa, 2014), increased information exchange with other providers and patients (Audet, Squires, & Doty, 2014; Jamoom et al., 2013), and perceived benefits of CDS for error prevention (King et al., 2014). Most of these early results represented physician opinion (see Audet et al., 2014; Jamoom et al., 2013; King et al., 2014), not objectively measured outcomes.

Effects of meaningful use on quality of care. Studies conducted after HITECH Act implementation found few objectively measured improvements in quality associated with use of E-HRs (see Harle, Cook, Kinsell, & Harmon, 2014; Harman, Rost, Harle, & Cook, 2012; M. J. Miller et al., 2017) or with meaningful use achievement (see Afonso et al., 2017; Grinspan et al., 2017; Jung et al., 2017; Kern et al., 2015; Samal et al., 2014;

Unruh et al., 2017), although providers that applied for meaningful use may have had better care processes prior to implementation (Grinspan et al., 2017). Associations of E-HR use with care metrics included an increased likelihood of prescribing an opioid for chronic pain (Harle et al., 2014), no change or reduced likelihood of treatment for depression (Harman et al., 2012), and no significant difference in depression screening rates among patients prescribed a medication that could cause depressive symptoms (M. J. Miller et al., 2017). Results of the meaningful use studies, all conducted in single states or health systems rather than in national samples, included no significant change in eight measures of quality (e.g., vaccination, cancer screening) among Medicaid primary care providers (Grinspan et al., 2017); improvements in one screening measure, but not in other screenings or in hospitalization rates among Medicare providers (Jung et al., 2017); no significant change on any of nine quality measures in a large primary care provider sample (Kern et al., 2015); and no significant difference in Medicare beneficiary hospital readmission rates (Unruh et al., 2017). An exception was a study conducted in one academic medical center, which identified improvements in four measures, no change in two, and one worsened, after progression from stage 1 to stage 2 (Levine et al., 2017).

A persistent challenge to improving quality of care with meaningful use is override, in which physicians do not accept or even view a CDS recommendation (Baysari, Tariq, Day, & Westbrook, 2017). Reported rates of override during prescribing with CDS have remained high for 20 years, ranging from 49–96% in studies published before 2010 (Isaac et al., 2009; van der Sijs, Aarts, Vulto, & Berg, 2006), from 53–60% in studies of one academic medical system published in 2013 and 2014 (Nanji et al., 2014; Slight et al., 2013), and from 73–94% in recent studies (Genco et al., 2016; Nanji et al., 2018). One large health system reported a 69% override rate for high- or medium-severity alerts when a customized alerting database was used for outpatient prescribing in 2014–2015, which increased to 92% when the same health system switched to an industry award-winning (K. Murphy, 2019) commercial system (Wright et al., 2018).

Related to high override rates is the commonly documented problem of excessive noise-to-signal ratio (Marcilly, Ammenwerth, Vasseur, Roehrer, & Beuscart-Zéphir, 2015), referring to the inundation of providers with clinically unimportant or questionable warnings (Carli, Fahrni, Bonnabry, & Lovis, 2018; Horsky, Phansalkar, Desai, Bell & Middleton, 2013; Zazove et al., 2017). One systematic review of studies with standard statistical measures of accuracy applied to CDS warnings found sensitivity (percentage of harms detected) ranging from 38–91% and positive predictive values (PPV; percentage of warnings that represent true harms) of only 8–14% for drug-dosage interaction and 2–48% for drug-drug interactions, although PPV was better in more advanced systems at 17–97% (Carli et al., 2018). Similarly, in one system that required physicians to enter into the E-HR their reasons for overrides, retrospective clinical reviews conducted by a multidisciplinary team found that 53% of overrides for outpatients (Nanji et al., 2014) and 61% of overrides for inpatients (Nanji et al., 2018) were clinically appropriate.

**Systematic evidence of harms**. Systematic investigations of technology-related harm included a comprehensive quantitative analysis of U.S. data based on computerized prescribing errors reported to the U.S. Pharmacopeia MEDMARX system (Schiff et al., 2015), coupled with naturalistic observation of order entry using 13 different E-HR

systems to determine how those errors might have occurred (Slight et al., 2016). Investigators found that 79% of erroneous prescriptions reported to MEDMARX could be ordered in the E-HR, typically with either no difficulty (28%) or after minor adjustments (28%), and often (61%) with no CDS-delivered warning (Schiff et al., 2015). Examples included a 1000-fold overdose of thyroid hormone and a potentially dangerous disease-antidiabetic medication combination. In a follow-up analysis, Amato et al. (2017) studied all prescribing errors at six sites participating in a study of computerized prescribing and found that 52% were technology-related, including 7% in which the technology facilitated the error and 45% in which the technology failed to prevent the error. Commonly reported consequences of technology-related errors include delay or duplication of treatment and incorrect medication or dosage (Amato et al., 2017; Howe et al., 2018; Korb-Savoldelli et al., 2018; Slight et al., 2016).

Increases in physician workload. Instead of the improvements in efficiency envisioned by proponents of CDS and meaningful use, investigators using time-motion analyses found that electronic technologies may increase physician administrative workload, from 16% to 28% of work time spent on documentation in one meta-analysis (see Baumann, Baker, & Elshaug, 2018). Among these findings were 49% of the inoffice day spent on E-HR tasks and only 27% with patients, plus 1–2 hours after-work time on the E-HR in a four-state study of office-based physicians (Sinsky et al., 2016) and 52% of total visit-related time devoted to E-HR tasks by family practitioners in Texas (Young, Burge, Kumar, Wilson, & Ortiz, 2018). Added workload does not appear to be alleviated by increased experience in using the E-HR. Arndt et al. (2017) conducted a time-motion analysis using E-HR event-logging records over a 3-year period beginning 5 years after full implementation of an award-winning E-HR (K. Murphy, 2019) in one large health system and found that physicians spent an average of 5.9 hours per 11.4-hour workday on the E-HR, of which 44% was for clerical work and 24% for inbox management.

**Cognitive demands of meaningful E-HR use**. The cognitive challenges encountered by physicians with meaningful use of CDS and E-HRs fall into several categories, all related to human-machine-environment interaction. These include problems of usability, unanticipated user responses, business practices, and training gaps. These challenges are linked to evidence of a lack of basis in psychological theory, discussed in this section, and to physician opinions about E-HRs and meaningful use, discussed in the next section.

*Usability*. Gaps in E-HR usability, defined as human-machine-environment interactions that do not produce the intended outcome, have been identified as an important source of CDS- and E-HR-related errors (Ratwani et al., 2016; Ratwani et al., 2018). E-HR system devices and messaging commonly do not conform to humancomputer interface design standards for colors, fonts, placements, and message content (Horsky et al., 2013; Savoy, Patel, Flanagan, Weiner, & Russ, 2017; Virginio & Ricarte, 2015). Using a 26-item instrument validated for measurement of CDS-alert compliance with human-factors design principles, Phansalkar et al. (2014) found that among 14 different systems, performance scores ranged from 31–71%, averaging 53%. Results were particularly poor for clarity, underlying logic and prioritization of alerts, and provision of suggested actions. Commonly identified problems include incomplete screen layout, such as showing only a partial medication list (Brown et al., 2017); inconsistent medication names (Quist et al., 2017; Schiff et al., 2016); "dropdown" and "autopopulate" lists that contain both incorrect and correct options; and incorrect CDS content, such as wrong medication choice information or failure to identify combination products accurately (Brown et al., 2017; Quist et al., 2017; Slight et al., 2016).

*Unanticipated user responses*. "Workarounds" developed by staff because of functionality problems, or because staff do not know how to use the intended functionality, may create safety hazards (Schiff et al., 2016). Examples include ordering or discontinuing a medication in a free-text field instead of a drug-order field, preventing checks on safety or dosage (Slight et al., 2016) or resulting in duplicate therapy (Yang et al., 2018), and manual processes developed because of poor functionality for the clinical task, such as inability to order different dosages of the same medication for morning and evening administration (Slight et al., 2016). Automation bias, which is over-reliance on technology at the expense of cognitive processing of relevant information, has also been documented in CDS-assisted medication orders (Lyell et al., 2017; Lyell, Magrabi, & Coiera, 2018).

On-site customization of E-HR features can also compromise system function (Ratwani et al., 2018). In a qualitative study by Slight et al. (2016), investigators found at one facility a dangerous flaw of which management had been unaware until informed by the research team; all E-HR alerts had been inadvertently turned off 6 months previously during a system upgrade. At a different site, investigators found that an information systems director had suppressed the E-HR's ability to identify duplicate medications in one screen to reduce system "noise" (Slight et al., 2016, p. 313).

Business practices. The business practices of E-HR vendors may contribute to negative physician experience with systems in several ways. First, proprietary technology may hamper health care coordination because different systems do not share information (Ratwani et al., 2016; Samal et al., 2016), a problem described in one review as an "interprofessional Tower of Babel" (Bernstein, Kogan, & Collins, 2014, p. 229). Researchers who studied one integrated behavioral-medical provider network reported a complex work-around necessary because one mental health center (MHC) and its integrated physician office used different E-HRs: daily medication lists printed by the MHC were manually recorded by a medical office physician assistant on paper, which was scanned for the medical office E-HR, with updates then manually keyed into the MHC's system (Cifuentes et al., 2015). A related challenge is that contractual arrangements may limit the ability of E-HR users and researchers to report usability problems in the detail necessary for investigation and correction, such as providing visual images of problematic order entry screens (Ratwani et al., 2019). There is no central federal repository of information about E-HR-related adverse events, such as that currently used to report medical device-related adverse events to the FDA.

Finally, despite the assumption that meaningful use would facilitate qualityimprovement efforts (Buntin et al., 2010), one mixed-methods study of 1,492 geographically diverse U.S. practices found limited ability to generate clinically meaningful reports because vendors charged high fees for minimal customization (e.g., reporting by date range or by clinician) or required office staff to learn database query language (Cohen et al., 2018). Although 82% of participants were using an ONC-certified system, only 61% could generate clinical quality reports from the E-HR.

*Training gaps*. An additional problem inhibiting meaningful use is lack of alignment between medical training content and the skills necessary to use CDS in making medical decisions (Hersh et al., 2014; Pageler, Friedman, & Longhurst, 2013). One detailed assessment of this issue, which resulted in a call for massive medical school curricular reform (Stead et al., 2011), was published in April 2011, the month that meaningful use filings began (see Wright et al., 2013). This timing highlights the contrast between the way that physicians had been trained and the new expectations for medical practice quickly placed on them. Unmet training needs are commonly mentioned in discussions of E-HR usability challenges (Ratwani et al., 2016).

# Meaningful Use: Summary and Implications for a Theory-Based Model

The evidence reviewed in this section suggested that although physicians recognize the potential value of CDS and E-HRs (Schiff et al., 2016), they experience substantial challenges in meaningful use of these technologies in clinical practice. These challenges include excessive noise-to-signal ratio and the related problem of overrides, usability problems and behavioral responses in the practice environment not anticipated by system developers, business practices that impair quality improvement, and gaps between medical education content and training needs.

The field of psychology suggests an explanation for these challenges that may be framed within the social cognitive theoretical construct of human-environment interaction (Bandura, 1989), a failure of E-HR system design to account for the ways and environmental circumstances in which people interact with technology (Savage et al., 2017). Holden (2011), a cognitive health psychologist who specializes in human-factors analyses of individual-device-environment interactions, has described E-HR system failures as the result of simplistic paradigm that fails to address cognition as a mediator between computer systems and work output. Consistent with Bandura's notion of interactive agency, although he did not cite it explicitly, Holden suggested that unexpected user behaviors, such as "workarounds," result from a process of adaptation that allows physicians to cope both with the complexity inherent in medical practice and with new complexities introduced by E-HRs. To the extent that the adaptation described by Holden was the result of a medical education process intended to produce autonomous and flexible cognition (see Berkhout et al., 2018), it is reasonable to suggest that physicians think and behave creatively when exposed to electronic technology because they are trained, as an occupational norm, to do so in response to any new environmental condition (Bandura, 2001). If so, the expectations of E-HR-system proponents that physicians would readily adopt suggestions produced by CDS, and that failure to do so would represent "irrational" thinking (Cho & Bates, 2018, p. 114), were contrary to psychological theory.

This theory-based assessment is consistent with the evidence about CDS available prior to passage of the HITECH Act in suggesting no significant association of CDS with prescribing behavior. In addition to informing the hypothesis for RQ1, the assessment and supporting evidence provided a process measure to explain physician attitudes toward meaningful use and technologies mandated by the HITECH Act, discussed next.

# **Physician Opinions About Meaningful Use**

Given the problems that physicians encounter in using E-HRs for clinical care, negative opinions of them, expressed in peer-reviewed survey reports (Emani et al., 2017; Shanafelt et al., 2016; Weeks et al., 2015) and in a growing volume of popular-press accounts (Fry & Schulte, 2019; Gawande, 2018; J. Levinson et al., 2017) and white papers (Henry, 2018), are not surprising. These reactions are consistent with the issues identified in research on outcomes of CDS and E-HRs and comprise two main areas of concern.

# **Concerns Expressed by Physicians**

The first area of concern is lack of clinical benefit or the introduction of clinical harms. In the first physician survey conducted after HITECH Act implementation, 59% of respondents said (agreed or strongly agreed) that meaningful use would contribute to decline in "the art of medicine", 50% said that it would improve quality of care, and 30% said that it would ensure accurate patient information (Weeks et al., 2015, p. 126). In separate surveys conducted, respectively, before and after qualification for meaningful use at two academic medical centers, rates of agreement or strong agreement with statements about possible quality improvements from meaningful use declined, from 29% to 21% on improvement in patient-centeredness, from 39% to 31% on decreases in medical errors, and from 27% to 21% on the ability to deliver high-quality care (Emani et al., 2014, 2017).

The second area of concern is relegation of clerical tasks to physicians instead of to administrative support staff who were previously responsible for these functions, which one survey respondent described as analogous to "asking the pilot to scrub the floor rather than flying the plane" (Emani et al., 2017, p. 1048). Shanafelt et al. (2016) noted a strong association between E-HR use, time spent on clerical tasks, and occupational dissatisfaction. A related concern is the belief that time spent in the E-HR, "checking off boxes" (Emani et al., 2017, p. 1048), detracts from engagement with and care for the patient (Colligan et al., 2016; Gawande, 2018).

These negative opinions may be exacerbated by increasing system sophistication. In one survey of primary care physicians, Babbott et al. (2014) found that degree of E-HR sophistication was positively associated with job stress and negatively associated with job satisfaction. Similarly, in the academic medical center survey, opinions about meaningful use were less positive among stage 2 than stage 1 providers (Emani et al., 2017). Perhaps indicating the degree of user frustration with CDS, investigators in one large hospital network that is a leader in the study of E-HRs (see Schiff et al., 2016) developed a "cranky comments heuristic" after noticing that certain text patterns in physician overrides (e.g., multiple sequential exclamation points and words like "dumb" and "please stop") often accurately identified problems in CDS logic (Aaron, McEvoy, Ray, Hickman, & Wright, 2019, p. 37). Systematic investigation of these "cranky comments" increased predictive accuracy of error identification and produced the unexpected finding of malfunctions in at least 26% of the E-HR's decision rules.

# **Physician Opinions: Summary and Implications for a Theory-Based Model**

Literature reviewed for this study suggested generally poor opinions of meaningful use, and of technologies promoted by meaningful use, among physicians. This lack of value physicians ascribe to these technologies suggests, according to selfdetermination theory, that the meaningful use program represents controlled motivation. Supporting this interpretation was a commentary in which a group of physicians, among them a former hospital vice president of information technology (J. Levinson et al., 2017), described the problem with E-HRs as a combination of clinically inappropriate design and coercion: "people who take care of patients did not design or choose these systems. They were foisted upon us" (para. 6). This theory-based understanding was the foundation of the hypothesis for RQ2, which is detailed in Chapter 3.

# **Summary**

In this chapter, I considered social cognitive theory as a framework within which ongoing reciprocal engagement of humans with their environments can be characterized as a continuous process, informed by knowledge, of adaptation to changing circumstance. I described the knowledge available to physicians in making ADHD medication prescribing decisions, the medical training and values that influence their decisionmaking processes, and barriers to evidence-based medical practice. In the final sections of the chapter, I considered inconsistencies, suggested by the literature review, between the effects of widespread adoption of electronic technologies that were envisioned by HITECH Act developers and those indicated by psychological theory and evidence. Proponents of the HITECH Act assumed that implementation of sophisticated electronic technology in the medical practice environment would change not only prescribing behavior, but also cognitive patterns of medical decision-making. In contrast, the theory-based approach suggested that those cognitive patterns are deeply engrained as a result of long-standing professional traditions, are the product of limited observational learning opportunities for use of electronic technologies in decision-making, and are unlikely to change without retraining, if at all. Moreover, literature suggested that dysfunction in E-HR systems has produced new challenges to patient safety that threaten what physicians are trained to believe is their highest occupational norm, engaging with and providing high-quality care to patients, and that the primary problem CDS was intended to address, lack of readily available knowledge, is only one of several important barriers to compliance with guideline recommendations. Finally, the literature review suggested extensive, empirically supported opposition among physicians both to E-HRs as currently implemented and, more broadly, to regulatory mandates to use them.

The review also suggested several gaps in the research literature, which were addressed in this study. Foremost, no studies comparing theory-based with atheoretical approaches to interventions on physician behavior were identified. Additionally, although the theory-based assessments discussed in this chapter appear to explain survey findings that most physicians have subjectively unfavorable experiences with and opinions of CDS and meaningful use, specific evidence about the associations of these policies with objectively measured prescribing behaviors is limited. Studies that used objective behavioral measures to assess outcomes of meaningful use were based on single facilities or states, rather than on nationally representative data. Finally, as a relatively new topic with important population-health implications, potentially unsafe ADHD-medication prescribing is understudied.

Whether a theory-based approach better explains this prescribing behavior than does the atheoretical approach used in HITECH Act development was the core empirical question underlying the research questions and hypotheses presented in Chapter 3. Also presented in Chapter 3 are an overview of the study design, a detailed description of the nationally representative archival data set that was the study data source, and definitions of all study variables. The population, sampling frame, sampling methodology, and sample inclusion and exclusion criteria are described, as is the statistical methodology for comparing the predictive accuracy of the atheoretical and theory-based models.

#### Chapter 3: Research Method

Suboptimal outcomes associated with widespread implementation of electronic technologies in U.S. medical practices, including problems in safety (Brown et al., 2017; Schiff et al., 2016) and usability (Ratwani et al., 2016), have been attributed by some observers to design flaws (Phansalkar et al., 2014) resulting from inconsistencies between system features and psychological theory or evidence about human-machine-environment interaction (Ratwani et al., 2016; Savage et al., 2017). Similarly, the strategy of paying physicians to perform according to externally determined metrics, which was foundational to the HITECH Act of 2009 (see Buntin et al., 2010), has been criticized for inconsistency with psychological theories of human motivation (Himmelstein et al., 2014; Kao, 2015). Evidence of an association between physician occupational dissatisfaction and use of E-HRs (Shanafelt et al., 2016), particularly of more sophisticated systems (Emani et al., 2017), supports these concerns.

To address the understudied question of whether theory-based interventions have the potential to produce better outcomes than the more typical (L. Liang et al., 2017) atheoretical approaches to changing physician behavior, the purpose of this quantitative study was to compare two models of potentially unsafe ADHD-medication prescribing for adults: one theory based and the other atheoretical. In this chapter, I present information about the study's sampling frame and design; the archival data set that was analyzed to answer the research questions; operationalization of all study variables; and methods for statistical analyses, including quantitative comparison of the predictive accuracy of the theory-based and atheoretical models.

#### **Research Design and Rationale**

The study was a retrospective, cross-sectional analysis of visits made by adults to U.S. office-based physicians, recorded and publicly available in the archival NAMCS data set. This research design addressed several gaps in available theory-based information about interventions intended to change physician behavior. Foremost, the study provided, for what the literature review suggested is the first time, a quantitative comparison of theory-based and atheoretical approaches to the prediction of physician prescribing behaviors. Additionally, the study provided U.S. national information about the associations of CDS and meaningful use with an objective behavioral measure of prescribing, improving on previous assessments based mostly on subjective measures of physician opinion (see Emani et al., 2017; King et al., 2014) or on single-facility or single-state samples (see Grinspan et al., 2017; Levine et al., 2017). Finally, the study provided theory-based information about potentially unsafe prescribing of ADHD medications to adults, a relatively new topic in the literature on evidence-based prescribing (Fairman et al., 2018). Use of the NAMCS, a nationally representative source of data on objectively measured prescribing behaviors, facilitated fulfillment of these goals for the research.

The outcome (DV) for this study was potentially unsafe prescribing of ADHD medications to adults, measured as a binomial, based on two clinical scenarios: (a) potentially unsafe medication versus a safer treatment among all adults with ADHD who were prescribed any treatment (i.e., either an ADHD medication or psychotherapy) and (b) potentially unsafe medication versus any other option (i.e., safer medication or no medication) among adults with CVD or SUD for whom an ADHD medication was potentially unsafe. These measures were defined using sources presented in Chapter 2, including evidence-based guidelines (see Bolea-Alamañac et al., 2014; Post & Kurlansik, 2012) and federal prescribing information (see FDA, 2002, 2007a).

The key predictors (IVs) of interest were environmental factors: (a) CDS and meaningful use provisions (in both the theory-based and atheoretical models, with opposing hypotheses), (b) derivation of physician revenue from patient satisfaction or volume (theory-based model only), and (c) nature of experience (professional relationship) with the patient and medication (theory-based model only). Additional predictor variables, included in both models, were knowledge measures. These included clinical and demographic characteristics of the patient and physician specialty.

# Methodology

# **Target Population and Sample**

The target population for this research was office visits made by patients aged 17 years or older to U.S. office-based physicians. This target population was chosen because CDS and meaningful use were intended to address decision-making, including prescribing, that takes place during physician-patient encounters, including office visits (see Blumenthal & Tavenner, 2010) and because diagnostic criteria for ADHD apply to persons aged 17 years or older (American Psychiatric Association, 2013). The estimated total target population size exceeded 662 million office visits in 2016, reported by the CDC in its annual summary of NAMCS results (Rui & Okeyode, 2019).

Archival data set sampling process. The NAMCS probability sampling design is multistage, stratified, and cluster randomized (CDC, 2019b). Sequential sampling stages include (a) random selection of physicians, using national lists provided by the American Medical Association (AMA) and American Osteopathic Association (AOA), stratified by each of 15 specialties (e.g., general practice, internal medicine, cardiovascular disease, psychiatry); (b) random selection of 1 week (of 52) for each sampled physician; and (c) simple random sampling of visits within that week (CDC, 2015a). Sampling weights provided in the data set are calculated by the NCHS as multiplicative inverses of sample selection probabilities, with additional adjustments for nonresponse based on numerous indicators of physician characteristics obtained from AMA and AOA lists and from an initial interview with the physician or office staff (Hing et al., 2016; U.S. Department of Commerce, 2016). More detail on these methods is provided below in the section on archival data collection, guality, and screening.

**Subsample of archival data set for current study**. The study sample included all office visits made by patients aged 17 years or older from 2014 to 2016, excluding visits made for emergency care or to a surgeon. These respective exclusions were made using the NAMCS field ERADMHOS, which indicates that the patient was sent directly from the office to an emergency room or hospital, and SPECCAT, which includes a code for surgical care specialty. Visits were further subsampled to include only those made by patients with an ADHD diagnosis in Scenario A and by patients with CVD or SUD in Scenario B. Methods of measurement for diagnoses are described under Operationalization of Constructs. Archival data collection procedures. After physicians are sampled from the AMA and AOA lists, they are contacted by letter from the NCHS and advised to expect additional contact from an NAMCS field worker, a representative of the U.S. Bureau of the Census (n.d.). Physicians can access an online informational web page that explains the survey's purpose and importance, as well as the legal authority under which it is conducted. After physicians agree to voluntary participation, field workers administer an initial induction interview, which is used to gather general information about the physician and office setting, including revenue sources, practice ownership, meaningful use status, and use of various E-HR and CDS functions (U.S. Department of Commerce, 2016).

For each sampled visit, NAMCS field workers use the medical record to abstract items according to a standardized protocol that is detailed in an automated, laptop-based tool (CDC, 2019b). Visit-related measures include patient demographics (e.g., age, sex, race); payment sources for the visit (e.g., private insurance, Medicaid); clinically important biometrics and health behaviors (e.g., blood pressure, tobacco use; body mass index); up to five listed diagnoses made at the visit; a complete list of prescribed medications and treatments, including psychotherapy, with an indicator of whether each medication is new or continued from a previous visit; whether the physician seen at the visit is the patient's primary care provider; and number of visits made by the patient to the office during the previous 12 months (CDC, 2019b).

In addition to these visit-related variables, field workers collect indicators of numerous clinically important medical conditions regardless of when these were diagnosed, based on a prompt that asks, "Regardless of the diagnoses written above, does the patient now have..." (CDC, 2019b, p. 50). For example, a patient with depression who sees a physician for an ear infection would have the infection recorded in the visit diagnosis list, and depression recorded as a medical condition indicator from the entire medical record, regardless of whether depression was diagnosed at the visit. Medical condition indicators are considered a "gold standard" against which the accuracy of visit diagnoses may be measured (Asao, McEwen, Lee, & Herman, 2015, p. 650). Medical condition indicators relevant to the current study included measures of ADHD, CVD, SUD, depression, renal (kidney) disease, and diabetes (see CDC, 2019b).

Archival data quality, cleaning, and screening. Data collection procedures for the NAMCS are regularly assessed in ongoing quality-improvement processes (CDC, 2019b; Rui & Okeyode, 2019). Recent studies and recommendations are summarized in Table 3. These evaluations suggest that NAMCS data are reliable and valid. Additionally, a comprehensive assessment of sample external validity in 2012 based on numerous factors indicated nonsignificant differences between participants and nonparticipants on most measures prior to weighting, and minimal (< 1–2 percentage points for all but one indicator) potential nonresponse bias on visits after weighting (Hing et al., 2016). A caveat to these assessments is that NAMCS methods are reviewed annually and sometimes updated with changes that are typically, but not always, minor, so that evaluations of data quality performed in one year may not fully represent the effects of methods in other years. Details of sampling methods and weight calculations during the study period and of the NCHS analysis of nonresponse bias (Hing et al., 2016) are shown

in Appendix A.

# Table 3

# Recent Quality Assessments of NAMCS Data

Assessment type (source)	Reason	Methods and results	Recommendation
Accuracy of induction interview (Halley et al., 2017)	Policy changes, including E-HRs, affecting practice environment	Ethnographer-observed induction interview Most items answered easily Minor difficulties in addressing some administrative items	Instruction to ask administrative staff when physician is unsure
Coding quality (Rui & Okeyode, 2019)	Regular validation process	Validation sample of 11.6% of records reviewed by external auditor Error rates of 0.03–0.8%	No protocol change
Accuracy of ICD-10 coding (D. T. Lau, Strashny, Phan, Blum, & Burke- Bebee, 2018)	Industry-wide transition from ICD-9 to ICD-10 system	All visits from final quarter of 2014 coded using both methods Error rate of 5%	Minor changes to instructions for coding and record abstracting
Nonresponse bias (Hing et al., 2016; Appendix A)	Decline in physician participation rate <sup>a</sup>	Before weighting, no significant differences between participants and nonparticipants on the majority of 82 indicators; modest (typically 1–5 percentage point) differences on a minority of indicators; large (10–13 percentage point differences only on visit volume quartiles	Overall assessment of minimal nonresponse bias after weighting Could not rule out bias on unmeasured characteristics
		After weighting, minimal (< 1–2 percentage point) potential bias on all indicators except visit volume (maximum difference of 8 percentage point potential bias for lowest visit volume quartile)	

*Note*. E-HR = electronic health record; ICD = International Classification of Diseases.

<sup>a</sup>Participation, defined as consenting and providing data for at least one sampled visit, exceeded 70% prior to 2002 (Hing, Schappert, Burt, & Shimizu, 2005) but had declined to 38.4% by 2012 (Hing et al., 2016) and was 29.5–39.3% in 2014–2016 (CDC, 2017, 2018, 2019b).

Concordant with these assessments of data quality, NAMCS data are used as

nationally representative in an extensive body of peer-reviewed literature, including

academic research and public health surveillance reports (CDC, 2019c). NAMCS

measures of E-HR use and features demonstrated good convergent validity with those obtained from other national samples, including American Board of Family Medicine professional certification data collected from 85% of U.S. family practitioners (Xierali et al., 2013) and the Health Tracking Physician Survey (Li, 2011).

### Quantitative assessment of sample size adequacy for archival data set.

Because of the complex sampling design, the NCHS does not recommend a priori power calculations to determine the adequacy of NAMCS sample size (CDC, 2019b). Instead, the NCHS recommends post hoc assessments of statistical reliability, using software that adjusts for the design effect (i.e., homogeneity of variance; see Groves et al., 2009), such as the SPSS Complex Samples module (CDC, 2019b). Estimates that do not conform to statistical reliability standards are generally not reported by the NCHS or, depending on the nature of the problem, are flagged for higher-level review prior to publication (Parker et al., 2017).

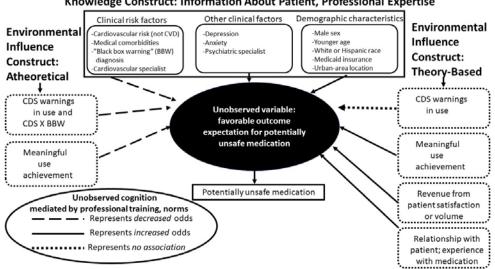
The recommended method for determining statistical reliability depends on the type of estimate. All estimates other than proportions (i.e., percentages) are considered statistically reliable if they meet both of two criteria: (a) the relative standard error (ratio of the standard error to the estimate) is  $\leq$  30% and (b) the estimate is based on  $\geq$  30 cases (CDC, 2019b). For proportions, estimates should meet all of the following criteria: (a) design-effect adjusted denominator of  $\geq$  30 visits; (b) total absolute width of the 95% confidence interval (CI), calculated using a method appropriate for complex samples, of < 0.30; and (c) relative CI (absolute CI width divided by the estimate) of  $\leq$  130% (Parker et al., 2017). If the absolute CI width is unusually small (< 0.05), the NCHS also

recommends ensuring > 8 degrees of freedom. The SPSS Complex Samples procedure for CI estimation is based on the logit-transformation method (IBM SPSS, n.d.), which in simulation analyses produced results similar to those of the Clopper-Pearson method (Neusy & Mantel, 2016) used by the NCHS (Parker et al., 2017).

# **Operationalization of Constructs**

In this section, I describe a priori plans for operationalization of all variables. As described later in this chapter, a priori planned statistical analyses included assessments of sample size, multicollinearity, and statistical reliability. For a few predictor variables, these assessments resulted in post hoc changes to the a priori definitions described here. These changes, along with the rationales for each, are explained in Chapter 4.

Figure 2 summarizes the study's two statistical models, one theory based (right side) and the other atheoretical (left side). The figure depicts the cognitive act of



Knowledge Construct: Information About Patient, Professional Expertise

*Figure 2.* Summary of statistical models. BBW = black-box warning; CDS = computerized decision support.

prescribing as an integration and synthesis of information from various sources (knowledge construct, top, solid-line rectangles), influenced by environmental factors (dotted rectangles), to create outcome expectations (unobserved variable, center) for each potential decision (Bandura, 1989; Kelder et al., 2015). Arrows indicate hypothesized associations. Because knowledge construct variables were hypothesized to act in the same way in both the theory-based and atheoretical models, they were included in both models, although not specifically addressed by any study research question.

**Knowledge construct predictors**. Table 4 shows definitions of all knowledge construct predictors grouped by the categories shown at the top of Figure 2. The overall approach to measurement of the variables was similar to that used by Fairman et al. (2018), with modifications to reflect NAMCS data formats, particularly the availability of medical condition indicators. For clinical risk, summary indices planned a priori included a cardiovascular risk score developed for office-based practice to estimate baseline risk of a cardiac event in people without CVD (D'Agostino et al., 2008) and the Charlson Comorbidity Index, a validated summary measure of chronic disease burden based on mathematically weighted combinations of diagnoses (Quan et al., 2011).

Additional clinical risk measures included whether the patient had a medical condition indicating a black-box (highest-severity) warning level; and whether the physician was a cardiologist, indicating both expertise for assessment of cardiovascular disorders and a need for specialty-level cardiac care. Other relevant clinical measures included the psychiatric comorbidities of depression and anxiety (see Mao & Findling, 2014) and whether the prescriber was a psychiatrist, indicating both expertise for

# Table 4

# Knowledge Construct Independent (Predictor) Variables and Definitions

Construct type	NAMCS variable name or measurement method
Clinical risk, cardiovascular <sup>a</sup>	WARVES variable name of measurement method
Age	AGE
BMI	BMI
SBP, treated	BPSYS, NCMED (indicates new or continued prescription; combine with medication lists in
SBP, untreated	Appendix B to identify antihypertensives)
Current smoking	USETOBAC
Diabetes	DIABTYP0; DIABTYP1; DIABTYP2 (TYP indicates diabetes type)
Diabetes	DIADTITO, DIADTITT, DIADTITZ (TTT indicates diabetes type)
Clinical risk, Charlson Comorbid	lity Index <sup>b</sup>
Cancer, nonmetastatic	CANCER condition indicator; ICD-9 and ICD-10 codes to measure metastasis (weight = 2)
Cancer, metastatic	CANCER condition indicator; ICD-9 and ICD-10 codes to measure metastasis (weight = 6)
Connective tissue /rheumatic	ICD-9 and ICD-10 codes (weight $= 1$ )
disease	
Dementia	ALZHD condition indicator (weight $= 1$ )
Diabetes requiring medication	DIABTYP0; DIABTYP1; DIABTYP2; medication lists in Appendix B to identify
treatment, uncomplicated	antidiabetic medications (weight $= 1$ )
Diabetes with complications	ICD-9 and ICD-10 codes (weight = $2$ )
(renal, eye, neurologic)	
HIV	HIV condition indicator (weight $= 6$ )
Liver disease, mild	ICD-9 and ICD-10 codes (weight $=$ 1)
Liver disease, severe	ICD-9 and ICD-10 codes (weight = $3$ )
Myocardial infarction history	ICD-9 and ICD-10 codes (weight $=$ 1)
Paraplegia	ICD-9 and ICD-10 codes (weight = $2$ )
Peptic ulcer	ICD-9 and ICD-10 codes (weight $=$ 1)
Peripheral vascular disease	ICD-9 and ICD-10 codes (weight $=$ 1)
Pulmonary disease	ASTHMA or COPD condition indicators; ICD-9 and ICD-10 codes for other lung diseases
	(weight = 1)
Renal disease	CKD, CRF, or ESRD (weight $= 2$ )
~~	
<u>Clinical risk, other</u>	
"Black box" warning diagnosis	ETOHAB; SUBSTAB
Cardiologist	SPECR physician specialty code; $08 = cardiovascular$ disease
Other clinical factors	
Depression	DEPRN condition indicator
Anxiety	ICD-9 and ICD-10 codes
Psychiatrist	SPECR physician specialty code; 11 = psychiatry
r syematrist	Si Dere physician speciary code, i i = psychiary
Demographic characteristics	
Male sex	SEX; $1 = \text{female}; 2 = \text{male}$
Younger age	AGE; groups aged 18–25 years; 26–49 years; 50 years or older (McCabe et al., 2019)
White or Hispanic Race	RACERETH; 1 = White non-Hispanic; 2 = Black non-Hispanic; 3 = Hispanic; 4 = other,
*	non-Hispanic
Medicaid insurance	PAYTYPER indicates primary expected source of payment for the visit; 1 = private
	insurance; 2 = Medicare; 3 = Medicaid, CHIP, or other state-based program
Urban location	MSA; $1 =$ metropolitan statistical area; $2 =$ not a metropolitan statistical area

*Note.* Variable names shown in all caps indicate NAMCS fields. ICD codes are in Appendix C. Sources for NAMCS variable information were CDC (2017, 2018, 2019b). BMI = body mass index; CKD = chronic kidney disease; COPD = chronic obstructive pulmonary disease; CRF = chronic renal failure; ESRD = end-stage renal disease; ETOHAB = alcohol abuse; HIV = human immunodeficiency virus; ICD = International Classification of Diseases; MSA = metropolitan statistical area; PVD = peripheral vascular disease; SBP = systolic blood pressure; SUBSTAB = substance abuse.

<sup>a</sup>Summary score indicates likelihood of a cardiac event (D'Agostino et al., 2008). <sup>b</sup>Weighted results are summed to indicate total comorbidity burden (Quan et al., 2011). CEBVD, CHF, and myocardial infarction are typically included in the Charlson comorbidity index but were excluded a priori because they were included in the outcome measure.

assessment of psychological disorders and increased likelihood of prescribing an ADHD medication despite potential risks (see Leslie et al., 2012). Demographic characteristics commonly associated with controlled substance prescribing included male sex, younger adult age, White or Hispanic race, Medicaid insurance, and urban-area office location (see Fairman et al., 2017; McCabe et al., 2019; Rigg & Monnat, 2015).

**Environmental-influence construct predictors**. Definitions of environmental predictors, categorized by theoretical construct, are shown in Table 5. Except where otherwise indicated, all were drawn from the induction interview. To address the findings of Halley et al. (2017) that physicians may have difficulty recalling administrative arrangements in that interview, the a priori statistical analysis plan included validation of meaningful use reports against ONC standards for E-HR functionality (see Patel, Jamoom, Hsiao, Furukawa, & Buntin, 2013). Because medication-related CDS is just one of many meaningful use criteria (Wright et al., 2014), it was expected a priori that many physicians would have used CDS without achieving meaningful use. It was also expected that a small number of physicians would have achieved meaningful use without CDS because of exemptions from some core measures (e.g., for writing fewer than 100 prescriptions annually; see Wright et al., 2014).

Additional classification methods were planned for the two environmentalconstruct variables unique to the theory-based models (bottom two sections of Table 5). The a priori definition of revenue from patient volume or satisfaction was based on meeting any of the following criteria: (a) Compensation was based in part on satisfaction surveys (COMPSAT). (b) Compensation was based in part on the practice's financial

# Table 5

Environmental Construct Independent (Predictor) Variables and Definitions

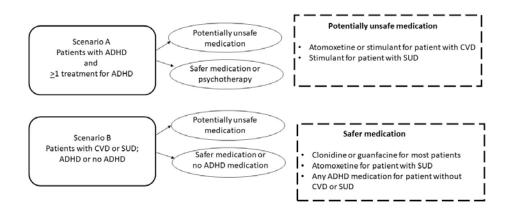
Variable	Definition
Meaningful use, both atheo	retical and theory-based models
EMEDREC	Whether the practice has an E-HR: 1 = yes, all electronic; 2 = yes, part paper, part
	electronic; 3 = no
HHSMU	Whether the practice E-HR meet meaningful use criteria: $1 = yes$ ; $2 = no$ ; code as
	2 if no E-HR
PRMCARER	Percentage of practice revenue from Medicare (to be used only to assess whether physician may have been subject to penalties for failure to achieve meaningful use): $1 = \le 25\%$ ; $2 = 26-50\%$ ; $3 = 51-75\%$ ; $4 = >75\%$
ECPOE, ECPOER,	Validation of meaningful use status (core E-HR functioning; all years): electronic
ESCRIP, ESCRIPR	prescribing and prescription transmission; recording of patient demographics,
EDEMOG, EDEMOGR	medication allergy lists, and problem lists; CDS for guideline-based care
EMEDALG,	reminders and warnings (Patel et al., 2013)
EMEDALGR	
EPROLST, EPROLSTR	
EREMIND, EREMINDR	
EWARN, EWARNR	
CDS, both atheoretical and	theory-based models
ECPOE, ECPOER	Whether the office has computerized capability to order prescriptions
	electronically: $1 = \text{yes}$ ; $2 = \text{no}$
EWARN, EWARNR	Whether the electronic prescribing function warns of drug interactions or contraindications: $1 = yes$ ; $2 = no$ (code as 2 if no electronic prescribing function)
Revenue, theory-based mod	del only
COMPFIN	Binomial indicator of compensation based on financial performance of practice
COMPSAT	Binomial indicator of compensation based on satisfaction surveys of this
	physician's patients
EMPSTAT	Employment status; 1 = full owner; 2 = part owner; 3 = employee; 4 = contractor
PHYSCOMP	Best description of physician's compensation: $1 =$ fixed salary; $2 =$ share of
	practice billings or workload; $3 = mixed$ ; $4 = hourly$ ; $5 = other$
PRPATR	Percentage of revenue that comes from patient payments: $1 = \le 25\%$ ; $2 = 26-50\%$
	3 = 51–75%; 4 = > 75%
REVFFSR	Percentage of revenue that comes from a usual and customary fee-for-service rate
	$1 = \le 25\%$ ; $2 = 26-50\%$ ; $3 = 51-75\%$ ; $4 = > 75\%$
	ionship, theory-based model only
SENBEFOR <sup>a</sup>	New or established patient: $1 = $ established; $2 = $ new patient
PRIMCARE <sup>a</sup>	Whether this physician is the patient's primary care provider: $1 = yes$ ; $2 = no$
PASTVIS <sup>a</sup>	Number of visits this patient made to this practice in past 12 months (interval-
	scale)
NCMED <sup>a</sup>	Whether the ADHD medication is new or continued (i.e., is patient history with
	medication known to the physician)

Note. Variable names shown in all caps indicate NAMCS fields. Sources for NAMCS variable information were CDC (2017, 2018, 2019b). ADHD = attention-deficit hyperactivity disorder; CDS = computerized decision support; E-HR = electronic health record; NAMCS = National Ambulatory Medical Care Survey.

<sup>a</sup>Indicates a variable collected from the medical record rather than the induction interview.

performance (COMPFIN) or on share of practice billings (PHYSCOMP). (c) Physician was a full owner or part owner of the practice (EMPSTAT). (d) Percentage of revenue from either patient payments or fee-for-service payments exceeded 25% (PRPATR and REVFFSR). A priori planned categories for the physician-patient relationship were as follows: patient is new (i.e., no previous relationship, SENBEFOR = 2; reference group); patient is established, but physician is not the primary care provider (SENBEFOR = 1; PRIMCARE = 2); physician is the primary care provider (PRIMCARE = 1). Additional categorizations based on number of previous visits (PASTVIS), depending on the variable's distribution and available sample size, were also included in the a priori plan.

**Dependent variable (outcome) measures**. Figure 3 summarizes the binomial dependent variable measures and definitions used in each of the two clinical scenarios.



*Figure 3.* Scenario subsamples (rectangles, left side) and treatment options. Indicator of clonidine or guanfacine safety for most patients means that uses of clonidine are potentially unsafe in patients with severe CVD, end-stage renal disease, low blood pressure, or slow heart beat (see FDA, 2010). Uses of guanfacine are potentially unsafe in patients with low blood pressure or slow heart beat (see FDA, 2013). No instances of potentially unsafe use of clonidine or guanfacine were observed in the final study sample. See Appendix C for diagnosis codes. ADHD = attention-deficit hyperactivity disorder; CVD = cardiovascular disease; SUD = substance use disorder.

For both scenarios, lists of safer treatment choices were based on treatment guidelines current during the study period, which recommended atomoxetine for patients at risk of abuse (see Bolea-Alamañac et al., 2014; Fields et al., 2017; Post & Kurlansik, 2012), and on federal prescribing guidance (FDA 2002, 2007a). Thus, although a current European guideline recommends extended-release stimulants or lisdexamfetamine as appropriate alternatives for patients with SUD (Kooij et al., 2019), they were not defined as such in this study. For the psychotherapy option in Scenario A, the a priori plan was to use the NAMCS indicators, PSYCHOTH, which indicates whether the physician recommended any treatment intended to change the patient's behaviors or symptoms, and MENTAL, which indicates mental health counseling (CDC, 2019b). Table 6 specifies the a priori methods for measuring the diagnoses represented in Figure 3.

Table 6

-			
Diagnosis	Role in	Role in	NAMCS variable name or measurement method
	Scenario A	Scenario B	
ADHD	Subsampling criterion	None	ICD-9 and ICD-10 diagnoses until 2016. Medical condition indicator beginning in 2016
CVD <sup>a</sup>	Reflected in the outcome	Subsampling criterion	Medical condition codes: CAD, CEBVD, CHF, or IHD; or ICD-9 or ICD-10 codes: angina, arrhythmia, cardiomegaly, cardiomyopathy, congenital heart anomaly, hypertensive heart disease, history of heart attack, or valvular disorder
SUD	Reflected in the outcome	Subsampling criterion	ETOHAB; SUBSTAB <sup>b</sup>

Measures o	f Scenaric	o Subsamplir	ig and Desi	gnation of	<sup>c</sup> Potentiallv l	Unsafe Prescription
	,	······································	0	0		

*Note.* Variable names shown in all caps indicate NAMCS fields. Sources for NAMCS variable information were CDC (2017, 2018, 2019b). ADHD = attention-deficit hyperactivity disorder; CAD = coronary artery disease; CEBVD = cerebrovascular disease; CHF = congestive heart failure; CVD = cardiovascular disease; IHD = ischemic heart disease; NAMCS = National Ambulatory Medical Care Survey; SUD = substance use disorder.

<sup>&</sup>lt;sup>a</sup>Adapted from Fairman et al. (2018) to indicate serious CVD, accounting for differences between claims-based and NAMCS coding (L. Davis, personal communication, August 5, 2019). <sup>b</sup>Data collectors are advised to code for ETOHAB if the medical record indicates "alcoholism, excessive alcohol use, heavy, problem drinking, binge, or chronic drinking/drinker" (CDC, 2019b, p. 144) and for SUBSTAB if it indicates "addiction, illicit drug use, or injection/intravenous drug use/user" (p. 146).

### **Statistical Analysis Plan**

The study research questions and hypotheses are summarized below.

RQ1: What is the quantitative association of medication-related CDS in the practice environment with potentially unsafe prescribing of ADHD medications, measured as a binomial, in a logistic regression model that accounts for knowledge construct variables?

 $H_01$ : (theory-based). Medication-related CDS is not significantly associated with potentially unsafe prescribing of ADHD medications.

 $H_a$ 1: (atheoretical). Medication-related CDS is associated with decreased odds of potentially unsafe prescribing of ADHD medications, particularly for patients who have a medical condition with a black-box warning.

RQ2: What is the quantitative association of meaningful use in the practice environment with potentially unsafe prescribing of ADHD medications, measured as a binomial, in a logistic regression model that accounts for knowledge construct variables?

 $H_0$ 2: (atheoretical). Meaningful use is associated with decreased odds of potentially unsafe prescribing of ADHD medications.

 $H_a$ 2: (theory-based). Meaningful use is associated with increased odds of potentially unsafe prescribing of ADHD medications.

RQ3: Which model—that based on atheoretical interventions, or that based on theory-derived predictors—better explains the binomial measure of potentially unsafe ADHD-medication prescribing, where better explanation is defined as coefficients in the expected direction, predictive accuracy measured with the c-statistic, and model fit measured with the –2LL statistic?

 $H_0$ 3: The atheoretical model better explains potentially unsafe prescribing of ADHD medications.

 $H_{\rm a}$ 3: The theory-based model better explains potentially unsafe prescribing of ADHD medications.

**Software and testing procedures**. In accordance with NCHS guidance for NAMCS data (CDC, 2019b), all analyses were performed using the SPSS Complex Samples module (v. 25.0), which adjusts variance estimates and statistical test results for the sampling design effect (see Groves et al., 2009). Statistical significance tests were based on an a priori alpha value of .05. The first analytic step was to characterize the four outcome measure groups (two scenarios, binomial measure of potentially unsafe versus safer for each) on all variables shown in Tables 4 and 5, assessing the statistical reliability of subgroup estimates. These assessments were used to identify variables for inclusion in remaining analyses and to calculate estimates of statistical precision for all results.

**Statistical testing procedures**. To answer the study research questions, I conducted bivariate and logistic regression analyses using Complex Samples procedures for four models—atheoretical and theory-based for each of the two clinical scenarios. Bivariate analyses included a description of sample characteristics for each of the two scenarios, and calculations of rates of potentially unsafe prescribing for each sample subgroup. In the first stage of multivariate modeling, I assessed coefficients for multicollinearity using a method recommended by Midi, Sarker, and Rana (2010).

Specifically, because multicollinearity diagnostics are not available for logistic regression in SPSS, I performed linear regressions of the outcome measures on predictors solely for the purpose of obtaining tolerance and variance inflation statistics, which are standard collinearity measures (see Warner, 2013). Despite the binary dependent variable, this procedure was appropriate because these measures are affected only by relationships among independent variables, not by independent-dependent variable relationships (Midi et al., 2010). I tested the remaining predictors in logistic regression models for statistical reliability based on NCHS standards (see CDC, 2019b). As planned a priori, I assessed predictors for inclusion in the final models based both on the results of these tests and on theoretical considerations.

In the final modeled logistic regressions, odds ratios and 95% CIs indicated the odds multiplier for each predictor (e.g., meaningful use) relative to its corresponding reference category (e.g., no meaningful use; see Warner, 2013). CI spans from < 1 to > 1 indicated nonsignificant associations. To answer RQ1 and RQ2, respectively, I compared the two competing models on coefficients for CDS and meaningful use.

RQ3 was answered by comparing the predictive accuracy of the atheoretical with theory-based models, based on three standard criteria. The first criterion was whether coefficients for each of the environmental predictors were in the expected directions (e.g., odds ratio > 1 where a positive predictor was hypothesized; see Warner, 2013). The second criterion was predictive accuracy based on the concordance (c) statistic, which measures the percentage of all possible combinations of paired cases in the data set with divergent outcomes (i.e., one visit potentially unsafe, the other safer) in which the

prediction and outcome are concordant (i.e., the predicted probability of a potentially unsafe prescription is greater for the potentially unsafe case than for the safer case; see Austin & Steyerberg, 2012). A c-statistic value of .5 indicates that a model performs no better than chance, and a 1 indicates perfect prediction.

The third criterion was statistical significance of improvement in fit, comparing the theory-based with the atheoretical models, using a  $\chi^2$  test of change in –2LL, with degrees of freedom equal to the difference in the number of model predictors (Pampel, 2000). Because the SPSS Complex Samples logistic regression procedure does not report –2LL automatically, I calculated –2LL for each of the two competing models using the SPSS Compute function and the standard formula below, applied to each visit case:

$$LL_{i} = (Y \times \ln [P]) + ((1 - Y) \times \ln [1 - P]));$$

then summed across the data set using the Complex Samples frequencies procedure to adjust totals for the design effect (see Groves et al., 2009);

$$-2LL_{sum} = -2\sum_{i=1}^{n} LL_i$$

where Y is the actual outcome, P is the predicted probability of the outcome, and ln indicates a natural-log transformation (see Pampel, 2000).

### **Threats to Validity**

**Internal**. As in any study with a nonexperimental design, the foremost threat to internal validity was the possibility of influence on the study outcome by unmeasured confounding factors (see Warner, 2013), such as symptom severity, patient demands, or features of the medical practice environment not captured in the study predictors (IVs).

The measures of model accuracy and fit, described previously, informed an assessment of this issue by providing an indication of the overall quality of the models. An additional potential confounding factor was the imposition of meaningful use penalties (see Monica, 2017), which could not be measured directly using NAMCS data. A sensitivity analysis estimated the potential effect of this factor as the number of visits made to providers who had not achieved meaningful use by 2015 and derived at least 51% of revenue from Medicare (PRMCARER). The possibility of residual confounding was considered in interpretation of the results.

An additional potential threat to internal validity was the lack of direct information about psychological mediators, such as physician cognition or emotion, that might have been obtained from a qualitative or survey study of physician experiences with or opinions of E-HRs. Mitigating this potential threat, the current study's hypotheses were informed by a large body of qualitative and quantitative evidence about the effects of E-HR use in routine practice (see Schiff et al., 2016). Another possibility was misclassification of exposure because of omissions of relevant data on psychiatric diagnoses (e.g., SUD) or procedures (e.g., psychotherapy) from the medical record (see Madden et al., 2016). I assessed these situations with data transformations and sensitivity analyses, consistent with APA standards for analyses of archival data (see Applebaum et al., 2018), and accounted for these assessments in data interpretation.

The final threat to internal validity was the possibility that CDS warnings were not transmitted successfully to, or viewed by, physicians. A related question is the degree to which CDS systems placed a higher priority on black-box patient diagnoses than on other potential safety issues. To validate the use of a black-box warning as indicating a greater probability of a high-severity alert in a CDS, I reviewed information provided by several proprietary knowledge bases, which are sources used by system developers in populating CDS algorithms (see C. M. Cheng, DeLizza, & Kapusnik-Uner, 2013; C. M. Cheng, DeLizza, & Kapusnik-Uner, 2014; Fung, Kapusnik-Uner, Cunningham, Higby-Baker, & Bodenreider, 2017). Searches were conducted manually for three medications, amphetamine, atomoxetine, and methylphenidate, using subscriptions available by membership in a health sciences university community for three knowledge bases: Facts and Comparisons (Wolters Kluwer, 2019a), Lexicomp (Wolters Kluwer, 2019b), and Micromedex (IBM Watson, 2019). In the three knowledge bases, black-box warnings were displayed prominently, on the drug information landing screen for Facts and Comparisons and Lexicomp, and via a designated tab for black-box warnings in Micromedex. Additionally, First Databank, another commonly used information source (see Fung et al., 2017), reported an initiative to represent black-box content comprehensively in CDS one year prior to the current study's start date (see C. M. Cheng et al., 2013). Because of the many different systems and configurations in use in the United States (CDC, 2015c), this validation exercise does not prove that all CDS warnings for these medications accurately represented black-box information. It does indicate that the hypothesized interaction effect for black-box warnings in the atheoretical model was reasonable.

**External**. Several potential limitations on external validity were noted prior to data analysis. One possibility considered was that NAMCS participants and

nonparticipants differed in unmeasured ways that affected the generalizability of the data, even after application of weights to adjust for sampling design and nonresponse. Previous quantitative research suggested against this possibility, including the NCHS finding of minimal nonresponse bias measured across numerous physician and visit characteristics in 2012 (see Hing et al., 2016; Appendix A) and several studies finding little nonresponse bias in physician surveys with low response rates (see McFarlane et al., 2007; Willis et al., 2013; Ziegenfuss et al., 2012). Nonetheless, to assess this possibility, study analyses included comparisons with other available published data on adult patients diagnosed with ADHD, CVD, or SUD (see Compton et al., 2018; Fairman et al., 2017; Kooij et al., 2019; Xian et al., 2019) or using prescribed ADHD medications (see Compton et al., 2018; Fairman et al., 2018). A comparison with available national data on E-HR use (ONC, 2019) was also performed.

It is also possible that patients with a formal diagnosis of ADHD, a selection criterion for Scenario A, were not representative of all U.S. residents who have ADHD. Previous research has found that ADHD diagnosis and treatment vary by demographic characteristics, such as race or geographic location, to a degree that is unlikely to be explained by neurobiology (Fairman et al., 2017; Gellad et al., 2014). This potential threat to external validity was partly addressed by Scenario B, which was not limited to patients with an ADHD diagnosis. The sample also lacked external validity for patients referred to emergency care, such as for an acute cardiac event, and for surgeons.

An additional threat to external validity arose from the decision by the NCHS to allow physicians to submit patient E-HRs in lieu of on-site data collection in 2016 (CDC, 2019b). Because these data could not be included in the final 2016 data set, and because the technological capabilities or practice patterns of physicians who chose E-HR data collection may have systematically differed from those of other participants, I performed sensitivity analyses on key findings excluding 2016, to assess whether any external validity problem caused by this issue affected study results.

# **Ethical Procedures**

NAMCS data are collected under provisions of the NCHS Ethics Review Board (2018), which reviews all protocols for treatment of human subjects. Data are publicly available online without permission or registration required for access. They are anonymous and include no identifiable information about patients or physicians. Details that might have the potential to identify a person or visit are truncated (e.g., age 92 or older; body mass index less than 12 or greater than 64; CDC, 2019b). Thus, ethical considerations related to recruitment, participant refusal, data collection, and confidentiality were not applicable in this study. The Walden University Institutional Review Board (IRB) approved the study on October 29, 2019 (approval number 10-29-19-0761704). I considered careful interpretation and dissemination of study findings as the most important ethical consideration for this project because of the visibility of the topics of E-HRs (e.g., Fry & Schulte, 2019) and substance abuse (e.g., Seth et al., 2018). Accordingly, data interpretations were conservative, emphasizing limits on statistical reliability and considering the current study findings in the context of previous research on physicians' responses to interventions on their behavior.

### Summary

This quantitative study comprised retrospective, cross-sectional analyses of a nationally representative sample of U.S. office-based physician visits made by adults. The study outcomes (DVs) were binary indicators of whether a potentially unsafe medication was prescribed, based on objective behavioral measures. Predictors (IVs) were grouped into categories of knowledge constructs (e.g., patient characteristics, clinical risk, physician specialty) and environmental constructs (i.e. CDS, meaningful use, revenue sources, and experience with the patient (i.e., nature of physician-patient professional relationship) and medication (i.e., whether new or continued). Standard statistical measures from logistic regression analyses, including odds ratios, 95% CIs, and measures of predictive accuracy and goodness of fit, were used to compare the relative merits of theory-based and atheoretical approaches to explaining the study outcomes.

In Chapter 4, I present study findings. These include descriptive characteristics of the sample and both bivariate and multivariate analyses of the relationships between the outcomes and predictors. Also included are assessments of sample generalizability, quantitative measures of multicollinearity and reliability, and sensitivity analyses to assess the potential effects of threats to external and internal validity on study results.

#### Chapter 4: Results

The purpose of this quantitative study was to assess the relative strengths of atheoretical and theory-based approaches to promotion of evidence-based medicine by comparing logistic regression models on standard measures of accuracy and fit. The binary outcome (DV) measure was potentially unsafe prescribing of ADHD medications for adults seen in office-based physician visits. Key predictor (IV) measures, representing environmental constructs in social cognitive theory, included CDS, meaningful use, revenue derived from patient volume or satisfaction, and experience with the patient and medication. Additional predictors were knowledge-construct variables, including expertise (i.e., physician specialty) and information necessary for prescribing (e.g., patient characteristics; Kelder et al., 2015). These knowledge-construct predictors were considered exogenous to the office visit and were treated as equivalent in the two models. Research questions and hypotheses included the following:

RQ1: What is the quantitative association of medication-related CDS in the practice environment with potentially unsafe prescribing of ADHD medications, measured as a binomial, in a logistic regression model that accounts for knowledge construct variables?

 $H_0$ 1: (theory-based). Medication-related CDS is not significantly associated with potentially unsafe prescribing of ADHD medications.

 $H_{a}1$ : (atheoretical). Medication-related CDS is associated with decreased odds of potentially unsafe prescribing of ADHD medications, particularly for patients who have a medical condition with a black-box warning.

RQ2: What is the quantitative association of meaningful use in the practice environment with potentially unsafe prescribing of ADHD medications, measured as a binomial, in a logistic regression model that accounts for knowledge construct variables?

 $H_02$ : (atheoretical). Meaningful use is associated with decreased odds of potentially unsafe prescribing of ADHD medications.

 $H_a$ 2: (theory-based). Meaningful use is associated with increased odds of potentially unsafe prescribing of ADHD medications.

RQ3: Which model—that based on atheoretical interventions, or that based on theory-derived predictors—better explains the binomial measure of potentially unsafe ADHD-medication prescribing, where better explanation is defined as coefficients in the expected direction, predictive accuracy measured with the c-statistic, and model fit measured with the –2LL statistic?

 $H_0$ 3: The atheoretical model better explains potentially unsafe prescribing of ADHD medications.

 $H_{\rm a}$ 3: The theory-based model better explains potentially unsafe prescribing of ADHD medications.

In this chapter, I explain sequential steps in data collection and processing, discuss characteristics of patients and physicians included in each of the study's two clinical scenarios, and assess the sample's external validity by comparing its characteristics with those of other large samples. Following a descriptive overview of rates of potentially unsafe prescribing, I consider the assumptions and findings of the logistic regression analyses and of several sensitivity analyses. The chapter concludes with a summary of answers to the research questions. Throughout the chapter, counts of visits are raw and unweighted, percentages and odds ratios (ORs) are weighted as nationally representative estimates, and all statistical tests and confidence intervals (CIs) are adjusted for the multistage sampling design using the IBM SPSS (V25.0) Complex Samples module.

### **Data Collection and Processing**

After receiving approval from the Walden University IRB to access the study data on the NCHS website, I downloaded all NAMCS records of U.S. office-based physician visits made from 2014 to 2016 and combined them into a single analytic file. The file contained all study predictors (IVs) and data needed to compute the binary outcome (DV), as described in Chapter 3. From that data set of visits (unweighted N = 87,207), I excluded visits made by patients younger than 17 years (n = 12,939) or by those sent to emergency care (n = 344), and visits made to surgeons (n = 25,640), leaving an unweighted total of 48,284 visits.

### **Post Hoc Analytic Adjustments**

During initial data processing and prior to creation of the cohorts (i.e., groups of visits) for Scenario A and Scenario B, I identified several unexpected practice patterns. These, along with the data transformations used to resolve them and rationales for each, are summarized in Table 7. In accordance with the recommendations of the APA (Applebaum et al., 2018), which represent general reporting standards for quantitative research, and of the International Society for Pharmacoeconomics and Outcomes Research, which are specific to archival medical data (Berger, Mamdani, Atkins, &

# Table 7

Practice pattern	Data modification	Rationale
<ul> <li>Missing data on BMI and blood pressure for 47% of visits.</li> <li>Unable to calculate the planned cardiovascular risk score.</li> </ul>	Replace risk score with interval scale age.	<ul> <li>Imputation technique not feasible because of large number of affected records.</li> <li>Age known to be the primary predictor of cardiovascular risk.<sup>a</sup></li> </ul>
<ul> <li>Missing data on meaningful use variable for 1,231 of 48,284 visits.</li> <li>Most were "unknown" in induction interview.</li> </ul>	Base meaningful use indicator, when missing, on specific system functions (e.g., electronic problem lists, electronic reminders).	• In a priori validation assessment, 96% of physicians who reported meeting meaningful use criteria had 6 or 7 of required functions, and 83% had all 7.
• Generic, rather than brand, forms of Kapvay and Intuniv were prescribed.	Code generics as Kapvay and Intuniv for patients with ADHD and without hypertension.	• Consistent with product labels for these medications. <sup>b</sup>
• For 230 of 2,270 substance abuse visits, counseling was provided without an explicit diagnosis of SUD.	Count the provision of alcohol abuse counseling or substance abuse counseling as an indicator of substance use disorder.	<ul> <li>Substance abuse counseling is recommended for hazardous use, even if not dependent.<sup>c</sup></li> <li>Many abuses of ADHD medications are hazardous but not necessarily dependent.<sup>d</sup></li> </ul>
• For 1,181 visits provided by psychiatrists or mental health providers, no explicit code for psychotherapy or counseling was included in the record.	Count a visit with a mental health provider or psychiatrist as psychological counseling, even if not explicitly coded as such.	<ul> <li>Excluding these as "no treatment" visits from Scenario A could have resulted in external validity error</li> <li>975 included a diagnosis of a psychiatric disorder</li> </ul>
• The variable REVFFSR, planned for use as an indicator of patient revenue, was coded for a higher than expected number of visits and may have represented a payment calculation method rather than source of payment.	Remove fee-for-service revenue from the definition of patient-derived revenue. Base only on the other a priori indicators: compensation type, ownership status, patient payments, and payment on satisfaction measures.	<ul> <li>No published criteria for patient- derived revenue were identified in the literature review.</li> <li>Of 31,306 visits coded with REVFFSR, 9,097 were to physicians paid a salary, and 11,891 to physician employees.</li> </ul>

Data Modifications Made After Accessing Data and Prior to Analyses of Results

*Note.* Generic names for Kapvay and Intuniv, respectively, are clonidine and guanfacine. ADHD = attention-deficit hyperactivity disorder; BMI = body mass index; REVFFSR = percentage of revenue from "usual, customary, and reasonable fee-for-service" (CDC, 2019b, p. 79); FDA = U.S. Food and Drug Administration.

<sup>&</sup>lt;sup>a</sup>Karmali, Goff, Ning, and Lloyd-Jones (2014). <sup>b</sup>FDA (2010, 2013). <sup>c</sup>Moyer and Preventive Services Task Force (2013); B. Shapiro, Coffa, and McCance-Katz (2013). <sup>d</sup>Compton et al. (2016); Weyandt et al. (2016).

Johnson, 2009), I planned three sensitivity analyses to assess the effects of these data transformations: (a) exclude substance abuse visits in which abuse counseling was provided without a specific diagnosis of SUD, (b) exclude visits made to mental health professionals without a specific indicator for psychotherapy, and (c) modify the definition of patient-derived revenue to reflect only direct financial compensation. These sensitivity analyses, along with the analysis of results excluding 2016 that was planned a priori, are reported in the Additional Analyses section later in the chapter.

## **Formation of Scenario Cohorts**

Of 48,284 sampled visits, 902 included a diagnosis of ADHD. Of these, 810 qualified for inclusion in the Scenario A cohort by the prescribing of a treatment: medication only (n = 300, 35.5%), psychotherapy or counseling only (n = 108, 11.9%), or both (n = 402, 52.6%). The Scenario B cohort comprised 9,101 visits made by patients with CVD only (n = 6,858, 72.3%), SUD only (n = 1,963, 24.1%), or both CVD and SUD (n = 280, 3.6%). Of Scenario B visits, 155 (1.6%) included the prescribing of ADHD medication. Of Scenario B cohort visits where medication was prescribed, 88 (54.8%) were made by a patient with an ADHD diagnosis.

### **Statistical Testing Procedures**

As planned a priori, the statistical testing process included assessments of sample size adequacy and multicollinearity, discussed in this section, and logistic regression coefficient statistical reliability. These tests were used to measure adherence of analyses to NCHS statistical reliability standards (see CDC, 2019b) and to the assumptions of logistic regression analysis (see Warner, 2013).

**Sample size adequacy**. Sample size assessments of the four study subgroups (i.e., binary indicator of potentially unsafe medication versus safer option for each of two scenarios) produced mixed findings. Most estimates in Scenario A (Appendix D) and nearly all in Scenario B (Appendix E) met NCHS standards for CI width. However, no estimates in Scenario A had a design effect-adjusted denominator of  $\geq$  30 (see Parker et al., 2017). In Scenario B, estimates for the potentially unsafe medication group, but not for the safer group, met the denominator standard.

For two predictors (IVs), the cell (subgroup) sizes in the crosstabulation between the independent and dependent variables were so small that the variables had to be excluded from multivariate modeling. The first was black-box warning in Scenario A, because only nine of 81 potentially unsafe prescriptions were for patients without SUD. The second was continued versus new prescription in Scenario B, because nearly all (11 of 12) safer prescriptions were continued (i.e., only one new).

**Multicollinearity assessments**. Multicollinearity must be assessed when using multivariate techniques because excessive overlap in variance among independent variables makes model coefficients unreliable (Fox, 1991). Using the method described by Midi et al. (2010), I performed linear regression analyses to assess multicollinearity based on tolerance (i.e.,  $1 - R^2$  for each predictor regressed on all other predictors; see Warner, 2013) and on variance inflation factor (i.e., reciprocal of tolerance, a measure of coefficient instability; see Fox, 1991). Because one variable, age, showed considerable multicollinearity with the a priori age-category indicators (aged 26–49 years; aged  $\geq$  50 years; Appendix F), I replaced the categorical variables with interval-scale age.

Statistics for CDS and meaningful use did not indicate excessive multicollinearity (models without interaction terms: tolerance = .360–.414 for Scenario A; tolerance = .572–.574 for Scenario B), likely because the requirement for CDS in meaningful use may be waived (see Wright et al., 2014). A follow-up analysis (not shown in appendix) indicated that of those with meaningful use, 6.3% in Scenario A and 3.1% in Scenario B did not have CDS.

### Results

## **Sample Description**

Sample characteristics for visits in each clinical scenario are shown in Table 8. Several differences between the cohorts were consistent with the selection criteria for each. In Scenario A, the plurality (47.8%) of adult patients treated for ADHD were aged 26–49 years; in Scenario B, most (81.8%) patients with CVD or SUD were aged 50 years or older, likely because the most prevalent selection criterion in this group was CVD. Mean (standard deviation) ages were 35.8 (14.4) years in Scenario A and 64.3 (17.1) years in Scenario B. Consistent with these demographic characteristics, private insurance was the dominant source of payment (57.0%) in Scenario A, whereas Medicare was predominant (54.2%) in Scenario B.

Depression and anxiety were more common in Scenario A (35.1% and 28.7%, respectively), than in Scenario B (16.3% and 6.1%, respectively). Consistent with these differences, psychiatric visits were common (60.6%) in Scenario A, but most Scenario B visits (69.5%) were provided by physicians who did not specialize in either cardiology or psychiatry. Use of CDS and achievement of meaningful use were more common in

# Table 8

	Scenari	o A: patients with	ADHD	Scenario B:	patients with CVD	or SUD
	Unweighted	Weighted % <sup>a</sup>	95% CI	Unweighted n	Weighted % <sup>a</sup>	95% CI
	<u>n</u>					
All patients	810	100.0	NA	9,101	100.0	NA
Age group (years) <sup>b</sup>						
17–25	251	31.0	[26.2, 36.2]	259	3.0	[2.3, 3.8]
26–49	401	47.8	[41.6, 54.0]	1,326	15.2	[13.1, 17.6]
50 or older	158	21.3	[17.1, 26.1]	7,516	81.8	[79.2, 84.2]
Sex						
Female	423	53.4	[48.0, 58.7]	4,192	46.1	[44.2, 48.0]
Male	387	46.6	[41.3, 52.0]	4,909	53.9	[52.0, 55.8]
Race and ethnicity						
White, non-Hispanic	708	86.3	[82.2, 89.6]	7,503	77.4	[74.5, 80.1]
Black, non-Hispanic	34	4.7	[2.8, 7.8]	735	9.4	[8.0, 10.9]
Hispanic	43	5.6	[4.0, 8.0]	571	9.3	[7.3, 11.8]
Other	25	3.4	[2.0, 5.5]	292	3.9	[3.1, 4.9]
Primary payment source						
Private	439	57.0	[47.0, 66.5]	2,670	31.8	[29.5, 34.1]
Medicaid	95	13.1	[8.4, 19.9]	663	7.6	[6.2, 9.4]
Medicare	46	5.6	[3.5, 9.0]	4,725	54.2	[51.5, 56.9]
Other	189	24.2	[15.1, 36.5]	440	6.4	[4.7, 8.7]
Office location						
Urban	756	91.9	[80.3, 96.9]	8,120	90.0	[86.8, 92.6]
Nonurban	54	8.1	[3.1, 19.7]	981	10.0	[7.4, 13.2]
Physician specialty						
Cardiology	3	0.2	[0.1, 1.0]	2,882	25.2	[20.7, 30.2]
Psychiatry	493	60.6	[50.8, 69.6]	492	5.3	[4.0, 7.0]
Neither of these	314	39.2	[30.2, 49.0]	5,727	69.5	[64.6, 74.0]
Black-box diagnosis						
Yes	105	11.4	[8.0, 16.0]	2,243	27.7	[24.3, 31.3]
No	705	88.6	[84.0, 92.0]	6,858	72.3	[68.7, 75.7]
Charlson comorbidities <sup>c</sup>						
None	767	94.1	[91.1, 96.1]	5,257	56.7	[53.4, 60.0]
One	35	4.3	[2.7, 6.9]	1,921	21.1	[19.2, 23.1]
Two	6	0.9	[0.3, 2.8]	1,150	12.8	[11.4, 14.3]
Three or more	2	0.7	[0.1, 3.6]	773	9.4	[7.0, 12.5]
Psychiatric comorbidities						
Depression	307	35.1	[28.8, 41.9]	1,443	16.3	[14.6, 18.1]
Anxiety	215	28.7	[22.6, 35.6]	502	6.1	[4.7, 7.9]
Relationship with patient						
New	66	9.5	[6.5, 13.5]	1,133	10.7	[9.3, 12.2]
Established, not PCP	503	64.8	[57.1, 71.8]	4,610	44.2	[39.7, 48.8]
PCP	220	25.7	[19.4, 33.3]	3,147	45.1	[40.8, 49.4]
Environmental features						
CDS	469	65.1	[53.3, 75.3]	7,901	89.6	[86.4, 92.1]
Meaningful use	474	60.9	[49.2, 71.5]	8,036	87.8	[84.4, 90.6]
Patient-derived	732	92.0	[86.1, 95.6]	7,435	85.7	[82.4, 88.5]
revenue						

Sample Characteristics, U.S. Office-Based Physician Visits Made by Adults, 2014–2016

*Note.* ADHD = attention-deficit hyperactivity disorder; CDS = computerized decision support; CI = confidence interval; CVD = cardiovascular disease; NA = not applicable; PCP=primary care provider; SUD = substance use disorder. <sup>a</sup>Percentage of total visits after application of sample weights, accounting for design effect (Groves et al., 2009) using IBM SPSS for

<sup>a</sup>Percentage of total visits after application of sample weights, accounting for design effect (Groves et al., 2009) using IBM SPSS for Complex Samples. Design effect-adjusted denominators < 30 for all estimates; interpret results cautiously. <sup>b</sup>Mean (standard deviation) ages (years) were 35.8 (14.4) in Scenario A and 64.3 (17.1) in Scenario B. <sup>c</sup>Based on weighted combinations of diagnoses, summed to indicate total comorbidity burden (Quan et al., 2011).

Scenario B (89.6% and 87.8%, respectively) than in Scenario A (65.1% and 60.9%, respectively), likely reflecting greater adoption of E-HRs by nonspecialists than by specialists (see Patel et al., 2013).

# **Assessment of External Validity**

Comparisons of patient and provider-office characteristics in the present sample with those of national and other large-sample data suggested generally good external validity (Appendix G). A few exceptions were consistent with methodological differences between the current study sample and those of previous work. The most notable was that the reported rates of prescribed stimulant use among persons with SUD were much higher in a household survey by Compton et al. (2018), such as 25.8% of those with opioid use disorder, than in the current study of office visits (4.1%). Despite this difference, the rate of SUD among adults with ADHD was reported in a review article as 11% (Kooij et al., 2019), compared with 11.4% in the present sample of visits made by adults receiving treatment for ADHD (i.e., either medication or psychotherapy). Also similar were the rates of E-HR use reported by the U.S. ONC (2019) for 2014–2015 (82.8–86.9%) as a percentage of physicians, compared with this sample's percentage of visits in that time period (89.1%).

Characteristics of patients with CVD reported in a large registry study (Xian et al., 2019) were similar, but not identical, to those of patients with CVD in the present national sample, with statistically significant differences on Pearson  $\chi 2$  test (http://vassarstats.net/newcs.html) due partly to large sample size (N = 3,232 in Xian et al., 2019; N = 7,138 in the current study). Examples include prevalence rates for diabetes

(39.8% versus 31.8%, respectively,  $\chi 2[1] = 62.92$ , p < .001), hypertension (85.2% versus 74.0%,  $\chi 2[1] = 158.3$ , p < .001), and percentage female (36.2% versus 46.3%,  $\chi 2[1] = 90.55$ , p < .001). Comparisons to the sample of patients with ADHD reported by Fairman et al. (2018) were similar for percentage female (53.3% in the present sample, 51.1% reported by Fairman et al., 2018) and percentage with SUD (11.7–18.8% vs. 10.0%, respectively), but the age distributions differed somewhat. These differences were not tested for statistical significance because of large sample size (N = 91,588) in the study by Fairman et al. When interpreting these results, researchers should note that the study by Fairman et al. was limited to commercially insured patients.

### **Bivariate Measures of Study Outcomes and Knowledge Construct Predictors**

Of visits included in Scenarios A and B, respectively, 81 (weighted 8.3%, 95% CI [5.6, 12.1]) and 143 (weighted 1.5%, 95% CI [1.1, 2.0]) included the prescribing of a potentially unsafe medication (see Table 9). In Scenario A, significant bivariate knowledge-construct predictors of potentially unsafe prescribing included male sex and White, non-Hispanic race. In Scenario B, significant bivariate knowledge-construct predictors included younger age; male sex; White, non-Hispanic race; private or other non-public payment source; psychiatrist specialty; depression; and anxiety. In both scenarios, black-box medical condition was a significant positive predictor, although the rates for Scenario A are difficult to interpret because of the small cell sizes described previously.

# Table 9

Percentage of Visits Resulting in Potentially Unsafe Prescription for ADHD Medication, by Knowledge-Construct Predictors, U.S. Office-Based Physician Visits Made by Adults, 2014-2016

	Scenario A	A: patients with	ADHD	Scenario B: pat	ients with CVI	O or SUD
	Weighted % <sup>a</sup>	95% CI	<u>P</u>	Weighted % <sup>a</sup>	<u>95% CI</u>	<u>P</u>
			value <sup>b</sup>			<u>value<sup>b</sup></u>
All patients	8.3	[5.6, 12.1]	NA	1.5	[1.1, 2.0]	
Age group (years)			.182			< .001
17–25	6.2 <sup>d</sup>	[3.1, 12.3]		8.5	[4.7, 14.9]	
26–49	10.7	[6.7, 16.6]		4.4	[2.9, 6.5]	
50 or older	5.8 <sup>c,d</sup>	[2.9, 11.5]		0.7	[0.4, 1.1]	
Sex			.039			.040
Female	6.0 <sup>c</sup>	[3.7, 9.7]		1.1	[0.8, 1.6]	
Male	10.8	[2.6, 6.7]		1.8	[1.2, 2.7]	
Race and ethnicity			.037			< .001
White, non-Hispanic	9.1°	[6.1, 13.4]		1.8	[1.3, 2.5]	
Black, non-Hispanic	5.5 <sup>c,d</sup>	[1.7, 16.2]		0.5 <sup>d</sup>	[0.2, 1.6]	
Hispanic	2.5 <sup>c,d</sup>	[0.6, 9.7]		$0.2^{d}$	[0.1, 0.7]	
Other	$0.7^{c,d}$	[0.1, 5.5]		0.5 <sup>d</sup>	[0.1, 2.8]	
Primary source of payment		[,]	.097		[,]	< .001
Private	6.6 <sup>c</sup>	[4.2, 10.3]		2.2	[1.4, 3.2]	
Medicaid	6.1 <sup>c,d</sup>	[2.6, 13.7]		1.5 <sup>d</sup>	[0.7, 2.9]	
Medicare	5.5 <sup>c,d</sup>	[1.7, 16.5]		0.2 <sup>d</sup>	[0.1, 0.4]	
Other	15.3 <sup>c,d</sup>	[6.6, 31.5]		8.4 <sup>c</sup>	[4.6, 14.8]	
Office location	1010	[010, 0110]	.740	011	[, 1]	.503
Urban	8.1°	[5.4, 12.0]	.,	1.5	[1.1, 2.1]	10 00
Nonurban	10.3 <sup>c,d</sup>	[2.5, 33.6]		1.1 <sup>d</sup>	[0.5, 2.6]	
Physician specialty	1010	[=10,0010]	.261		[0.0, 2.0]	< .001
Cardiology	Not calculated;	n = 3		0.3 <sup>c</sup>	[0.1, 0.7]	
Psychiatry	8.7°	[5.1, 14.6]		13.5	[8.8, 20.3]	
Neither of these	7.3	[4.3, 12.0]		1.0	[0.7, 1.5]	
Black-box diagnosis	7.5	[1.5, 12.0]	<.001	1.0	[0.7, 1.0]	< .001
Yes	67.8 <sup>d</sup>	[50.2, 81.5]	<.001	4.1	[2.8, 5.8]	< .001
No	$0.6^{c,d}$	[0.3, 1.2]		0.5	[0.3, 0.9]	
Charlson comorbidities <sup>e</sup>	0.0	[0.3, 1.2]	.719	0.5	[0.3, 0.9]	.060
None	8.0 <sup>c</sup>	[5.3, 12.0]	./1)	2.1	[1.5, 2.9]	.000
One	14.2 <sup>c,d</sup>	[5.2, 33.3]		0.7	[1.3, 2.9] [0.4, 1.3]	
Two	Not calculated;	L / J		0.7°	[0.4, 1.5] [0.1, 3.8]	
Three or more	Not calculated; <i>i</i>			0.7 <sup>b,c</sup>		
Depression	not calculated; I	$i - \Delta$	.732	0.7	[0.2, 3.0]	< .001
No	7.9°	[4.7, 13.2]	.132	1.1	[0.9.1.6]	< .001
Yes	7.9° 8.9	L / J		1.1 3.4	[0.8, 1.6]	
	8.9	[5.5, 14.1]	.099	5.4	[2.2, 5.2]	.004
Anxiety	0.50	[( 2 14 2]	.099	1.20	[10 10]	.004
No	9.5°	[6.2, 14.2]		1.3°	[1.0, 1.8]	
Yes	5.3 <sup>c,d</sup>	[2.7, 10.1]		3.6 <sup>d</sup>	[1.8, 7.2]	

Note. ADHD = attention-deficit hyperactivity disorder; CI = confidence interval; CVD = cardiovascular disease; SUD = substance use disorder.

<sup>a</sup>Percentage of total visits after application of sample weights, accounting for design effect (see Groves et al., 2009). <sup>b</sup>Pearson χ2 test, adjusted for design effect (see Groves et al., 2009). Indicates an estimate that failed the design effect-adjusted denominator check. <sup>d</sup>Indicates an estimate that failed checks on absolute or relative confidence interval width. <sup>e</sup>Based on weighted combinations of diagnoses, summed to indicate total comorbidity burden (Quan et al., 2011).

### Assessment of Assumptions for Logistic Regression Analysis

Logistic regression analysis facilitates quantitative assessments of the associations of predictor variables with binary outcomes (DVs). The study data and model met assumptions for the technique, including an outcome with two, mutually exclusive categories (i.e., potentially unsafe versus safer) and statistically independent observations (see Warner, 2013). An assumption common to all multivariate techniques, that the model be correctly specified (see Warner, 2013), is assessed in the presentation of results for RQ3.

## **Statistical Reliability of Logistic Regression Coefficients**

Predictors chosen for inclusion in the models were based on the literature review described in Chapter 2. Initial logistic regression modeling of all predictors revealed that most coefficients did not meet NCHS statistical reliability standards of relative standard error  $\leq$  30% and  $\geq$  30 cases (see CDC, 2019b; Appendix H). Using the a priori procedures described in Chapter 3, I made decisions about these coefficients based on statistical and theoretical considerations. To balance statistical precision against inclusion of all coefficients suggested by the theoretical frameworks, I removed from the equations any knowledge-construct factor meeting both of the following criteria: (a) the standard error exceeded the absolute value of the coefficient estimate ( $\beta$ ), and (b) the estimate was based on < 30 cases. For the measures of physician-patient relationship, this change was made by replacing the graded measure, encompassing both primary care provider relationship and number of previous visits, with a single dummy-variable indicator for primary care provider. I maintained the integrity of the process by making only one such

decision rule, applying it equally to both models and scenarios, and testing no additional decision rules or models. It should be noted that even after this procedure, most coefficients did not meet NCHS standards; results should be interpreted cautiously.

# **Assessments of Study Research Questions**

Final, full logistic regression analyses for the atheoretical and theory-based models are shown in Appendix I and Appendix J, respectively. The tables accompanying the analyses of each research question, shown in the next section, are excerpts of relevant sections from each of these full models. As planned a priori, both the atheoretical and theory-based models included knowledge-construct factors. Both models included coefficients for the environmental-construct predictors CDS and meaningful use, with competing hypotheses for each. The theory-based model included, in addition, predictors for patient-derived revenue, primary care provider relationship with the patient, and experience with the medication (i.e., continued versus new).

Both models were statistically significant overall for both scenarios: atheoretical models, Scenario A  $\chi 2(9) = 31.03$ , p < .001, Scenario B  $\chi 2(12) = 306.59$ , p < .001; theory-based models, Scenario A  $\chi 2(12) = 36.41$ , p < .001, Scenario B  $\chi 2(13) = 305.68$ , p < .001 (Table 10). Knowledge-construct predictors significantly associated with potentially unsafe prescribing were similar in the atheoretical and theory-based models (Appendix I; Appendix J) and consistent with most bivariate results described previously. These included older age in Scenario B and anxiety in both scenarios, which were negatively associated with the outcome, and psychiatric care in both scenarios, which was positively associated with the outcome.

## Table 10

Model Statistics, Scenarios A and B, Complex Samples Logistic Regression Analyses of U.S. Office-Based Physician Visits Made by Adults, 2014–2016

	Scenario A: patients with ADHD, potentially unsafe prescription versus any other treatment (safer medication or psychotherapy)	Scenario B: patients with CVD or SUD, potentially unsafe prescription versus no potentially unsafe prescription
Atheoretical model		
Unweighted number of visits	669	8,685
Number of physicians (strata)	301 (101)	1659 (130)
"c" (concordance) Statistic	.572	.870
Nagelkerke R <sup>2</sup>	.099	.243
Model $\chi^2$ (critical $\chi^2$ ; df), p	31.03 (16.92; df = 9), <i>p</i> < .001	306.59 (21.03; df = 12), <i>p</i> < .001
Theory-based model		
Unweighted number of visits	669	8,685
Number of physicians (strata)	301 (101)	1659 (130)
"c" (concordance) Statistic	.587	.871
Nagelkerke R <sup>2</sup>	.116	.243
Model $\chi^2$ (critical $\chi^2$ ; df), p	36.41 (21.03; df = 12), <i>p</i> < .001	305.68 (22.36; df = 13), <i>p</i> < .001

*Note.* Critical  $\chi 2$  calculated for  $\alpha = .05$ . ADHD = attention-deficit hyperactivity disorder; CVD = cardiovascular disease; df = degrees of freedom; LL = log likelihood; SUD = substance use disorder.

## **Results for RQ1: CDS**

RQ1 addressed the association of CDS with the binary outcome of potentially unsafe prescribing. The theory-based hypothesis was that CDS is not significantly associated with the study outcome; and the atheoretical hypothesis was that CDS is associated with a significant decrease in the outcome, especially for patients with blackbox warning status. As described previously, the black-box variable, and its interaction term with CDS, could not be tested in Scenario A because of small cell counts.

In the atheoretical models, CDS was not significantly associated with the outcome in either clinical scenario (Scenario A: OR = 0.538, 95% CI [0.127, 2.284]; Scenario B: OR = 0.245, 95% CI [0.053, 1.137]; Table 11). In Scenario B, the interaction term for CDS with black-box warning was also nonsignificant (OR = 1.836, 95% CI [0.400, 8.428]). Results for CDS were similarly nonsignificant in the theory-based model of Scenario A (OR = 0.570, 95% CI [0.128, 2.531]) but indicated a significant decrease in

odds of the outcome in Scenario B (OR = 0.402, 95% CI [0.180, 0.898]). The

nonsignificant results should be viewed as inconclusive because the coefficients were not

statistically reliable. Based on the one significant result observed, findings indicated

partial support for the atheoretical hypothesis that CDS is associated with decreased odds

of prescribing potentially unsafe ADHD medications to adults.

Table 11

Results for CDS, Scenarios A and B, Complex Samples Logistic Regression Analyses of U.S. Office-Based Physician Visits Made by Adults, 2014–2016

		Scenario A: patients with ADHD, potentially unsafe prescription versus any other treatment (safer medication or psychotherapy)				potentia	lly unsa	fe prescr	h CVD or SUD, iption versus no rescription
Predictor	Reference	<u>β</u>	<u>SE</u>	OR	<u>95% CI</u>	<u>β</u>	<u>SE</u>	OR	<u>95% CI</u>
	<u>Group</u>								
Atheoretical m	nodel								
CDS	No CDS	-0.620	.733	0.538	[0.127, 2.284]	-1.406	.782	0.245	[0.053, 1.137]
$\text{BBW}\times\text{CDS}$	No	Not incl	uded in	model; r	removed in	0.608	.777	1.836	[0.400, 8.428]
	interaction	sample s	sample size-adequacy test						
Theory-based	model								
CDS	No CDS	-0.563	.756	0.570	[0.128, 2.531]	-0.913	.410	0.402	[0.180, 0.898]

*Note.* **Bold text** denotes a statistically significant predictor. Excerpted from full atheoretical and theory-based models shown in Appendix I and Appendix J, respectively. ADHD = attention-deficit hyperactivity disorder; BBW = black-box warning; CDS = computerized decision support; CI = confidence interval; CVD = cardiovascular disease; OR = odds ratio (exponentiated  $\beta$ ); SE = standard error; SUD = substance use disorder.

### **Results for RQ2: Meaningful Use**

RQ2 addressed the association of meaningful use achievement with the study outcome, with decreased odds hypothesized in the atheoretical models and increased odds

hypothesized in the theory-based models. In the atheoretical models, the coefficients for

meaningful use were positive and statistically significant in both Scenario A (OR =

4.961, 95% CI [1.124, 21.898] and Scenario B (OR = 2.865, 95% CI [1.265, 6.488];

Table 12). Results were similar in the theory-based models, although the coefficient in

Scenario A was not statistically significant (Scenario A: OR = 4.046, 95% CI [0.823,

19.884]; Scenario B: OR = 2.922, 95% CI [1.275, 6.698]). Thus, results generally

supported the theory-based hypothesis, suggesting meaningful use is associated with

approximately tripled odds of prescribing potentially unsafe ADHD medications to

adults.

Table 12

Results for Meaningful Use, Scenarios A and B, Complex Samples Logistic Regression Analyses of U.S. Office-Based Physician Visits Made by Adults, 2014–2016

		potenti other tr	Scenario A: patients with ADHD, potentially unsafe prescription versus any other treatment (safer medication or psychotherapy)				Scenario B: patients with CVD or SUD, potentially unsafe prescription versus no potentially unsafe prescription		
Predictor	<u>Reference</u> Group	<u>β</u>	<u>SE</u>	<u>OR</u>	<u>95% CI</u>	<u>β</u>	<u>SE</u>	<u>OR</u>	<u>95% CI</u>
<u>Atheoretical r</u> Meaningful use		1.602	.753	4.961	[1.124, 21.898]	1.053	.417	2.865	[1.265, 6.488]
<u>Theory-based</u> Meaningful use		1.398	.807	4.046	[0.823, 19.884]	1.072	.423	2.922	[1.275, 6.698]

*Note.* **Bold text** denotes a statistically significant predictor. Excerpted from full atheoretical and theory-based models shown in Appendix I and Appendix J, respectively. ADHD = attention-deficit hyperactivity disorder; CI = confidence interval; CVD = cardiovascular disease; OR = odds ratio (exponentiated  $\beta$ ); SE = standard error; SUD = substance use disorder.

# **Results for RQ3: Predictive Accuracy and Model Fit**

Changes to several environmental-construct predictors, described previously, prevented full testing of either the atheoretical or theory-based models. These changes included (a) removal of the term for interaction of CDS with black-box warning in Scenario A, (b) removal of the indicator for continued versus new prescription in Scenario B, and (c) recoding of the variable for physician-patient relationship to a binary indicator of primary care provider status in both scenarios. Assessments of the relative merits of the atheoretical and theory-based models included whether coefficients were in the predicted direction; the c (concordance) statistic, which measures predictive accuracy; and change in the -2LL statistic, which measures model fit.

**Direction of coefficients**. As noted in the discussions of RQ1 and RQ2, results for CDS were inconclusive but provided some support for the atheoretical hypothesis, and results for meaningful use supported the theory-based hypothesis. Two additional coefficients for variables unique to the theory-based models were not statistically significant: primary care provider status in both scenarios (Scenario A: OR = 0.873, 95% CI [0.287, 2.656]; Scenario B: OR = 1.088, 95% CI [0.475, 2.495]) and experience with the medication (i.e., continued versus new prescription) in Scenario A (OR = 0.773, 95% CI [0.438, 1.366]; Table 13). The coefficient for patient-derived revenue in Scenario A indicated significantly reduced odds of the outcome (OR = 0.390, 95% CI [0.156,

Table 13

Results for Variables Unique to the Theory-Based Models, Scenarios A and B, Complex Samples Logistic Regression Analyses of U.S. Office-Based Physician Visits Made by Adults, 2014–2016

		Scenario A: patients with ADHD, potentially unsafe prescription versus any other treatment (safer medication or psychotherapy)				Scenario B: patients with CVD or SUD, potentially unsafe prescription versus no potentially unsafe prescription			
Predictor	<u>Reference</u> Group	<u>β</u>	<u>SE</u>	<u>OR</u>	<u>95% CI</u>	ß	<u>SE</u>	<u>OR</u>	<u>95% CI</u>
Patient- derived revenue	No revenue on this basis	-0.941	.465	0.390	[0.156, 0.976]	0.113	.374	1.119	[0.538, 2.330]
PCP	Physician is not the PCP	-0.136	.564	0.873	[0.287, 2.656]	0.085	.423	1.088	[0.475, 2.495]
Continuing prescription	New prescription	-0.257	.289	0.773	[0.438, 1.366]			model; rea quacy test	

*Note.* **Bold text** denotes a statistically significant predictor. ADHD = attention-deficit hyperactivity disorder; CI = confidence interval; CVD = cardiovascular disease; OR = odds ratio (exponentiated  $\beta$ ); PCP = primary care provider; SE = standard error; SUD = substance use disorder.

(0.976]), contrary to the theory-based hypothesis. In Scenario B, the coefficient for patient-derived revenue was not significant (OR = 1.119, 95% CI [0.538, 2.330]).

**C** (concordance) statistic. The c-statistic is measured on a scale of .5, indicating a model that performs no better than random assignment, to 1.0, indicating a model that perfectly predicts the outcome (Austin & Steyerberg, 2012). As noted in the description of Table 10, both the atheoretical and theory-based models had weak predictive accuracy (.572 and .587, respectively) for Scenario A, whereas both models had excellent predictive accuracy (.870 and .871, respectively) for Scenario B. These findings indicated that the Scenario B model was generally better specified than was the Scenario A model. Additionally, these c-statistics indicated only modest improvement for the theory-based model in Scenario A, and no improvement in Scenario B, compared with the atheoretical model.

Statistical significance of change in model fit. Results of tests of between-model differences in fit are shown in Table 14. For both Scenarios A and B, results indicated change in model  $\chi^2$  less than critical  $\chi^2$  for the theory-based model compared with the atheoretical model, indicating no significant improvement in goodness of fit.

**Summary of results for RQ3**. Assessments of coefficient direction produced mixed results, mostly in favor of the atheoretical model. Only the results for meaningful use were consistent with the theory-based hypotheses. Moreover, the theory-based models did not improve predictive accuracy or fit compared with the atheoretical models. Nonetheless, findings for RQ3 should be viewed as somewhat inconclusive because

### Table 14

Atheoretical and Theory-Based Model Fit, Scenarios A and B, Logistic Regression Analysis of U.S. Office-Based Physician Visits Made by Adults, 2014–2016

		patients with DHD	Scenario B: patients with CVD or SUD		
	Atheoretical	Theory-based	Atheoretical	Theory-based	
Baseline (no predictor) model -2LL	410.09	410.09	1335.71	1335.71	
Model –2LL	379.07	373.69	1029.11	1030.02	
Model $\chi^2$ (change in -2LL)	31.03	36.41	306.59	305.68	
Model $\chi^2$ change: atheoretical to theory	-based models				
Degrees of freedom (change in		3	1		
number of variables )					
Model χ2 (change)	5	.38	-0.91		
Critical $\chi^2$ (df), $\alpha = .05$	7.8	1 (3)	3.84 (1)		

Note. ADHD = attention-deficit hyperactivity disorder; CVD = cardiovascular disease; df = degrees of freedom; LL = log likelihood; SUD = substance use disorder.

neither the atheoretical nor theory-based models could be fully tested, and because of modest predictive accuracy in the models of Scenario A.

### **Additional Analyses**

Sensitivity analyses, logistic regression models. Sensitivity analyses included calculations of model c-statistics, ORs, and 95% CIs for key environmental-construct predictors under several conditions: (a) excluding 2016, (b) excluding visits with substance abuse counseling but no code for SUD, and (c) modifying the definitions of patient-derived revenue (Table 15). A planned sensitivity analysis of visits to mental health professionals without a specific indicator for psychotherapy was not performed because it affected only six visits in Scenario A, and, by design, it did not affect Scenario B, in which neither selection criteria nor outcome were affected by psychotherapy.

Findings for meaningful use and primary care provider relationship were consistent across most models. For CDS, sensitivity analyses were consistent with main findings in Scenario A, but four of seven analyses in Scenario B indicated an association

# Table 15

Sensitivity Analyses on Key Findings, Logistic Regression Models of U.S. Office-Based Physician Visits Made by Adults, 2014–2016

		CDS	Meaningful use	Primary care provider	Patient-derived revenue	C- statistic
	n	OR [95% CI]	OR [95% CI]	OR [95% CI]	OR [95% CI]	statistic
Scenario A, atheoretical						
Original model	669	0.538	4.961	NA	NA	.572
-		[0.127, 2.284]	[1.124, 21.898]			
Exclude 2016	540	0.379	5.488	NA	NA	.576
		[0.053, 2.699]	[0.731, 41.184]			
A priori definition, SUD <sup>a</sup>	662	0.492	4.839	NA	NA	.569
-		[0.115, 2.101]	[1.099, 21.320]			
Scenario A, theory-based						
Original model	669	0.570	4.046	0.873	0.390	.587
0		[0.128, 2.531]	[0.823, 19.884]	[0.287, 2.656]	[0.156, 0.976]	
Exclude 2016	540	0.420	4.795	0.651	0.593	.587
		[0.050, 3.516]	[0.515, 44.607]	[0.248, 1.707]	[0.161, 2.184]	
A priori definition, SUD <sup>a</sup>	662	0.519	3.893	0.719	0.370	.582
-		[0.115, 2.347]	[0.779, 19.455]	[0.257, 2.016]	[0.146, 0.936]	
Patient revenue,						
ownership or share <sup>b</sup>	669	0.501	4.188	0.837	0.410	.587
-		[0.116, 2.165]	[0.872, 20.117]	[0.326, 2.146]	[0.194, 0.865]	
Scenario B, atheoretical						
Original model	8,685	0.245	2.865	NA	NA	.870
-		[0.053, 1.137]	[1.265, 6.488]			
Exclude 2016	7,429	0.219	1.805	NA	NA	.887
		[0.064, 0.751]	[0.732, 4.450]			
A priori definition, SUD <sup>a</sup>	8,487	0.245	2.865	NA	NA	
-		[0.053, 1.142]	[1.254, 6.544]			
Scenario B, theory-based						
Original model	8,685	0.402	2.922	1.088	1.119	.871
0		[0.180, 0.898]	[1.275, 6.698]	[0.475, 2.495]	[0.538, 2.330]	
Exclude 2016	7,429	0.497	1.782	1.247	0.970	.889
		[0.215, 1.150]	[0.708, 4.485]	[0.512, 3.039]	[0.405, 2.324]	
A priori definition, SUD <sup>a</sup>	8,487	0.396	2.904	1.124	1.066	.875
		[0.174, 0.902]	[1.253, 6.729]	[0.480, 2.631]	[0.486, 2.341]	
Patient revenue,		0.388	2.576	1.157	0.554	
ownership or share <sup>b</sup>	8,685	[0.169, 0.890]	[1.093, 6.073]	[0.507, 2.641]	[0.324, 0.948]	.867

*Note.* **Bold text** denotes a statistically significant predictor. CI = confidence interval; OR = odds ratio; SUD = substance use disorder. <sup>a</sup>Excludes visits in which a patient was defined as at risk of a potentially unsafe prescription solely by receiving substance abuse counseling, without a diagnosis of substance use disorder in the medical record. <sup>b</sup>Define patient-derived revenue only if physician is a full or part owner of the practice or describes the primary source of compensation as based on share of billings.

of CDS with reduced rates of potentially unsafe prescribing (e.g., Scenario B, atheoretical, excluding 2016: OR = 0.219, 95% CI [0.064, 0.751]). Considered together with the small sample size in Scenario A and the limited statistical reliability of the CDS

measure in both scenarios, the most reasonable conclusion from these findings is that

CDS may be associated with decreased potentially unsafe prescribing of ADHD medication, but results are uncertain.

Results were sensitive to the definition of patient-derived revenue (Table 15; Table 16). The a priori construct for this indicator was revenue derived from either patient satisfaction or volume. When the measure was narrowed to reflect a direct relationship between patient volume and compensation, defined as practice ownership or share of billings, theory-based model fit generally improved, with a significantly better fit in the theory-based than the atheoretical model of Scenario B. Additionally, in both scenarios, patient-derived revenue using the modified definition was associated with significantly decreased odds of the outcome (Scenario A: OR = 0.410, 95% CI [0.194, 0.865]; Scenario B: OR = 0.554, 95% CI [0.324, 0.948]). Thus, measuring patientderived revenue as direct financial compensation may improve model fit, but with an effect opposite that of the theory-based hypothesis.

Table 16

Change in degrees of freedom

Critical  $\chi 2$ ,  $\alpha = .05$ 

Derived Revenue, U.S. Offic	e-Based Physic	ian Visits Made	by Adults, 20.	14–2016
	Scenario A	A: patients with	Scenario B	: patients with
	A	ADHD	CVD	or SUD
	Original	Ownership or	Original	Ownership or
	definition	billing share	definition	billing share
Model $\chi^2$ (change in $-2LL$ )	5.38	7.02	-0.91	7.05

Logistic Regression Model Fit Changes Using an Alternative Definition of Patient-Derived Revenue, U.S. Office-Based Physician Visits Made by Adults, 2014–2016

*Note*. ADHD = attention-deficit hyperactivity disorder; CVD = cardiovascular disease; LL = log likelihood; SUD = substance use disorder.

3

7.81

1

3.84

1

3.84

3

7.81

**Follow-up bivariate analysis**. Although CDS and meaningful use achievement are linked because CDS is one criterion for meaningful use, a small number of sampled visits were made to physicians who qualified for meaningful use despite no medication-

related CDS (Scenario A: n = 37; Scenario B: n = 245). To explore the mutual associations of CDS and meaningful use with the outcome, I performed a descriptive follow-up analysis of rates of potentially unsafe prescribing, accounting for both variables (Table 17). Consistent with logistic regression findings, results suggested independent effects of CDS as a negative predictor, and meaningful use as a positive predictor, of the study outcome. An exception is that among those with CDS in Scenario B, rates were approximately equal for those with and without meaningful use.

Table 17

Rates of Potentially Unsafe Prescribing of ADHD Medications, by CDS Use and Meaningful Use Achievement, U.S. Office-Based Physician Visits Made by Adults, 2014– 2016

	Scenario A		Scenario B	
	With CDS	Without CDS	With CDS	Without CDS
	<u>% [95% CI]</u>	<u>% [95% CI]</u>	<u>% [95% CI]</u>	<u>% [95% CI]</u>
With meaningful use	9.5	17.5	1.2	7.7
	[5.6, 15.4]	[4.2, 50.7]	[0.8, 1.7]	[2.5, 21.1]
Without meaningful use	5.5	6.1	1.3	3.1
	[1.3, 20.1]	[3.1, 11.5]	[0.5, 3.3]	[1.6, 5.8]

*Note.* ADHD = attention-deficit hyperactivity disorder; CDS = computerized decision support; CI = confidence interval. <sup>a</sup>Pearson  $\chi^2$  test of between-group difference, comparing CDS versus no CDS, adjusted for complex sampling design (Groves et al., 2009).

Meaningful use penalties. As planned a priori, I estimated the number of

sampled visits made to physicians who might have been subject to meaningful use penalties. Counts were small: two of 810 in Scenario A, both in the safer treatment group; and 104 of 9,101 in Scenario B, 103 safer treatment and one potentially unsafe. The interpretability of these findings is limited because no specific indicator of meaningful use penalties was recorded in the NAMCS.

### Summary

This exploratory and preliminary assessment of the relative merits of atheoretical and theory-based models of potentially unsafe prescribing, a binary outcome measure, produced mixed findings. Results for RQ1, which assessed the association of CDS with the study outcome, were inconclusive in most main analyses; however, sensitivity analyses suggested an association of CDS with decreased odds of potentially unsafe prescribing, a finding not consistent with the theory-based hypothesis. Analyses of RQ2 suggested increased odds of the outcome for providers with meaningful use achievement, consistent with the theory-based hypothesis.

RQ3 was whether theory-based models improve predictive accuracy and fit, compared with atheoretical models. In addition to the finding for CDS described above, findings not consistent with theory-based hypotheses included a nonsignificant relationship between the outcome and primary care provider status; a reduced rate of the outcome for providers who derive revenue from patients, particularly when measured as direct financial compensation; and no significant improvement in fit for theory-based compared with atheoretical models except when patient-derived revenue was defined as direct financial compensation. Limiting these findings were low rates of statistical reliability for most coefficients, modest predictive accuracy for Scenario A, and the inability to test either model fully because of changes in several environmental-construct predictors made during data quality assessments.

In Chapter 5, I discuss the interpretation of study findings, overall and focusing on implications of the two unexpected results for CDS and for patient-derived revenue. I describe limitations, both those known a priori and those that became evident during data analysis. Comparing findings of this study with those of previous work, I describe recommendations for future research and practice. I close with discussions of the positive social changes that could result from a more interdisciplinary, psychology-informed approach to interventions on physician decision-making and of potential contributions health psychologists could make to these efforts. Chapter 5: Discussion, Conclusions, and Recommendations

To promote the well-being of individuals and populations, which is an APA (2014) objective for preventive health interventions, efforts to encourage evidence-based medical decision-making must cause more benefit than harm to patients and physicians. The current study was conducted in response to a possible association between the atheoretical foundation of the Health Information Technology for Economic and Clinical Health (HITECH Act and its unintended harms (see Ratwani et al., 2019; Schiff et al., 2015) and to calls in the health psychology literature for research that is based in theory, measures behavioral outcomes objectively, and assesses broad policy interventions affecting population health (see Conner & Norman, 2017; Prestwich et al., 2015; Prestwich et al., 2018). To assess whether a theory-based approach might improve on current, mostly atheoretical interventions on medical decisions (see L. Liang et al., 2017), I mapped constructs of social cognitive theory and self-determination theory to predictors of potentially unsafe prescribing of ADHD medications to adults, and compared two logistic regression models of this outcome: one atheoretical based on assumptions of HITECH Act proponents, and the other based on psychological theory and evidence.

In this chapter, I discuss the contributions and limitations of this study, and consider implications for theory-based research in health psychology and for positive social change. In considering these implications, I adopt contemporary definitions of (a) health psychology as an interdisciplinary field that applies psychological knowledge not only to individual health, but also to health care and health-related social policy (see Marks, Murray, Evans, & Estacio, 2015) and (b) health psychology-informed interventions as multilevel, having expanded beyond the discipline's initial focus on individuals and families to include health care providers, institutions, and communities (see Glanz, Rimer, & Viswanath, 2015). In accordance with this expanded view, I consider implications of the study findings for knowledge about health-system effects on medical decision-making, an environmentally influenced cognitive process (see Djulbegovic & Elqayam, 2017). I consider autonomous motivation as a key theoretical construct that may connect the findings of the current study with contemporary trends in health care delivery, informing future research applications of this study's theoretical constructs to decisions made by physicians. Finally, I suggest the potential for contributions by health psychologists, both to research and to physician-focused interventions conducted as part of multidisciplinary team collaboration.

### **Study Findings and Interpretation**

Findings provided only limited support for theory-based hypotheses. The RQ1 hypothesis of a nonsignificant association between computerized decision support (CDS) and the outcome, framed by social cognitive theory and informed by literature on cognitive norms in medical practice, was not supported. Also not supported were the RQ3 hypotheses of increased rates of the outcome for those who derive revenue from patient volume or satisfaction, and of better predictive accuracy and fit for theory-based than for atheoretical models. Countering these findings was support for the self-determination theory-based RQ2 hypothesis of a positive relationship between meaningful use of electronic health records (E-HRs), as required by the HITECH ACT, and the outcome. Somewhat limiting the contribution of these results to knowledge about

health-system influences on medical decision-making, neither model could be fully tested because of the removal or recoding of several environmental-construct predictors, and because statistical reliability of the multivariate estimates was suboptimal. In this section, I interpret three key findings in the context of the study literature review.

### **RQ1: CDS**

Study findings suggested an association between medication-related CDS and reduced odds of the study outcome. This finding is consistent with research implicating time constraints and lack of awareness of guidelines, respectively, as systemic and cognitive barriers to evidence-based practice (see F. Fischer et al., 2016). However, this association is inconsistent with the two main conclusions of the literature review. The first conclusion was that CDS guidance may conflict with cognition shaped by medical training, which emphasizes individual biomedical expertise (see Berkhout et al., 2018; Stead et al., 2011) and attention to individual patient needs (see Arts et al., 2016). This point is especially important when framed in social cognitive theory, with its emphasis on occupational norms as a key determinant of behaviors, values, and personal identity (see Bandura, 2001). The second conclusion was that CDS has produced suboptimal results in prior research, including high override rates (see Wright et al., 2018), failure to conform to standards from human-factors psychology (see Phansalkar et al., 2014), and minimal or null effects in most office-based studies (see M. J. Miller et al., 2017; Moja et al., 2014). In this section, I consider two key points in interpretating this finding: heterogeneity in previous research on CDS, and the use of social cognitive theory when studying CDS.

Heterogeneity in previous research. Many assessments of null effects for CDS in previous research were based on review articles and meta-analyses comprising studies with heterogeneous samples and outcomes, such as hospital length of stay in inpatients, use of antibiotics, mortality, health-related quality of life, and virologic failure in patients with human immunodeficiency virus (Bright et al., 2012; Moja et al., 2014). Results of the current study may reflect unique characteristics of this sample and prescribing problem, a fluctuation typical in research of this type. Such heterogeneity in results for various types of medical decisions has been observed in the few cognitive theoryinformed studies of health care decision-making, such as R<sup>2</sup> values ranging from 0.1% to 40% for cognitive theory-based studies of physician behaviors in the systematic review by Godin et al. (2008). Although this heterogeneity may reflect methodological differences, as suggested by Godin et al., a later study of physicians and nurses in the United Kingdom, conducted using a uniform methodology applied to various diabetes care behaviors, similarly indicated considerable variation in percentage of variance explained by social cognitive theory, ranging from 9% for providing weight counseling to 50% for foot examinations (Presseau et al., 2014). Therefore, the type of health decision being studied, which is a function of the specific clinical scenario faced by the physician, may affect the explanatory power of a theoretical construct or intervention. Because clinical scenario is generally not modifiable, Presseau et al. (2014) suggested that identifying modifiable intervention-related factors, which may affect either intention or the gap between intention and behavior, is important in theory-based investigations of medical decision-making.

In that respect, the consistency of guidance for ADHD medications over the 3year study period may provide valuable information in this research. This consistency may have contributed to study findings by making the need for a CDS warning in E-HRs, or for acceptance of the warning by physicians, particularly clear. Both the American family practitioner guidelines current during the study period (Post & Kurlansik, 2012) and a later British guideline (Bolea-Alamañac et al., 2014) addressed the possibility of stimulant misuse and recommended atomoxetine for patients with substance use disorder (SUD). Although the family practitioner guideline did not recommend cardiovascular risk assessment, the British guideline did. A U.S. Substance Abuse and Mental Health Services Administration (2013) publication prior to the current study period documented a 3.5-fold increase in ADHD-medication emergency department visits by adults from 2005 to 2010, consistent with later published evidence about the risks of stimulant overdose (Fulde & Forster, 2015). Finally, FDA safety guidance for ADHD medications, used in defining the outcome measure, did not change during the study period. Therefore, it is possible, although not investigated in this study, that this consistency influenced the credibility of the information for physicians, a factor identified as important in qualitative research on their use of informational resources (see Cook et al., 2013).

Aligning with this possibility, although also not measuring it directly, investigators in a failed theory-based intervention to promote the prescribing of thiazides (a type of blood pressure medication) attributed their results, in part, to extensive exposure to information about thiazides prior to the study (Presseau et al., 2016). Family physicians included in that sample reported high baseline rates of intentions to prescribe thiazides, positive beliefs about them, perceptions that others thought they should prescribe them, and self-efficacy for prescribing (Presseau et al., 2016). These results may be framed within the social cognitive theory suggestion that observational learning of a behavior (e.g., prescribing) is more likely when knowledge is delivered by influential sources, which can include mass media or information delivered by role models (Bandura, 1999; Kelder et al., 2015). Knowledge consistently provided by multiple sources, including medical literature and federal guidance about ADHD medications, may have represented such influence for the physicians in the current study. Nonetheless, whether these psychological mediators directly influenced ADHD prescribing was not measured, a point revisited in discussions of study limitations and recommendations for future research.

Effect of using social cognitive theory. Another possible explanation for the positive results for CDS may stem from the inclusion of both CDS and meaningful use in this study's conceptual models. This design decision reflected the holistic nature of social cognitive theory, which acknowledges different types of environmental influences that may either facilitate or prevent desired behaviors, such as opportunities for learning, as well as physical barriers, rewards, or punishments (see Kelder et al., 2015). This theoretical feature is important because HITECH Act proponents intended CDS and meaningful use to affect different constructs: readily available knowledge (i.e., removing a cognitive barrier at the individual level; see Bates et al., 2003) for CDS, and motivation to use that knowledge (i.e., rewarding desired behavior at the system level; see Buntin et al., 2010) for meaningful use. Moreover, CDS and meaningful use represented two

distinct, albeit related, policy interventions (Wright et al., 2014). However, no previous research identified in this study's literature review addressed these interventions simultaneously. It was feasible to do so in the current study because of the large national sample of 301 physicians in Scenario A and 1,659 physicians in Scenario B.

In contrast, investigators studying one provider office would typically be unable to measure CDS and meaningful use simultaneously because a single office-based system either does or does not meet meaningful use requirements. Therefore, it is possible that in work conducted after the HITECH Act implementation, the effects of the two variables decreased odds for CDS and increased odds for meaningful use—counteracted each other, resulting in a null overall effect. This explanation is supported by the multivariate findings and by the follow-up bivariate analysis of CDS and meaningful use reported in Chapter 4, which suggested opposing effects for these two interventions. If so, the current study contributes to knowledge about social cognitive theory-based analyses of medical decisions by highlighting the possibility of disparate effects for health-system environmental influences that are targeted to knowledge, such as CDS, versus motivation, such as meaningful use.

More broadly, the finding may suggest a benefit of the multilevel approach used in contemporary definitions of health psychology (see Glanz et al., 2015) and in social cognitive theory, which recognizes ongoing mutual interactions of environment and individual (see Bandura, 1989). In discussing the value of applying social cognitive theory to health-promotion efforts, Bandura (2004) noted that the theory is one of only two theoretical approaches to encompass both individual-level factors (e.g., knowledge, self-efficacy) and health-system factors, including social or economic structures, that may pose barriers to desired health behaviors. In an earlier article, Bandura (2001) suggested that psychology contributes to positive change by "discovering principles about how to structure environments" (p. 13). A multilevel perspective on human-environment interaction enables researchers to study the effects of health-system interventions on individual health-related behaviors and changes in practice that may promote better intervention development.

Social cognitive theory does not alone indicate whether a given type of reward will act as a facilitator or barrier to good decision-making. Rather, social cognitive theory provides a theoretical framework within which specific environmental effects can be analyzed. Self-determination theory was used in the current study to address that gap in social cognitive theoretical constructs. Findings for meaningful use, framed within that theory, are discussed next.

#### **RQ2: Meaningful Use**

Results of this study suggested increased odds of potentially unsafe prescribing among meaningful use providers. The current study extended the available base of evidence on meaningful use, as a macrolevel economic structure that may influence the health-related behaviors of individuals (see Bandura, 2004), in two ways. First, rather than self-reported behavior or opinion, which may lack validity (see Conner & Norman, 2017), current study results represent an objectively measured behavior, meeting a recently identified need in health psychology (see Prestwich et al., 2018). Second, the use of a national sample extended knowledge derived from previous studies of objective behavioral outcomes that were conducted in single states or health systems (see Grinspan et al., 2017; Jung et al., 2017; Kern et al., 2015; Levine et al., 2017; Samal et al., 2014; Unruh et al., 2017). This national scope was consistent with the multilevel focus of health promotion suggested by Bandura (2004) and with recent calls in the health psychology literature for research on population-level influences on health (see Conner & Norman, 2017). In the next section, I interpret this finding in the context of previous research on meaningful use, and consider the finding in light of self-determination theory.

**Previous research on meaningful use**. Like state- or institution-level research, the current study did not produce favorable findings for the meaningful use program, but the findings of minimal or mixed results in previous research contrast with the finding of approximately tripled odds of potentially unsafe prescribing in the current study. This discrepancy may be attributable to the specific prescribing problem addressed in this research. Like studies of CDS, research on meaningful use is heterogenous and has covered diverse topics including vaccination, cancer screening, hospitalizations, and quality of primary care. Such heterogeneity in studies of medical decisions is typical (see Godin et al., 2008; Moja et al., 2014), representing a known challenge in applying single theoretical constructs or theories to different health-related behaviors (Presseau et al., 2014), particularly in health psychology where consideration of broad systemic influences on various populations and health outcomes is considered important (APA, 2014; Bandura, 2004; Marks et al., 2015).

Findings of two studies comparing offices with and without meaningful use, conducted in a large health system with a single E-HR including CDS (Samal et al.,

2014; Levine et al., 2017), suggest another possible explanation for the present research finding of relatively large effects of meaningful use. Both studies, like most other previous research, produced mixed outcomes for meaningful use, with better results on a few measures and worsened or similar results on others. However, the difference for patients with depression was the largest observed in either study; 42% of patients in meaningful use offices and 68% of those in offices without meaningful use received depression treatment for  $\geq$  12 weeks (Samal et al., 2014).

The similarity of that study's result for depression and the current study's result for ADHD medications may represent a phenomenon described by Cifuentes et al. (2015): the challenge of carrying out interprofessional communications among behavioral and medical providers, the clinical ideal for patients with ADHD (Kooij et al., 2019), using electronic means. For example, one qualitative focus-group study of health professionals in an academic medical center, conducted approximately 2 years after implementation of an E-HR, indicated several cognitive and work-process challenges related to the replacement of face-to-face with electronic communication, such as variations in ways that different specialists (e.g., physical therapist versus physician) recorded information in E-HR fields and lack of confidence that notes were being received or read by others (Bardach, Real, & Bardach, 2017). This explanation is also supported by qualitative research, conducted by a social cognitive psychologist who specializes in human-factors engineering (i.e., human-computer-environment interaction) in health care, documenting new challenges in interprofessional communications after E-HR implementation (Holden, 2011). Examples included extra time spent typing messages via email instead of having a conversation; perceptions of communications as less clinically complete because of the constrained E-HR format; and problematic workprocess changes, such as the actions of one physician who avoided E-HR data entry requirements for in-person medical orders by stepping into the hallway and calling nurses from his cell phone. Together, these findings suggest that the negative effects of meaningful use described by clinicians in surveys (e.g., Emani et al., 2017) may be exacerbated in mental health care, such as for ADHD, partly because of the added burden E-HRs may pose for interprofessional communications. Implications of this suggestion for additional research are discussed later in the chapter.

Self-determination theory and meaningful use. The finding of higher odds of potentially unsafe prescribing for meaningful use providers is consistent with several conclusions reached in the synthesis of self-determination theory with findings of the literature review. First, self-determination theory indicates an association between controlled motivation and poor task performance (Deci & Ryan, 2008a). Second, also consistent with self-determination theory, surveys of physicians documented opposition to the meaningful use program based on lack of clinical benefit, introduction of clinical harms, and diversion from important medical care tasks to clerical work (Emani et al., 2017; Shanafelt et al., 2016; Weeks et al., 2015), resulting in a perception of being forced by meaningful use requirements to use technologies that do not provide value (J. Levinson et al., 2017; Weeks et al., 2015). Findings of the current study are also consistent with the results of a meta-analysis linking task-contingent tangible rewards with decreased intrinsic motivation (Deci et al., 1999) and of a study conducted in a single corporation, which indicated that managerial agreement with self-determination principles (e.g., promoting autonomy, considering subordinate perspectives) was associated with better employee perceptions of the company and job satisfaction, except under adverse economic conditions (Deci et al., 1989).

Thus, although autonomous motivation was not directly measured in the current study, and no research applying self-determination theory to medical decision-making was identified in the literature review, results generally support the use of selfdetermination theoretical constructs, particularly autonomous motivation, in predicting medical decisions. However, these findings contrast with those for patient-derived revenue, which was based on the same theory. In the next section, I consider this discrepancy.

### **Patient-Derived Revenue: Coefficient Evaluation in RQ3**

Several findings for patient-derived revenue were not as hypothesized according to self-determination theory. In the main theory-based analysis of Scenario A, revenue derived from either patient volume or satisfaction was associated with reduced odds of potentially unsafe prescribing of ADHD medications. Additionally, sensitivity analyses produced the unexpected finding that narrowing the definition of this predictor to direct financial compensation alone, measured as either practice ownership or share of billings, was associated with reduced odds of potentially unsafe prescribing in both Scenario A and Scenario B. Moreover, use of the narrower definition improved model fit, suggesting better explanatory power when basing the patient-derived revenue measure solely on direct monetary compensation without considering revenue derived indirectly from bonus payments based on patient satisfaction measures. Such a pattern might seem to suggest a purely economic, rather than psychological, phenomenon.

Interpretation of this seemingly anomalous finding should reflect the theoretical rationale of the a priori hypothesis for patient-derived revenue in this study. This hypothesis was based on the constructs of integrated and identified motivation, which are subtypes of autonomous motivation produced by external rewards for a valued outcome (Deci & Ryan, 2008b; Prestwich et al., 2018), and on evidence that physicians value patient relationships (Colligan et al., 2016; Tak et al., 2017). The rationale underlying the hypothesis was that physicians would attempt to preserve the valued outcome of patient relationships by prescribing even if potentially unsafe, a phenomenon described in research suggesting fear of lost patient relationships as a determinant of potentially inappropriate prescribing (Anderson et al., 2014; Sirdifield et al., 2013; Wallis et al., 2017). Thus, as external rewards linked to the valued outcome of patient relationships, both direct financial compensation from patients and bonus payments based on patient satisfaction would be expected to have the same effect, according to this application of the theory: increasing autonomous motivation for the valued goal of retaining relationships, thereby increasing potentially unsafe prescribing.

A simpler and more direct application of the theoretical construct of autonomous motivation, specifically the assertion that perceived autonomy improves task performance (Deci & Ryan, 2008a), would have produced an alternative hypothesis that obtaining revenue directly from patient care activities increases a physician's sense of autonomy, thereby improving medical decision-making, the physician's primary task, and reducing the rate of potentially unsafe prescribing. This alternative hypothesis, which would have been supported by study findings, is also consistent with several contemporary trends in health care, all linked with the theoretical construct of autonomous motivation.

Autonomy and quality of care. The first is a desire expressed by physicians for greater control over medical practice (J. Shapiro, Astin, Shapiro, Robitshek, & Shapiro, 2011), particularly on tasks that promote patient well-being, which physicians are trained to see as their highest obligation (Cooke et al., 2006). Concern over lost autonomy has been reflected in physician commentaries implicating the supplanting of clinical judgment with E-HR-delivered guidance as a key cause of frustration, burnout, and departures from the practice of medicine (Wright & Katz, 2018). Corroborating the importance of control over medical practice for physicians, one mixed-methods analysis of a diverse sample of physicians suggested that occupational satisfaction is increased by practice ownership and by authority to make business decisions, such as the purchase of new medical equipment, that affect quality of care (Friedberg et al., 2013). These findings suggest that physicians perceive autonomy as important for the quality of care that they provide. Such a perception is unsurprising given the process of medical education, described in Chapter 2, which is intended to prepare physicians for lifelong, self-direct learning and independent decision-making to promote the well-being of patients (ACGME, 2019; Berkhout et al., 2018).

**Innovative delivery arrangements**. This desire for autonomy may be responsible for the second, relatively recent, phenomenon of direct patient contracting, such as "concierge" or retainer-fee arrangements that minimize third-party influence on physician-patient relationships by asking patients to pay for personalized care and enhanced access (Doherty & Medical Practice and Quality Committee [MPQC], 2015). These arrangements were described in one literature review as a way to combat requirements, such as excessive paperwork and restrictions on office visit time, that "are undermining traditional medical practices" (Doherty & MPQC, 2015, p. 951). Although the prevalence of direct patient contracting arrangements is difficult to estimate, it appears to be increasing, prompting a call from the American College of Physicians for "independent research" to evaluate both the factors underlying these arrangements and their effects on "access to care, especially for vulnerable populations" (Doherty & MPQC, 2015, p. 951).

**Physician employment**. Both trends and the current study findings should be interpreted in the context of a much broader trend: the long-term decline in the rate of practice ownership among physicians in the United States, estimated at 72% in 1994 (Kletke, Emmons, & Gillis, 1996), 53% in 2012, and 46% in 2018 (Kane, 2019). Accompanying this trend was an increased rate of employment in practices owned by hospitals or health systems (Kane, 2019) to approximately 44% of U.S. physicians in 2018 (Physicians Advocacy Institute, 2019). Compared with physician-owned practices, hospital-owned practices have higher rates of some recommended care processes, such as discussing clinical quality data (28% and 44%, respectively) and writing quality reports (64% and 79%, respectively; Lindner et al., 2019). Nonetheless, these hospital-owned arrangements, intended to improve care coordination, have instead been associated in a limited body of research with few or no effects on quality of care (Scott, Orav, Cutler, &

Jha, 2017; Short & Ho, 2019) and with increased use of services providing minimal clinical benefit (Mafi, Wee, Davis, & Landon, 2017). The current study's findings on meaningful use (i.e., increased odds of potentially unsafe prescribing) and direct financial compensation (i.e., decreased odds) are consistent with this previous work and extend knowledge by suggesting that the loss of autonomy derived from meaningful use, and the increased autonomy derived from direct financial compensation, may predict quality of prescribing, a type of medical task not previously assessed in this body of research.

**Application to theory**. Viewed as a whole, these findings suggest autonomy as a core determinant of intrinsic motivation for medical practice, consistent with self-determination theory (Deci & Ryan, 2008a) and with concerns expressed in the literature about how extrinsic rewards for performance on externally determined metrics affect the quality of health care (Himmelstein et al., 2014; Kao, 2015). Broadly, the findings again point to the value of multilevel psychological perspectives on health, as described by Bandura (2004). Specifically, meaningful use and practice-ownership structures may be appropriately framed as system-level influences on physicians and their decisions, potentially affecting the health of individual patients (Marks et al., 2015).

#### Limitations of the Study

Before considering the implications of this study, important limitations should be acknowledged. These include limitations on internal validity, external validity, and scope. Most were anticipated a priori, and some were addressed with sensitivity analyses.

### **Internal Validity**

**No direct measurement of mediators**. Although study hypotheses were developed by linking theoretical constructs to predictors and outcomes, these constructs (e.g., outcome expectations, value) were not directly measured. Whether physicians received or read CDS-delivered guidance is also unknown. For this reason, study results represent intention-to-treat estimated associations of environmental characteristics with prescribing behaviors, not direct measures of the psychological experiences underlying those behaviors. Mitigating this limitation, study hypotheses were based on a large body of qualitative and quantitative evidence about cognitive and emotional response to meaningful use, CDS, and E-HRs (e.g., Emani et al., 2017; Slight et al., 2016).

Unmeasured confounding factors. As in any nonexperimental study, results could have been affected by unmeasured confounding factors, such as symptom severity, demands for medication from patients or family members, or unmeasured features of the medical practice environment. Physicians who achieved meaningful use may have systematically differed from other physicians in ways, such as attitudes toward clinical guidelines or comfort with technological devices, that could have affected the relationships between CDS or meaningful use and the study outcome but could not be measured in this study. Potential attitudinal confounding factors include agreement or disagreement with guidelines (e.g., Cloutier et al., 2018; F. Fischer et al., 2016) or with their application to individual patient circumstances (Arts et al., 2016), or general propensity to practice evidence-based medicine. For example, Grinspan et al. (2017) found that even after statistical adjustments for several characteristics of patients (sex,

age, comorbidities, zip code) and physicians (generalist versus surgeon or medical specialist, sex, urban versus rural practice, and practice size), providers who chose meaningful use participation had slightly better care practices before meaningful use implementation than did nonparticipants.

Assessments of model quality and fit help to assess the possibility of such unmeasured confounding factors because they indicate the extent of residual confounding after multivariate adjustment (see Warner, 2013). In this study, logistic regression models of Scenario B were better specified and achieved better predictive accuracy than did models of Scenario A. Nonetheless, even with the approximately 87–89% predictive accuracy measured for Scenario B, and especially with the much lower 57–59% accuracy for Scenario A, the possibility of residual confounding remains.

**Misclassification of exposure**. Although the quality of coding by NAMCS data collectors is excellent (see D. T. Lau et al., 2018; Rui & Okeyode, 2019), the accuracy of data extracted from the medical record depends on the content of the record. Two challenges may have affected measurements in this study. First, ADHD did not become a medical condition indicator in the NAMCS until 2016 (CDC, 2019b). Thus, it may not have been recorded as a diagnosis in all visits in which ADHD medication was prescribed, even for patients who had ADHD. Second and related, "diagnosing for dollars" (Braun & Cox, 2005, p. 425), which is intentionally misdiagnosing mental health conditions to maximize reimbursement, and the tendency of patients to seek care from behavioral providers unknown to the physician (Madden et al., 2016) may have resulted in the omission of relevant psychiatric diagnoses from medical records. This problem

may have been the cause of one issue identified early in data processing, the provision of substance abuse counseling without a recorded diagnosis of SUD. Mitigating this limitation, this issue was identified in only a small proportion (230 of 2,270) substance abuse visits. Additionally, sensitivity analyses, which are the recommended approach to methodological concerns in analyses of archival medical data (Berger et al., 2009), suggested generally robust findings.

**Sample size**. A final limitation on internal validity, which was anticipated a priori but could not be quantified prior to accessing the NAMCS data, was small design effectadjusted sample size, particularly in Scenario A, likely because of the low, albeit increasing, prevalence of diagnosed and treated ADHD among U.S. adults (see Fairman et al., 2017). Because this problem affected the statistical precision of some bivariate estimates and most multivariate estimates, some of which did not meet NCHS statistical reliability standards (see CDC, 2019b; Parker et al., 2017), results should be considered preliminary. However, typical sample sizes in health psychology research on medical decisions are small: 56–80 per intervention subgroup in a theory-based process evaluation of the failed thiazide intervention (Presseau et al., 2016); 18 general practitioners in a theory-based assessment of antibiotic prescribing in Australia (Sargent, McCullough, Del Mar, & Lowe, 2017); 21-34 general practitioners per group in a randomized trial of a theory-based intervention on antibiotic prescribing in Sweden (Milos et al., 2013); and a total of 374 physicians in four theory-based studies of clinical decisions in the meta-analysis by Godin et al. (2008). Therefore, awareness of statistical

imprecision should be balanced against the contribution made by the large, national sample used in this research.

# **External Validity**

Two potential limitations on external validity were anticipated a priori and assessed in sensitivity analyses. One was the NCHS decision to allow E-HR submission in lieu of onsite data collection in 2016 (CDC, 2019b). Although this decision eventually resulted in the exclusion of these records from the NAMCS, sensitivity analyses suggested results were robust to this issue.

A second potential limitation was that NAMCS participants may have differed systematically from nonparticipants. Quantitative assessments, both in this study and in previous research, suggested against this possibility. First, as reported in Chapter 3, comparisons of NAMCS participants and nonparticipants suggested minimal or no nonresponse bias on more than 80 indicator categories after application of sample weights in a study by Hing et al. (2016). Second, two sets of numeric findings reported in Chapter 4, the use of numerous weighting strata (n = 101 in Scenario A and n = 130 in Scenario B) and similar characteristics of the current study sample and samples reported in previous research, suggested good external validity for target populations including patients with ADHD, CVD, or SUD. The E-HR use rate measured in this study was also similar to that reported in national samples during the study time period.

Further supporting confidence in the external validity of this study's findings is a body of research evidence indicating little to no nonresponse bias in surveys of physicians, despite low response rates. One was a "reluctant respondent" analysis, a commonly used bias-assessment technique (Goyder, 1987), which indicated that repeated efforts to contact nonrespondents to a physician survey on cancer care increased response rate without changing results (Willis, Smith, & Lee, 2013). Another study found no nonresponse bias on patient characteristics, including several clinical measures of diabetes management, in a physician survey with a 36% response rate (Ziegenfuss et al., 2012), and another showed only male sex and questionnaire length significantly associated with nonresponse in a physician survey with a 47% response rate (McFarlane, Olmsted, Murphy, & Hill, 2007).

Countering these quantitative assessments is the possibility of social desirability bias (Groves et al., 2009) or topic-salience bias (Goyder, 1987) in the decision to participate in the NAMCS. For example, in the process evaluation of the thiazide intervention, survey respondents were more likely than nonrespondents to be universityaffiliated (9% versus 2%, respectively, p = .009) and to belong to a professional physician organization (44% versus 31%, p = .030). Although those data were not weighted on numerous characteristics to adjust for nonresponse bias, as NAMCS data are, they suggested that physicians who are more knowledgeable or interested in evidence-based medicine may be more likely to respond to survey requests. Such attitudinal biases may be more nuanced and difficult to assess than the quantitative measures reported by Hing et al. (2016) or in previous studies (see McFarlane et al., 2007; Willis et al., 2013; Ziegenfuss et al., 2012). Thus, although many factors that typically affect survey response (Goyder, 1987) are either similar for all physicians (e.g., socioeconomic status) or adjusted by NAMCS weights (e.g., age group, sex), the possibility of nonresponse bias cannot be completely ruled out.

# **Study Scope**

The only major discrepancy between the sample characteristics and previously reported results was a higher use rate for prescribed stimulants reported by adults with SUD in household interviews (see Compton et al., 2018) than recorded in office visits in this study. This issue may reflect a constraint on study scope known a priori. Specifically, NAMCS records represent only information known to the physician (predictors) and decisions made by the physician (outcomes) during a single office visit, not actions taken by patients after the visit. Patients choose whether to seek recommended psychotherapy, fill prescriptions, take medications, or divert a controlled substance by selling or giving it away (Compton et al., 2018; Ford, Thomas, Byng, & McCabe, 2019). For this reason, results of this study do not generalize to all sources of potentially unsafe ADHD medications, including family and friends, a common source of illicit prescription medications for young adults (see McCabe, Teter, Boyd, Wilens, & Schepis, 2018). Unknown to the physicians in this study, patients with or without SUD may have diverted their prescribed medication to others, although SUD increases the likelihood of obtaining medication directly from a physician (see Compton et al., 2018; McCabe et al., 2018). Although this scope constraint has little relevance for the current study findings, which were limited a priori to medical decisions made during one office visit, it does highlight the value of current recommendations to query all young adults, not just those prescribed

controlled substances, regarding medication abuse (McCabe et al., 2019).

Communications of this type could not be assessed in this study.

Finally, also known a priori, results of this study do not generalize to every form of inappropriate prescribing of ADHD medications. Whether the patient's symptoms warranted a prescription, a medical judgment that may rely on information not recorded in the medical record, was not measured in this research. Thus, some potentially unsafe prescribing may have been medically necessary, and some safer prescribing may have been medically unnecessary. This question was beyond the scope of this study.

# **Recommendations for Future Research**

The foremost recommendation arising from the current study is a need for more theory-based analyses, and perhaps additional comparisons of atheoretical with theorybased approaches, in research on medical decision-making. Considering the limited body of theory-based research on medical decisions published in the 15 years since Bandura (2004) called for multilevel analyses of the effects that health-system structures have on individuals, a reasonable question for health psychology may be why so little scholarship in the field has addressed physicians' responses to health-system interventions on their behavior. Such a body of work would be consistent with the social cognitive theoretical construct of emergent interactive agency (Bandura, 1989); with Bandura's (2001) suggestion that psychology should inform the development of environmental structures to promote psychosocial health; and with the APA (2014) goal of using psychology to advance the well-being of individuals and populations. Nonetheless, as noted in Chapter 1, theory-based studies of physician decision-making (Godin et al., 2008) or of interventions on the medical decision-making process (L. Liang et al., 2017) are uncommon. Further highlighting the issue for health psychology, of 14 theory-based studies identified in reviews of guideline-promotion evaluations (see L. Liang et al., 2017, n = 8) or of physician behaviors (see Godin et al., 2008, n = 6), only two were published in health psychology journals; most were published in medical journals.

This problem has been observed in the field of health psychology as a whole, which, despite theories explicitly acknowledging environmental influences on psychological phenomena, has generally put most research focus on the behaviors and characteristics of individuals (Kelder et al., 2015; Sallis & Owen, 2015). In this section, I consider how this gap might be addressed in multilevel analyses of medical decisionmaking that acknowledge both environmental and individual influences, informing these suggestions with the findings of this study and previous research. The discussions below address psychological mediators, heterogeneity of outcomes, and research methods.

## **Psychological Mediators**

Findings of the current study suggested the feasibility of mapping theoretical constructs to archival data to predict prescribing decisions, with modest accuracy in Scenario A and excellent accuracy in Scenario B. Additional theory-based research could extend the current study's preliminary work by supplementing objectively measured behavioral data with survey data on psychological mediators (see Warner, 2013). Examples could include measures of behavioral intentions (see Presseau et al., 2016) in assessing CDS, or of motivation to practice medicine (see Himmelstein et al., 2014) in assessing meaningful use. Additionally, if independent associations of CDS and

meaningful use with prescribing behavior are confirmed in additional research, preferably with larger samples, mediation analysis could help to determine whether these interventions act on different psychological phenomena as intended by their developers: knowledge and cognition for CDS (see Bates et al., 2003) and motivation for meaningful use (see Buntin et al., 2010).

Such approaches could potentially contribute not only to the study of medical decisions, but also to the field of health psychology, where direct measurement of theoretical constructs is limited even in theory-based studies (see Prestwich et al., 2014; Prestwich et al., 2015). For example, in an analysis of all studies of diet or exercise interventions included in two systematic reviews published in health psychology journals (*Health Psychology Review* and *Health Psychology*), Prestwich et al. (2014) found that only 56% reported a basis in any psychological theory. Of the studies identified by their authors as theory-based, 10% linked all intervention components to one or more theoretical constructs; 45% linked at least one intervention component to theory; and 49% measured any theoretical constructs in the postintervention period.

Examination of psychological mediators would likely also have value for additional questions and health-system effects, consistent with the vision advanced by Bandura (2004). For example, the current study results for patient-derived revenue suggest a need for more research into the effects of practice ownership versus employment arrangements on physician decision-making and health care quality, perhaps along with assessment of direct patient contracting arrangements as suggested by the American College of Physicians (see Doherty & MPQC, 2015). Such research could be set in the social cognitive theoretical framework, with ownership arrangements as environmental facilitators or barriers (see Kelder et al., 2015) to making evidence-based medical decisions or to positive health outcomes for individual patients. In addition to psychological mediators described above, such as examining whether autonomous motivation mediates the association between practice ownership or direct contracting and quality of care (see Scott et al., 2017; Short & Ho, 2019), this work might also measure environmental mediators. Because preliminary research links hospital ownership with increased time spent on reporting tasks (Lindner et al., 2019), mediators might include E-HR use and time allowed for office visits.

**Context-specific assessment of mediators**. Research of this type could also facilitate richer exploration of interactions among different health-system initiatives. For example, research could assess whether practice ownership arrangements that enable physicians to choose or refuse meaningful use participation change the effect of meaningful use on task performance. Adding a direct measure of autonomous motivation to such an analysis would help to answer the question of whether the meaningful use effect is due to E-HR system features, which have been associated with occupational stress (see Babbott et al., 2014), or to autonomy as a core issue.

Similarly, research on whether locally developed CDS systems have lower rates of override than commercial systems do, as suggested in the research by Wright et al. (2018) in a single health system, might benefit from direct measurement of psychological mediators. Examples include intrinsic (i.e., task-specific) versus extraneous (i.e., devicerelated) cognitive load, automation bias (see Lyell et al., 2018), behavioral habituation (see Baysari et al., 2017), or perceived autonomy in the work context (see Deci et al., 1989). Findings for the first three mediators might suggest attributing override differences between locally developed and commercial systems to system features, whereas a finding for the fourth mediator might suggest that being forced to switch to a system over which physicians have no control negatively affects autonomous motivation and, therefore, task performance, independent of system features.

In addition to providing valuable information for improvement of decision support systems, analyses of this type might extend theory by linking specific theoretical constructs (e.g., cognitive load, autonomous motivation) to specific types of professional task performance outcomes. For example, to follow up on previous research suggesting an association between E-HR use and impaired interprofessional communication (Bardach et al., 2017; Holden, 2011), a study could address whether E-HRs have a greater effect on measures of cognitive load (see Lyell et al., 2018) for mental health care tasks, where greater interprofessional collaboration may be needed to address both physical and psychosocial needs (see Kooij et al., 2019), than for acute illnesses.

#### **Heterogeneity of Outcomes**

An additional research area, examination of clinical and theoretical factors underlying physician response to CDS-delivered guidance and other interventions on their behavior, is suggested by the heterogeneous results obtained for CDS in previous work (see Moja et al., 2014), by the somewhat positive results for CDS in the current study, and by the mixed outcomes of theory-based interventions (see Godin et al., 2008; Milos et al., 2013; Presseau et al., 2016). Previous work has examined the associations of types (e.g., drug-drug interactions, allergies) or severity of CDS messages with overrides (Nanji et al., 2014; Wright et al., 2018). To extend this work to E-HRs as a health-system intervention, a surveillance process similar to that currently used for medical devices (see Ratwani et al., 2019) could provide archival data on system features and outcomes. Analyses of these data could be framed in theory-based studies to provide guidance for future system development. The nature of these studies would depend on available data, but a health psychologist might, in general, supplement quantitative data (e.g., type of medication, length of medication list, patient age, diagnosis) with results of previous qualitative or quantitative research to identify situations where risk of technology-related adverse events is high. Possible examples include circumstances for which few opportunities for observational learning occur in medical training (see Stead et al., 2011); or lengthy lists of medications or diagnoses, which might increase likelihood of automation bias (see Lyell et al., 2018) or difficulties comprehending screen display (see Brown et al., 2017).

Because of evidence described previously that even the same theory-based intervention applied to different clinical scenarios may produce disparate results (Presseau et al., 2014), analyses of factors underlying the success or failure of E-HRs and of theory-based interventions should ideally measure and control for disease state, patient characteristics, and task. For example, Presseau et al. (2016) attributed the failure of their theory-based intervention on thiazide prescriptions to overwhelming intention to prescribe thiazides (5.93 on a 7-point scale) prior to the intervention. In addition to controlling for nonmodifiable clinical scenarios, as suggested by Presseau et al. (2014), such research could experimentally manipulate modifiable intervention features, such as the content of communications, as in a study of opioid-death notifications by Doctor et al. (2018); use of a peer-physician clinical "champion" to accompany an educational intervention, as in a study by Liebschutz et al. (2017); or implementation-intention training, as in a study by Saddawi-Konefka, Schumacher, Baker, Charnin, and Gollwitzer (2016). Additionally, fidelity to the underlying theory should be measured, as some purportedly theory-based work has employed techniques inconsistent with theoretical constructs (Prestwich et al., 2015). Challenges encountered in translating constructs to specific design features, such as when evidence from theory-based research conflicts with the needs or perceptions of participants, may help to explain these inconsistencies and should, ideally, be addressed during intervention design (see Witteman et al., 2017).

### **Research Methodology**

The field of psychology could contribute research expertise to studies of E-HRs in several ways, consistent with the objective of assessing the effects of health system-level interventions on individual experiences and behavior (see Bandura, 2003; Marks et al., 2015). Many of these derive from human factors psychology, a subspecialty focused on human-machine-environment interaction (Savage et al., 2017). However, because human-factors research is a diverse field, encompassing not only cognitive psychology but also informatics and industrial engineering (Holden, 2011; Lyell & Coiera, 2017; Ratwani et al., 2019), the interprofessional distinctions described in this section may be imprecise.

**Validated system-assessment tools**. One area where psychology could make an important contribution is the continued assessment of E-HR systems using validated

tools, such as the Instrument for Evaluating Human-Factors Principles in Medication-Related Decision Support Alerts (I-Me-DeSA; see Zachariah et al., 2011) or other human-factors standards, such as clarity, prioritization of clinical information presented on screen, and provision of actionable information (see Phansalkar et al., 2014). Not only the devices, but also the processes used to develop them, can be the subject of such human-factors assessment. Metrics for accepted design-process standards, which could become research questions in a qualitative or quantitative study, include whether users (e.g., physicians) were included in the design process, whether interfaces were evaluated against accepted graphical-display principles (e.g., for font, color, and layout), and whether formal usability testing was required prior to product launch (see Savage et al., 2017). A recommended process for health care settings is assessment of practiceenvironment requirements prior to the initial design phase, using observation, interviews, and analyses of task-related cognitive needs (Ray et al., 2019), ideal tasks for health psychologists trained in qualitative research techniques.

Automation-bias assessment. Although originating in fields other than health care (e.g., luggage screening and air traffic control; Lyell & Coiera, 2017), automationbias assessment has been applied to study the potential hazards of incorrect guidance delivered by CDS, which may encourage users to switch from an original, correct decision to an incorrect choice recommended by the system (Goddard, Roudsari, & Wyatt, 2014; Lyell et al., 2017). For example, Lyell et al. (2017) assessed performance on electronic-prescribing tasks in a sample of 120 medical students and found that correct CDS guidance reduced errors by 59%, but incorrect guidance increased errors by 87%. A gap in the automation-bias literature is that most studies have used experimental designs (see Lyell & Coiera, 2017), suggesting a need for naturalistic fieldwork to provide information about the conditions under which this problem is likely to occur (see Goddard, Roudari, & Wyatt, 2012). Environmental and psychological mediators that should be incorporated into these assessments include trust in the CDS system, complexity of verification tasks (i.e., determining whether a warning represents a true threat), workload, time constraints, and intrinsic task complexity (see Goddard et al., 2012), factors that may affect cognitive load (see Lyell & Coiera, 2017).

Physiological and psychological assessments of cognitive load. Studies assessing cognitive load during task performance, using either subjective scales or physiologic measures, could provide valuable information about psychological and biologic plausibility when assessing associations of E-HR features with medical decisions. Scales used in studies of mental workload associated with Web browsing (Jimenez-Molina, Retamal, & Lira, 2018) and learning activities (Skulmowski & Rey, 2017) include the NASA Task Load Index (NASA-TLX), which assesses mental and physical demands, effort, performance, and frustration, and cognitive-load surveys designed to distinguish intrinsic versus extraneous load types. A disadvantage of scales is that they are administered after task completion and do not allow for real-time assessment of task-related load, which is better assessed using physiologic techniques (Jiminez-Molina et al., 2018). These include pupillography (measures of changes in pupil diameter), which indicates sympathetic and parasympathetic nervous system responses; fixed (focused) versus saccadic (rapid) eye movements; electroencephalography, which provides measures of mental alertness and task difficulty; and skin conductivity. These measures can be combined and assessed in multifactorial experiments under various conditions. For example, Mazur et al. (2016) assessed the performance of 29 medical trainees on three clinical tasks using two different E-HRs, measuring subjective demand using NASA-TLX, task demands using time to task completion and number of clicks, and cognitive load using pupillary changes and electroencephalography. Results of that study suggested that E-HR type and clinical task interact in producing task demand, without a significant association between the physiologic measures and task performance.

**Validated opinion scale**. A standardized scale of physician opinions about E-HRs, developed and tested using accepted psychometric procedures (see DeVellis, 2017), would likely contribute a great deal to the understanding of how physicians perceive and experience electronic technologies. Of the survey studies of physician opinions about meaningful use, none included reliability or validity testing of questions about the program (Emani et al., 2014; Shanafelt et al., 2016; Weeks et al., 2014), and only one included a pilot test, which was conducted only on the principal investigators (Emani et al., 2014). Given findings of the current study and previous research suggesting autonomy as a core issue, the addition of a validated measure of autonomous motivation to such a survey might also provide helpful information about psychological factors underlying responses to E-HR implementation (see Emani et al., 2017).

**Theory-informed, system-wide evaluations**. Finally, to inform public policy consistent with APA (2014) objectives, health psychologists may wish to consider, where feasible, more theory-based analyses of the effects of population-level interventions on

medical decisions. Studies of individual characteristics alone, common in health psychology, do not address the effects of environmental factors (Kelder et al., 2015; Sallis & Owen, 2015), such as the health-system structures that Bandura (2004) implicated as important influences on individual health. An easily scalable analysis would apply the theoretical framework and data set used in this study to other disease states and drugs, preferably with a sample size sufficient for study of the interaction effects of ownership and health-system interventions described previously in this section.

### Implications

### **Positive Social Change**

Potentially unsafe prescribing of ADHD medications affects a small minority of adults, estimated in this study at 8.3% in the Scenario A analysis of adults treated for ADHD and 1.5% in the Scenario B analysis of adults with either CVD or SUD. Similarly, the study by Fairman et al. (2018) identified one-year prevalence rates of 2% for serious CVD and 11–19% for SUD among adults newly treated for ADHD with medications. Despite these relatively low prevalence rates, the prescribing problem measured in the current study has potentially important implications for two targets of health psychology-informed interventions intended to produce positive change (see Bandura, 2004): population health (see APA, 2014) and systemic interventions on medical decisions (see Glanz et al., 2015). Each target is discussed below.

**Population health**. Several trends and recent research findings suggest growing recognition of potentially unsafe prescribing of ADHD medications. These include recent FDA (2019) guidance on stimulants, which recommends assessment of heart rate and

blood pressure in the drug-development process; a report that from 2006–2016 in the United States, the 150% rate of increase in use of prescribed amphetamines far outpaced the 8% population growth (Piper et al., 2018); and the expansion of CDC drug surveillance efforts to include prescribed and nonprescribed stimulants (Kariisa et al., 2019). The risks of these trends were underscored by a recently reported 37% rate of increase from 2016–2017 in U.S. overdose deaths from psychostimulants with abuse potential, excluding cocaine but including prescribed stimulants and a few illicit drugs (Kariisa et al., 2019). In that regard, it is concerning that in the current study, having a black-box warning was, unexpectedly, positively associated with potentially unsafe prescribing despite the availability of atomoxetine and its recommended use for patients with SUD (Bolea-Alamañac et al., 2014; Post & Kurlansik, 2012). These findings suggest that effective health-system interventions to promote evidence-based practice in ADHDmedication prescribing may produce positive changes in population health, consistent with APA (2014) objectives.

Systemic interventions on medical decisions. Closely related to population health is the narrower concern of how interventions to promote evidence-based medicine affect physicians. Physicians commonly attribute occupational dissatisfaction and professional burnout to the increased clerical burden and diminished patient-engagement opportunities associated with E-HRs (Friedberg et al., 2013; Shanafelt et al., 2016; Wright & Katz, 2018). The HITECH Act is certainly not the only source of professional dissatisfaction for physicians; other sources include difficult relationships with payers (e.g., insurance companies, Medicare, Medicaid), patient nonadherence to medical advice, reductions in time allotted for visits, and managerial decisions perceived to diminish quality of care (Colligan et al., 2016; Friedberg et al., 2013). Nonetheless, the role of meaningful use as a large systemic intervention should not be overlooked because of its potential effects on the health of individual patients. These effects arise from two sources: medical errors caused or facilitated by technology (see Amato et al., 2017; Brown et al., 2017) and the health consequences that may result when physicians either cut back on practice hours or leave medicine altogether because of burnout (see Olson, 2017; Wright & Katz, 2018).

For example, in a 2014 survey of U.S. physicians regarding their plans for the coming 12 months, 20% reported an intention to reduce work hours and 2% a planned career change, and odds of making either change were multiplied by 1.81 (95% CI [1.49, 2.19]) for physicians evidencing burnout and by 1.44 (95% CI [1.16, 1.80) for those dissatisfied with their E-HR (Sinsky et al., 2017). Olson (2017) has suggested that these trends represent a "proverbial canary in the coal mine" (p. 1610) by highlighting the way that systemic dysfunction can damage the well-being and productivity of individual physicians, with unintended consequences that may include a reduction in the already tenuous supply of doctors available to care for patients. Recognizing environmental influences on health as Bandura (2001) did, Olson and others (see Card, 2018) have called for interventions to improve the wellness of health systems, not just the emotional resilience of individual physicians who must respond to systemic dysfunction. How health psychology might contribute to those efforts is discussed next.

### **Implications for Practice**

If confirmed by additional research, this study's findings may facilitate the design and evaluation of interventions that effectively increase evidence-based decisions with fewer unintended consequences than those currently experienced in medicine. These interventions, like the problems they are intended to address, represent complex interactions of medical practice environment with individual physician behaviors, consistent with the social cognitive theoretical framework for this research (see Bandura, 1989). Four strategies are discussed in this section: physician empowerment, balancing clinical relevance and uniformity, physician-patient relationships, and training delivered in interdisciplinary team contexts.

**Physician empowerment**. To the extent that autonomy is a core issue for physicians, greater physician empowerment in efforts to improve evidence-based practice, including E-HR system design, might improve not only the systems but also physician response to them by increasing perceived autonomy, as self-determination theory (see Deci & Ryan, 2008a) and the corporate study by Deci et al. (1989) suggest. A small body of evidence supports this strategy. For example, Gawande (2018) described the positive results achieved in one health system when a neurosurgical team met regularly to modify its commercial E-HR by removing clinically unimportant functions and adding useful ones. Although this story was reported only in the popular press, the strategy is supported by a summary of the literature on best practices for successful E-HR design, which recommended patient care-centered development by an interdisciplinary team including human factors psychology specialists, with extensive input and testing by physicians and patients (see Ray et al., 2019), consistent with the human-factors standards described previously. The strategy is also supported by the "cranky comments" study described in Chapter 2, which showed that physician complaints accurately identified dysfunctional CDS features (Aaron et al., 2018).

Generally, local physician participation in the design of systems to promote evidence-based care may be associated with acceptance of these systems and with positive outcomes for them (Milos, Westerlund, Midlöv, & Strandberg, 2014; Robbins et al., 2012), whereas replacing locally developed systems with large, commercial platforms can increase overrides of recommended actions (Wright et al., 2018). The positive outcomes of participatory approaches may be attributable, in part, to their implicit recognition of the biomedical expertise of physicians, a commonly expressed determinant of occupational satisfaction (see Friedberg et al., 2013). This effect is likely attributable to the training physicians receive, which shapes their occupational and personal identity (see Bandura, 2001) as autonomous, biomedical experts devoted to patient care (Berkhout et al., 2018; Cooke et al., 2006). Interventions that implicitly acknowledge this aspect of physicians' identity may be better received than those that remove opportunities for engagement with clinically important, biomedically challenging problems (see Colligan et al., 2016).

**Balancing clinical relevance and uniformity**. Apart from autonomy, but also suggesting value in local customization, is a need to address a common complaint about E-HRs and CDS: they may report metrics irrelevant to the clinical circumstance or patient (see Gawande, 2018; Schiff et al., 2016). This issue may help to explain the

relative successes of locally developed systems. Still, balanced against the human factors standard of end-user involvement (see Savage et al., 2017) and the widely recognized need for customization of E-HR functions to match the specific tasks and culture of a unique medical practice environment (see Ray et al., 2019) is the need for uniformity. Standardization of systems may promote evidence-based decisions, consistent with the original goal of CDS (see Bates et al., 2003), and facilitate the interoperability among systems necessary for care coordination (see Samal et al., 2016).

An emerging solution to this challenge is modular E-HR and CDS applications based on common knowledge bases, using software compatible with multiple E-HR system platforms (Haug, Narus, Bledsoe, & Huff, 2018; Samal, Amore, Bates, & Wright, 2017). Using this approach, provided by initiatives like the Substitutable Medical Apps Reusable Technologies project, an individual physician can choose individual "apps" suitable for the specialty and practice, providing a measure of autonomy over system design while ensuring that each app meets uniform standards (see Rosenbloom, Carroll, Warner, Matheny, & Denny, 2017). Examples include a pediatric growth chart app that began as a browser-based system at one children's hospital and is currently available on two major E-HR platforms (Haug et al., 2018), and a risk assessment tool for chronic kidney disease, developed by one hospital using a fully interoperable knowledge base and software (Samal et al., 2017). Health psychologists could serve on interdisciplinary teams that choose or redesign such apps, providing expertise on cognitive principles and facilitating discussions of the local needs that should, ideally, be the primary determinant of system configuration (see Ray et al., 2019).

Physician-patient relationships. A focus on physician-patient relationships, a commonality between the disciplinary interests of medicine and health psychology, may also be helpful. From the medical perspective, interventions that increase time spent in patient interaction, such as using medical assistants as E-HR "scribes" to reduce clerical burden, have been associated with improved job satisfaction (Sinsky et al., 2013). Moreover, the needs and opportunities for shared physician-patient decision-making are garnering increased attention in the medical literature (see Elwyn, Frosch, & Kobrin, 2016). From the health psychologist perspective, interpersonal communication in the medical encounter is recognized as an important determinant of high-quality medical decision-making (Duggan & Street, 2015). Thus, both disciplines should have an interest in studies or initiatives that measure or foster good physician-patient relationships, which physicians not only value (see Colligan et al., 2016; Tak et al., 2017), but also view as integral to high-quality patient care (see Friedberg et al., 2013). A unique contribution of health psychology to this endeavor is its multilevel focus, which enables an understanding of the effects of macrolevel trends on microlevel processes and outcomes (Bandura, 2004). A health psychologist can interpret physician-patient communication and decision-making in the context of broader social influences affecting both parties, such as consumerism in medicine (see J. Shapiro et al., 2011) or direct-to-consumer advertising of medications and laboratory tests (see Schwartz & Woloshin, 2019).

**Training in an interdisciplinary team context**. Although results for CDS were generally favorable in this study, the literature review suggested an unmet need for training that better reflects cognitive psychological principles by providing specific

guidance on use of CDS in expert decision-making, the primary goal of medical education (Berkhout et al., 2018). Specifically, the understanding that learning is facilitated by hands-on practice in relevant environmental contexts, which was derived from cognitive psychology (Cooke et al., 2006), underlies core medical training protocols (Berkhout et al., 2018) including clinical rotation experiences during medical school and extensive opportunities for supervised decision-making in real-world clinical settings throughout training (see Mowery, 2015). However, that context-specific training process typically does not account for CDS (Hersh et al., 2014; Pageler et al., 2013). For example, recently drafted milestones (competency benchmarks) for family practice trainees mention use of health information technology, specifically "documentation required for billing and coding," and suggest that a highest-level trainee may improve E-HR functionality (Anim et al., 2019, p. 10). However, these standards do not reference specific skills needed for a physician to apply CDS appropriately to an individual patient (Pageler et al., 2013). Such skills include critical evaluation of the guidance provided, ability to formulate questions that can be answered by CDS, use of CDS to identify and address limitations in the trainee's medical knowledge, and balancing E-HR-delivered information with the individual patient's history and physical examination results.

This gap between the training received by physicians and the environmental context in which they operate after graduation, which is highly likely to include CDS according to the results of this and previous research (see Hsiao & Hing, 2014), may help to explain the frustration that physicians express about using E-HRs for patient care activities, particularly when using sophisticated systems (see Emani et al., 2017). If so,

specific guidance to physicians on using E-HRs to facilitate, rather than supplant, their own clinical judgment may be helpful. Health psychologists, trained in principles of cognition and learning, might be ideal choices to design and deliver this education.

Such interventions could be carried out as part of a comprehensive strategy for interdisciplinary care teamwork, with collaboration of human factors psychologists to provide guidance on the cognitive effects of human-machine-environment interaction (Holden, 2011) and on cognitively appropriate system-development strategies described previously in this chapter (see Ray et al., 2019; Savage et al., 2017), informatics specialists in analysis of electronic health records to provide evidence-based suggestions for clinical priorities, and physicians as medical experts (see Holden et al., 2018). This approach would recognize both the inevitability and the value of electronic health data, while giving full weight to the biomedical expertise of physicians in making decisions about the care of their patients.

## Conclusion

In October 2019, a qualitative study, described by its authors as the first to use cognitive assessment techniques to improve E-HR inbox messaging, was published in *JAMA Network Open* (D. R. Murphy, Giardina, Satterly, Sittig, & Singh, 2019). Nearly 2 years earlier, a commentary in the *New England Journal of Medicine* had described an urgent need to "restore meaning and sanity for physicians," implicating E-HRs and meaningful use requirements as major contributors to physician burnout and its consequences: medical errors, mental health or substance abuse problems, and premature retirements (Wright & Katz, 2018, p. 310). That the 2019 study was published a decade

after HITECH Act passage illustrates the slow rate of adoption of psychology-informed scholarship in the efforts to promote evidence-based decisions. That both studies were published in prominent medical journals highlights the import of these issues for physicians.

In interpreting these trends, it is notable that both CDS and the HITECH Act were intended to act on psychological phenomena, cognition and motivation, respectively; yet, paradoxically, neither was based on any psychological theory. In this research, I explored the possibility that using theoretical frameworks in designing and testing health system interventions on physician behavior might result in improved medical decisions, with fewer unintended consequences. Results, although providing modest support for theorybased approaches, identified promising areas for future investigations in health psychology and highlighted autonomy as a theme that may tie together multiple threads of research on medical decision-making, including the current study. For physicians and, ultimately, for the patients they treat—the greatest need in promotion of evidencebased medicine may be for approaches that acknowledge and rely on their expertise, supporting them with high-quality analytics and education on using electronic tools in health care delivery, while returning to them the measure of control over medical decision-making warranted by their training.

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# Appendix A: National Center for Health Statistics Assessments of Nonresponse Bias to

# the 2012 National Ambulatory Medical Care Survey and Current Weighting Method

Characteristic	Indicators used for nonresponse bias estimate (Hing et al., 2016)
Age group	Less than 50 years, 50 years or older
Sex	Male, female
Census division (office location)	New England, Middle Atlantic, East North Central, West North Central, South Atlantic, East South Central, West South Central, Mountain, Pacific
Metropolitan status (office location)	MSA, not MSA
Type of doctor	Medicine, osteopathy
Specialty	General or family practice, internal medicine, pediatrics, general surgery,
	obstetrics and gynecology, orthopedic surgery, cardiovascular diseases,
	dermatology, urology, psychiatry, neurology, ophthalmology, otolaryngology,
	oncology, allergy, pulmonology, other specialties
Specialty category Practice type	Primary care, surgical, medical Solo, two physicians, group or HMO, medical school or government, other,
Tractice type	unclassified
Annual visit volume quartile	0–25, 26–50, 51–75, 76–100
State (office location)	Connecticut, Massachusetts, other New England, New Jersey, New York,
	Pennsylvania, Illinois, Indiana, Michigan, Ohio, Wisconsin, Iowa, Kansas,
	Minnesota, Missouri, other West North Central, Florida, Georgia, Maryland,
	North Carolina, South Carolina, Virginia, other South Atlantic, Alabama,
	Kentucky, Mississippi, Tennessee, Arkansas, Louisiana, Oklahoma, Texas,
	Arizona, Colorado, Utah, other Mountain, California, Oregon, Washington, other Pacific
Analyses before weighting for nonresponse	Statistically significant results (Hing et al., 2016) <sup>a</sup>
Comparison of physician respondents versus	Characteristics (%) of respondents vs. nonrespondents, respectively:
nonrespondents to the induction interview	New England 5.3% vs. 7.5%
(based on data provided by the AMA and	East North Central 14.2% vs. 11.3%
AOA)	East South Central 6.2% vs. 5.1%
	General or family practice 18.4% vs. 15.2%
	Pediatrics 12.1% vs. 7.7% Orthopedic surgery 4.1% vs. 5.2%
	Cardiovascular disease 3.1% vs. 4.4%
	Oncology 1.6% vs. 2.3%
	Primary care 48.8% vs. 43.6%
	Surgery 19.1% vs. 23.2%
	Solo practitioner 25.1% vs. 21.7%
	Of 39 state comparisons, 13 significantly differed; all by $< 1.5$ percentage points
Comparison of physicians providing $> 1$ visit	Characteristics (%) for those providing visit data vs. no visit data, respectively:
versus those providing no visits (based on	New England 5.3% vs. 6.8%
data provided by the AMA and AOA and, for	East South Central 6.6% vs. 5.2%
the visit quartiles, on physician induction	MSA 90.7% vs. 92.4%
interview or statistical estimates of	Non-MSA 9.3% vs. 7.6% General or family practice 19.7% vs. 15.6%
physician's visit volume)	Pediatrics 13.0% vs. 8.6%
	Cardiovascular disease 3.0% vs. 4.0%
	Oncology 1.5% vs. 2.1%
	Primary care 50.8% vs. 44.2%
	Surgical 18.7% vs. 22.0%
	Solo practitioner 26.2% vs. 22.2%
	Annual visit volume Quartile 1 32.3% vs. 20.5%
	Quartile 1 52.5% VS. 20.5% Quartile 2 19.8% vs. 28.5%
	Quartile 3 17.7% vs. 29.2%
	Quartile 4 30.2% vs. 21.8%
	Of 39 state comparisons, 10 significantly differed; all by < 1.5 percentage points

Analyses after weighting for nonresponse Statistically significant results (Hing et al., 2016)<sup>a</sup> Comparison of U.S. in-scope sample physicians Characteristics (%) of in-scope sample vs. respondents, respectively: with induction interview respondent physicians MSA 91.7% vs. 92.7% (based on data provided by the AMA and AOA) Non-MSA 8.3% vs. 7.3% Potential bias (absolute value of difference between in-scope sample and respondents) 0 (zero) bias for 62 estimates  $\leq$  1.0 percentage points for 18 estimates 2 estimates with bias > 1.0 percentage points: -Solo practitioner 1.7 percentage points (23.7% vs. 25.4%) -Group or HMO 1.3 percentage points (59.4% vs. 58.1%) Comparison of U.S. in-scope sample physicians Characteristics (%) of in-scope sample vs. those providing  $\geq 1$  visit, with physicians providing  $\geq 1$  visit (based on data respectively: provided by the AMA and AOA and, for the visit Solo practitioner 23.7% vs. 26.7% quartiles, on physician induction interview or Group or HMO 59.4% vs. 56.6% statistical estimates of physician's visit volume) Annual visit volume Quartile 1 25.0% vs. 33.2% Quartile 2 25.2% vs. 20.1% Quartile 3 24.8% vs. 17.9% Quartile 4 25.0% vs. 28.8% Of 39 state comparisons, 4 significantly differed; all differences < 1.5 percentage points Potential bias (absolute value of difference between in-scope sample and respondents) 0 (zero) bias for 37 estimates  $\leq$  1.0 percentage points for 39 estimates > 1.0 - < 2.0 percentage points for 4 estimates > 2.0 percentage points for 6 estimates: -Solo practitioner 3.0 percentage points -Group or HMO 2.8 percentage points -Annual visit volume (quartile 1: 8.2 percentage points; quartile 2: 5.1 percentage points; quartile 3: 6.9 percentage points; quartile 4: 3.8 percentage points) Comparison of estimated in-scope sample visits Characteristics (%) of visits, comparing estimated in-scope sample with NAMCS sample, respectively: with NAMCS sampled visits (based on data provided by the AMA and AOA and, for the visit MSA 91.1% vs. 89.5% quartiles, on physician induction interview or Non-MSA 8.9% vs. 10.5% statistical estimates of physician's visit volume) Oncology 1.8% vs. 1.4% Annual visit volume Quartile 1: 9.9% vs. 18.3% Quartile 3: 27.2% vs. 21.3% Of 39 state comparisons, 2 significantly differed, both < 0.5 percentage point Potential bias (absolute value of difference between in-scope sample visits and NAMCS sampled visits)  $\leq 0.5$  percentage points for 66 estimates > 0.5 - < 1.0 percentage points for 8 estimates  $> 1.0 - \le 2.0$  percentage points for 5 estimates > 2.0 percentage points for 2 estimates:

- > 2.0 percentage points for 2 estimates:
   -Annual visit volume (quartile 1: 8.4 percentage points; quartile 3: 5.9
- percentage points)

Summary of weight calculation procedures, 2014–2016 (CDC, 2017, 2018, 2019b)

Step 1: Calculate sample-selection weights based on multiplicative inverses (reciprocals) of sampling probabilities for (a) selecting physician from each stratum and (b) selecting a visit from the sampled physician, annualized based on a count of weeks in which physician saw patients. Sampling strata were defined as follows:

2014—Primary versus nonprimary care type, 25 geographic areas (nine Census divisions, 17 most populous states) = up to 50 strata

2015—Fourteen physician specialties, 20 geographic areas (four Census regions, 16 most populous states) = up to 280 strata 2016—Fourteen physician specialties, four Census regions = up to 56 strata

Because a stratum could contain no visits (e.g., if no visits were made by sampled adults to a particular specialist in a particular state), actual number of strata for the current study sample was unknown until data were accessed. The logistic regression models contained 301 physicians and 101 strata in Scenario A, and 1,659 physicians and 130 strata in Scenario B.

Step 2: Adjust for nonresponse, accounting for seasonality, number of weeks practiced during year, and number of visits during a typical week of practice. Weights accounted for nonresponse within the following strata:

2014—Fourteen physician specialties, 25 geographic areas, MSA status = up to 700 strata

2015—Fourteen physician specialties, 20 geographic areas, MSA status = up to 560 strata

2016—Three practice types and four regions = up to 12 strata; physicians who submitted E-HRs were treated as nonrespondents because their submissions could not be used

Step 3: Apply ratio adjustment to correct for differences in the sampling frame between time of sample selection and time of data collection, calculated for each physician specialty group and geographic area.

Step 4: Apply a weight-smoothing adjustment that corrects for outlier weights. Numerator and denominator, respectively, are total visit count in each group before and after trimming largest weights, for each physician group as defined in Step 2 above.

*Note.* Only statistically significant results (differences in percentages) are shown in the table. Comparisons on indicators not shown in the table were not statistically significant. For factors with multiple categories where  $\chi^2$  test was performed for the variable overall (e.g., Census, specialty), table presents only indicators where response rate significantly differed from national rate. Note that significant results for surgical specialties are described but not relevant because visits to surgeons were excluded from the current study sample. AMA = American Medical Association; AOA = American Osteopathic Association; E-HR = electronic health record; HMO = health maintenance organization; MSA = metropolitan statistical area; NAMCS = National Ambulatory Medical Care Survey; CDC = U.S. Centers for Disease Control and Prevention.

Anti	idiabetic		Antihypertens	ive
Sources	Drug Names	Sources 8 1	Drug Names, A to L	Drug Names, M to Z
CDC	Acarbose	CDC	Acebutolol	Mecamylamine
(2017); J.	Albiglutide	(2017);	Aliskiren	Metolazone
W. M.	Alogliptin	Fairman,	Amiloride	Metoprolol
Cheng,	Bromocriptine	Romanet,	Amlodipine	Methylclothiazide
Badreldin,	Canagliflozin	Early,	Atenolol	Methyldopa
Patel, and	Colesevelam	and	Azilsartan	Minoxidil
Bhatt	Dapagliflozin	Goodlet	Benazepril	(nontopical)
(2017)	Dulaglutide	(2019)	Betaxolol	Moexipril
	Empagliflozin		Bisoprolol	Nadolol
	Ertugliflozin		Candesartan	Nebivolol
	Exenatide		Captopril	Nicardipine
	Gliclazide		Carvedilol	Nifedipine
	Glimepiride		Chlorothiazide	Nisoldipine
	Glipizide		Chlorthalidone	Olmesartan
	Glyburide		Clonidine	Penbutolol
	Insulin		Diltiazem	Perindopril
	Linagliptin		Doxazosin	Pindolol
	Liraglutide		Enalapril	Prazosin
	Lixisenatide		Eplerenone	Propranolol
	Metformin		Eprosartan	Quinapril
	Miglitol		Felodipine	Ramipril
	Nateglinide		Fosinopril	Reserpine
	Pioglitazone		Furosemide	Spironolactone
	Pramlintide		Guanabenz	Telmisartan
	Repaglinide		Guanfacine	Terazosin
	Rosiglitazone		Hydralazine	Timolol
	Saxagliptin		Hydrochlorothiazide	Torsemide
	Semaglutide		Indapamide	Trandolapril
	Sitagliptin		Irbesartan	Treprostinil
	Tolbutamide		Isradipine	Triamterene
			Labetalol	Valsartan
			Lisinopril	Verapamil
			Losartan	

Appendix B: Antidiabetic and Antihypertensive Drug Names

Diagnosis	ICD-9 Codes	ICD-10 Codes
Angina	413 Angina pectoris	I20
Anxiety	300 Anxiety, dissociative and somatoform	F40
2	disorders	F41
		F42
		F44
		F45
Arrhythmias	426 Conduction disorders	I44
	427 Cardiac dysrhythmias	I45
	V45.0 Cardiac device in situ; unspecified,	I48
	pacemaker, automatic implantable defibrillator, or	I49
	other	Z95.0
		Z95.81
Attention-deficit hyperactivity disorder	314 Hyperkinetic syndrome of childhood	F90
Bradycardia (slow	427.89 Other specified cardiac dysrhythmias	R00.1
heartbeat)	426.0 Atrioventricular block, complete	I44.0
	426.1 Atrioventricular block other and unspecified	I44.1
	426.2 Left bundle branch hemiblock	I44.2
	426.3 Other left bundle branch block	I44.3
	426.5 Bundle branch block other and unspecified	I44.4
	2010 Danate cranen croen chief and anopeenied	I44.5
		I44.6
		I44.7
Cancer, metastatic	196 Secondary and unspecified malignant	C77
Culleor, illetustutie	neoplasm of lymph nodes	C78
	197 Secondary malignant neoplasm of respiratory	C79
	and digestive systems	C7B
	198 Secondary malignant neoplasm of other	012
	specified sites	
	199.0 Disseminated malignant neoplasm without	
	specification of site	
	199.1 Other malignant neoplasm without	
	specification of site	
Cardiac anomalies	745 Bulbus cordis anomalies and anomalies of	Q20
	cardiac septal closure	Q21
	746 Other congenital anomalies of heart	Q22
	747 Other congenital anomalies of circulatory	Q23
	system	Q24
	5,550	Q25
		Q26
		Q27
		Q28
Cardiomegaly	429.3 Cardiomegaly	I51.7
Cardiomyopathy	425 Cardiomyopathy	I31.7 I42
		I42 I43
		(appendix continu

# Appendix C: International Classification of Diseases Drug Codes

Diagnosis	ICD-9 Codes	ICD-10 Codes
Connective	517.1 Rheumatic pneumonia	M05
tissue/rheumatic	710.0 Systemic lupus erythematosus	M06
lisorder <sup>a</sup>	710.1 Systemic sclerosis	M32
	710.4 Polymyositis	M33.2
	714.0 Rheumatoid arthritis	M34
	714.1 Felty's syndrome	M35.3
	714.2 Other rheumatoid arthritis with visceral	
	or systemic involvement	
	714.81 Rheumatoid lung	
	725 Polymyalgia rheumatica	
Dementia (codes	290 Dementias	F03
used for verification	331 Other cerebral degenerations	G30
of the indicator) <sup>a,b</sup>		
Diabetes	250.4 Diabetes with renal manifestations	E10.2
complications <sup>a</sup>	250.5 Diabetes with ophthalmic	E11.2
1	manifestations	E13.2
	250.6 Diabetes with neurological	E14.2
	manifestations	E10.3
		E11.3
		E13.3
		E14.3
		E10.4
		E11.4
		E13.4
		E14.4
HIV (codes used for verification of the indicator) <sup>a</sup>	042 Human immunodeficiency virus [HIV] disease	B20
Hypertensive heart	402 Hypertensive heart disease	I11
disease	404 Hypertensive heart and chronic kidney disease	I13
Hypotension	458 Hypotension	195
Liver disease, mild	571.2 Alcoholic cirrhosis of liver	K70.2
	571.4 Chronic hepatitis	K70.3
	571.5 Cirrhosis of liver without mention of	K71.7
	alcohol	K73
	571.6 Biliary cirrhosis	K74.0
	and not severe	K74.2
		K74.3
		K74.4
		K74.5
		K74.6

	ICD-9 Codes	ICD-10 Codes
Liver disease,	572.2 Hepatic encephalopathy	K72.1
severe	572.3 Portal hypertension	K72.9
	572.4 Hepatorenal syndrome	K76.6
	572.8 Other sequelae of chronic liver disease	K76.7
Ayocardial	410 Acute myocardial infarction	I21
nfarction	412 Old myocardial infarction	I22
heart attack)		I23
istory <sup>a</sup>		I25.2
Paraplegiaa	342 Hemiplegia and hemiparesis	G04.1
	344.1 Paraplegia	G81
		G82.2
Peptic ulcer <sup>a</sup>	531 Gastric ulcer	K25
	532 Duodenal ulcer	K26
	533 Peptic ulcer site unspecified	K27
	534 Gastrojejunal ulcer	K28
Peripheral	443.9 Peripheral vascular disease, unspecified	I73.9
rterial disease	V43.4 Blood vessel replaced by other means	Z95.8
		Z95.9
Renal disease	585 Chronic kidney disease (ckd)	N18
codes used for verification of he indicator)	586 Renal failure, unspecified	N19
Pulmonary	490 Bronchitis, not specified as acute or chronic	J40
liseases <sup>a</sup>	491 Chronic bronchitis	J41
	492 Emphysema	J42
	493 Asthma	J43
	494 Bronchiectasis	J44
	495 Extrinsic allergic alveolitis	J45
	496 Chronic airway obstruction, not elsewhere	J46
	classified	J47
	500 Coal workers' pneumoconiosis	J60
	501 Asbestosis	J61
	502 Pneumoconiosis due to other silica or silicates	J62
	503 Pneumoconiosis due to other inorganic dust	J63
	504 Pneumonopathy due to inhalation of other dust	J64
	505 Pneumoconiosis, unspecified	J65
	or condition code for asthma or COPD	J66
		J67

	ICD-9 Codes	ICD-10 Codes
Substance use	291 Alcohol-induced mental disorders	F10
disorder (codes	292 Drug-induced mental disorders	F11
used for	303.xx Alcohol dependence syndrome	F12
verification of	304.xx Drug dependence	F13
the indicators)	305.xx Nondependent abuse of drugs	F14
	965.0 Poisoning by opiates and related narcotics	F15
	967 Poisoning by sedatives and hypnotics	F16
	969.1 Poisoning by phenothiazine-based	F18
	tranquilizers	F19
	969.2 Poisoning by butyrophenone-based	T40
	tranquilizers	T42.3x, T42.4x, T42.6x, T42.7x
	969.4 Poisoning by benzodiazepine-based	T43.6x
	tranquilizers	
	969.5 Poisoning by other tranquilizers	
	969.6 Poisoning by psychodysleptics	
	(hallucinogens)	
	969.7 Poisoning by tranquilizers, hallucinogens, or	
	psychostimulants	
	970 Poisoning by central nervous system stimulants	
Substance use	571.0 Alcoholic fatty liver	K70
disorder,	571.1 Alcoholic hepatitis	
alcoholic	571.2 Alcoholic cirrhosis	
effects on liver	571.3 Alcoholic liver damage	
Valvular	424.1 Aortic valve disorders	135
disorders, aortic	746.3 Congenital stenosis of aortic valve	I06
Valvular	424.0 Mitral valve disorders	I34
disorder, mitral	394 Diseases of mitral valve	I05
	396 Diseases of mitral and aortic valves	
Valvular disorder, pulmonary	424.3 Pulmonary valve disorders	I37
Valve disorder,	424.2 Tricuspid valve disorders, specified as	I36
tricuspid	nonrheumatic	I07
	397.0 Diseases of tricuspid valve	
Valve disorder,	424.9 Endocarditis, valve unspecified	I38
other		139
		108

*Notes.* Codes and descriptions were obtained from icd9data.com and icd10data.com. ICD-9 codes (U.S. Department of Health and Human Services, 1997) and a map from ICD-9-CM (clinical modification for U.S. health care) to ICD-10-CM (U.S. Department of Health and Human Services, 2015) are in the public domain. Although ICD-10-CM code files are publicly available for download from the CMS (2018a) website, the ICD-10, which was the basis for ICD-10-CM, is promulgated by the World Health Organization (CMS, 2018b). For this reason, the right-hand column does not contain verbatim descriptions of each code.

<sup>a</sup>Used in Charlson Comorbidity Index (Quan et al., 2011). <sup>b</sup>A dementia indicator was added to the survey in 2014 (CDC, 2018).

	Potentially unsafe medication				S	Safer medication or psychotherapy			
	п	% <sup>a</sup>	95% CI width	Relative CI width (%)	п	% <sup>a</sup>	95% CI width	Relative CI width (%)	
All patients	81	100.0	NA	NA	729	100.0	NA	NA	
Sex									
Female	31	39.0	27.0	69.2	392	54.7	11.1	20.3	
Male	50	61.0	27.0	44.3	337	45.3	11.1	24.5	
Age group (years)									
17–25	18	23.4	28.4	121.4	233	31.7	10.4	32.8	
26-49	52	61.6	29.6	48.1	349	46.5	12.8	27.5	
50 or older	11	15.0 <sup>b</sup>	20.0	133.3	147	21.8	9.3	42.7	
Race and ethnicity									
White, non-Hispanic	73	94.9	9.4	9.9	635	85.5	8.1	9.5	
Black, non-Hispanic	4	3.1 <sup>b</sup>	8.1	261.3	30	4.8	5.5	114.6	
Hispanic	2	1.7 <sup>b</sup>	6.3	370.6	41	6.0	4.3	71.7	
Other	2	0.3 <sup>b</sup>	2.2	733.3	23	3.6	3.8	105.6	
Primary payment source	-	0.5	2.2	155.5	20	5.0	5.0	105.0	
Private	36	44.0 <sup>b</sup>	36.5	83.0	403	58.2	20.5	35.2	
Medicaid	12	9.3 <sup>b</sup>	15.7	168.8	83	13.5	12.3	91.1	
Medicare	4	3.6 <sup>b</sup>	9.9	275.0	42	5.8	6.0	103.4	
Other	25	43.1 <sup>b</sup>	39.7	92.1	164	22.4	22.8	101.8	
Office location	25	45.1	57.1	72.1	104	22.4	22.0	101.0	
Urban	73	89.9	22.9	25.5	683	92.1	18.2	19.8	
Nonurban	8	10.1 <sup>b</sup>	22.9	226.7	46	7.9 <sup>b</sup>	18.2	230.4	
Physician specialty	0	10.1	22.)	220.7	40	1.)	10.2	230.4	
Cardiology			N	lot assessed; tota	l number	of visits -	3		
Psychiatry	42	64.1 <sup>b</sup>	32.1	50.1	451	60.3	19.9	33.0	
Neither of these	38	34.5 <sup>b</sup>	31.7	91.9	276	39.6	20.0	50.5	
Black-box diagnosis	50	54.5	51.7	)1.)	270	57.0	20.0	50.5	
Yes	72	93.9	10.6	112.9	33 <sup>b</sup>	4.0	5.4	135.0	
No	9	6.1 <sup>b</sup>	10.6	173.8	696	96	5.4	5.6	
Charlson comorbidities		0.1	10.0	175.0	070	70	5.4	5.0	
None	74	91.6	16.6	18.1	693	94.3	5.2	5.5	
One	6	7.4 <sup>b</sup>	16.3	220.3	29	4.1	4.4	107.3	
Two	0	7.4		lot assessed; tota				107.5	
Three or more				lot assessed; tota					
Psychiatric comorbidities			1	101 ussessed, tota	ii number	01 115113 -	- 2		
Depression, no	50	62.2 <sup>b</sup>	31.5	50.6	453	65.1	13.7	21.0	
Depression, yes	31	37.8 <sup>b</sup>	31.5	83.3	276	34.9	13.7	39.3	
Anxiety, no	65	81.7	21.5	26.3	530	70.4	13.8	19.6	
Anxiety, yes	16	18.3	21.5	117.5	199	29.6	13.8	46.6	
Relationship with patient	10	10.5	21.5	117.5	1))	27.0	15.0	40.0	
New	6	6.2 <sup>b</sup>	14.6	235.5	60	9.7	7.5	77.3	
Established, not PCP	47	72.7	27.2	37.4	456	9.7 64.1	15.5	24.2	
PCP	25	21.1	25.6	121.3	195	26.1	14.8	56.7	
Environmental features	23	21.1	23.0	121.3	175	20.1	17.0	50.7	
CDS, no	24	30.5 <sup>b</sup>	34.2	112.1	298	35.3	23.3	66.0	
CDS, ito CDS, yes	24 56	50.5 69.5⁵	34.2	49.2	413	64.7	23.3	36.0	
Meaningful use, no	25	27.8 <sup>b</sup>	34.2	49.2 110.4	311	40.1	23.5	58.9	
Meaningful use, yes	23 56	27.8° 72.2 <sup>b</sup>	30.7	42.5	418	40.1 59.9	23.6	39.4	
Patient revenue, no	11	17.9 <sup>b</sup>	28.2	42.3	418 67	59.9 7.1	23.0 9.0	126.8	
Patient revenue, no Patient revenue, yes	70	82.1	28.2 28.2	34.3	662	7.1 92.9	9.0 9.0	9.7	
Prescription type <sup>c</sup>	70	02.1	20.2	54.5	002	74.7	9.0	7.1	
New	15	21.7	22.9	105.5	116	17.5	9.8	56.0	
	15 66				505		9.8 9.8		
Continued	00	78.3	22.9	29.2	305	82.5	9.8	11.9	

Appendix D: Assessments of Sample Size Adequacy, Scenario A

Notes. CDS = computerized decision support; CI = confidence interval; NA = not applicable; NCHS = National Center for Health

Statistics; PCP=primary care provider; SE = standard error. <sup>a</sup>Percentages are based on weighted counts, not on the unweighted counts shown in the table. No estimates met the statistical reliability standard of design effect-adjusted denominator  $\geq$  30 (Parker et al., 2017).<sup>b</sup>Estimate does not meet statistical reliability standard for confidence interval width. <sup>c</sup>Limited to patients prescribed  $\geq$  1 medication.

		Potentially	unsafe med	ication	Safer medication or psychotherapy			
	n %		95% CI width	Relative CI width (%)	п	% <sup>a</sup>	95% CI width	Relative CI width (%)
All patients	143	100.0	NA	NA	8,958	100.0	NA	NA
Sex								
Female	58	34.3	21.4	62.4	4,134	46.3	3.8	8.2
Male	85	65.7	21.4	32.6	4,824	53.7	3.8	7.1
Age group (years)					, i i i i i i i i i i i i i i i i i i i			
17–25	26	16.9	18.3	108.3	233	2.8	1.5	53.6
26-49	20 75	44.9	24.1	53.7	1,251	14.8	4.4	29.7
50 or older	42	38.2	25.6	67.0	7,474	82.5	4.9	5.9
Race and ethnicity		00.2	2010	0710	,,.,.	0210	,	0.0
White, non-Hispanic	131	93.9	9.3	9.9	7,372	77.2	5.7	7.4
Black, non-Hispanic	5	3.4 <sup>b</sup>	8.9	261.8	730	9.5	2.9	30.5
Hispanic	4	1.4 <sup>b</sup>	3.5	250.0	567	9.4	4.5	47.9
Other	3	1.4 1.3 <sup>b</sup>	6.1	469.2	289	3.9	1.9	48.7
	5	1.5	0.1	409.2	209	5.9	1.9	40.7
Primary payment source Private	65	47.3	29.4	62.2	2,605	31.5	4.6	14.6
Medicaid	65 15	47.3 7.8 <sup>b</sup>	29.4 11.3	62.2 144.9	2,605 648	31.5 7.6	4.6 3.2	14.6 42.1
Medicare	17	8.0	10.1	126.3	4,708	54.9	5.3	9.7
Other	36	37.0 <sup>b</sup>	32.4	87.6	404	5.9	3.8	64.4
Office location					-		<b>F</b> 0	
Urban	133	92.5	14.0	15.1	7,987	90.0	5.9	6.6
Nonurban	10	7.5 <sup>b</sup>	14.0	186.7	971	10.0	5.9	59.0
Physician specialty								
Cardiology	9	5.0 <sup>b</sup>	9.7	194.0	2,873	25.5	9.6	37.6
Psychiatry	57	48.4 <sup>b</sup>	30.6	63.2	435	4.7	2.6	55.3
Neither of these	77	46.7	29.7	63.6	5,650	69.9	9.5	13.6
Black-box diagnosis								
Yes	113	75.6	26.0	34.4	2,130	27.0	7.0	25.9
No	30	24.4	26.0	106.6	6,828	73.0	7.0	9.6
Charlson comorbidities								
None	118	79.3	23.5	29.6	5,139	56.4	6.6	11.7
One	16	9.6	11.3	117.7	1,905	21.3	3.9	18.3
Two	5	6.3 <sup>b</sup>	26.3	417.5	1,145	12.9	3.0	23.3
Three or more	4	4.7 <sup>b</sup>	15.6	331.9	769	9.5	5.5	57.9
Psychiatric comorbidities								
Depression, no	88	62.8	24.7	39.3	7,570	84.1	3.5	4.2
Depression, yes	55	37.2	24.7	66.4	1,388	15.9	3.5	22.0
Anxiety, no	120	85.2	17.4	20.4	8,479	94.0	3.2	3.4
Anxiety, yes	23	14.8	17.4	117.6	479	6.0	3.2	53.3
Relationship with patient	20	1.110	1,111	11/10	.,,	010	0.2	0010
New	15	5.6 <sup>b</sup>	8.6	153.6	1,118	10.8	2.9	26.9
Established, not PCP	80	66.1	25.0	37.8	4,530	43.9	9.2	20.9
PCP	43	28.3	23.0	86.9	3,104	45.3	8.7	19.2
Environmental features	-13	20.5	27.0	00.7	5,104	-5.5	0.7	17.2
CDS, no	37	30.0	30.2	100.7	951	10.1	5.6	55.4
,	104	30.0 70.0	30.2	43.1		89.9	5.6	6.2
CDS, yes					7,797			
Meaningful use, no	33	19.6	20.8	106.1	1,032	12.1	6.2	51.2
Meaningful use, yes	110	80.4	20.8	25.9	7,926	87.9	6.2	7.1
Patient revenue, no	21	13.0 <sup>b</sup>	21.3	163.8	1,645	14.3	6.1	42.7
Patient revenue, yes	122	87.0	21.3	24.5	7,313	85.7	6.1	7.1

Appendix E: Assessments of Sample Size Adequacy, Scenario B

*Note.* Estimates for the variable indicating new versus continuing prescription could not be computed because only 1 visit included the prescribing of a medication that was both new and safer. CDS = computerized decision support; CI = confidence interval; NA = not applicable; NCHS = National Center for Health Statistics; PCP = primary care provider; SE = standard error.

<sup>a</sup>Percentages are based on weighted counts, not on the unweighted counts shown in the table. No estimates in the "safer" column met the statistical reliability standard of design effect-adjusted denominator  $\geq$  30 (Parker et al., 2017). Design effect-adjusted denominator for potentially unsafe prescriptions = 41. <sup>b</sup>Estimate does not meet statistical reliability standard for confidence interval width.

	Scenario A		Scenario B		
	Tolerance	Variance	Tolerance	Variance	
		inflation factor		inflation factor	
Atheoretical model					
Male sex	.925	1.081	.968	1.033	
Age group 26 to 49 years	.347	2.882	.179	5.586	
Age group 50 years or older	.131	7.646	.113	8.867	
White or Hispanic race	.969	1.032	.967	1.034	
Medicaid insurance	.905	1.105	.949	1.054	
Urban MSA	.825	1.212	.977	1.024	
Depression	.809	1.236	.863	1.158	
Anxiety	.823	1.215	.865	1.157	
Cardiology	Not include	ed in model; $n = 3$	.858	1.165	
Psychiatry	.627	1.596	.766	1.306	
Black-box warning	Not included	in model; $n = 72$ of	.106	9.391	
0		unsafe prescriptions			
Comorbidity index $\geq 1$	.922	1.084	.879	1.137	
Interval-scale age	.173ª	5.767	.307 <sup>b</sup>	3.260	
CDS	.419	2.389	.406	2.465	
$CDS \times BBW$	Not incl	uded in model	.121	8.260	
Meaningful use	.380	2.635	.574	1.741	
The					
<u>Theory-based model</u> Male sex	.912	1.096	.967	1.034	
Age group 26 to 49 years	.347	2.878	.182	5.488	
Age group 50 years or older	.128	2.878 7.787	.182	3.488 8.745	
White or Hispanic race	.960	1.042	.963	1.039	
Medicaid insurance	.900		.965		
		1.124		1.059	
Urban MSA	.751	1.332	.954	1.048	
Depression	.804	1.244	.860	1.163	
Anxiety	.823	1.216	.865	1.156	
Cardiology		ed in model; $n = 3$	.680	1.471	
Psychiatry	.330	3.029	.716	1.396	
Black-box warning		in model; $n = 72$ of	.598	1.671	
	• •	unsafe prescriptions	075	1.1.40	
Comorbidity index $\geq 1$	.909	1.100	.875	1.142	
Interval-scale age	.169°	5.914	.306 <sup>d</sup>	3.270	
CDS	.414	2.416	.572	1.750	
Meaningful use	.360	2.774	.574	1.742	
Patient-derived revenue	.910	1.099	.983	1.017	
PCP, $\geq 4$ visits	.599	1.670	.689	1.451	
PCP, $\leq 3$ visits	.510	1.961	.736	1.359	
Continuing prescription	.928	1.078		model; $n = 11 \text{ of } 12$	
			sater pre	escriptions	

Appendix F: Multicollinearity Assessments, Atheoretical and Theory-Based Models

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*Note.* Derived using method recommended by Midi et al. (2010). Tolerance for each predictor is 1 minus  $R^2$  for the regression of the predictor on all other predictors (Warner, 2013). Variance inflation factor is the reciprocal of tolerance. BBW = black-box warning; CCI = Charlson comorbidity index; CDS = computerized decision support; CVD = cardiovascular disease; MSA = metropolitan statistical area; PCP = primary care provider.

<sup>a</sup>After removal of the categorical age indicators, tolerance improved to .913, with variance inflation factor of 1.096. <sup>b</sup>After removal of the categorical age indicators, tolerance improved to .629, with variance inflation factor of 1.589. <sup>c</sup>After removal of the categorical age indicators, tolerance improved to .899, with variance inflation factor of 1.112. <sup>d</sup>After removal of the categorical age indicators, tolerance improved to .625, with variance inflation factor of 1.600.

#### Appendix G: Assessments of Sample External Validity Using National or Large-Sample

	Physicians		
Measure and source	Time period and unit	Benchmark percentage	Study sample % of
	of analysis	<b>i</b> @_	visits
	<u></u>		2014-2015
Use of E-HR (ONC, 2019)	2014-2015	82.8 in 2014	89.1
ese si 1 mil (er (er (e, 2017))	2011 2010	86.9 in 2015	0,11
Patier			
Demographic and clinical characteristics <sup>a</sup> (Xian et	Time period and unit	Benchmark percentage	Study sample % of
al., 2019)	of analysis		visits
	-		2014-2016
Female	2015, 133 practices	36.2	46.3
White	throughout the	87.3	76.8
Black	United States, % of	10.4	9.8
Hispanic	patients	6.8	9.3
Private insurance		56.5	49.0
Hypertension		85.2	74.0
Diabetes		39.8	31.8
Adults with a	ttention-deficit hyperactiv	ity disorder	
Comorbidities (Kooij et al., 2019)	Time period and unit	Benchmark percentage	Study sample % of
	of analysis		visits
			2014-2016
Anxiety	Review article; time	34	28.7
Substance use disorder	period not specified	11	11.4
Adult patients with attention-		der treated with medication	
Demographic and clinical characteristics (Fairman et	Time period and unit	Benchmark percentage	Study sample, % of
<u>al., 2018)</u>	of analysis		visits
			2014-2016
Female	2014–2015, privately	51.1	53.3
Age group (years)	insured enrollees		
25–34	aged 18-64 years	25.8	41.6
35–44	treated for ADHD	21.2	19.1
45–54	with medication <sup>b</sup>	14.0	23.3
55-64		5.7	16.0
Serious CVD		2.0	0.6
Substance use disorder		11.7–18.8°	10.0
Diabetes		3.1	1.8
Hyperlipidemia		11.5	4.8
Hypertension		11.5	8.3
	residents with substance us	e disorder	
Percentage reporting Time period and unit of	Benchmark pe	rcentage	Study sample
stimulant use analysis	-		% of visits
			2014-2016
(Compton et al., 2018)			2014 2010
(Compton et al., 2018) Alcohol use disorder Household surveys,	18.3%		4.1
· · · · · · · · · · · · · · · · · · ·	18.3% 29.1%		

#### Benchmarks

*Note.* ADHD = attention-deficit hyperactivity disorder; CVD = cardiovascular disease; E -HR = electronic health record; NAMCS = National Ambulatory Medical Care Survey; ONC = Office of the National Coordinator for Health Information Technology. "Patient characteristics for sample overall were calculated from the published article as weighted averages of characteristics reported separately for patients with cerebrovascular disease only, coronary artery disease only, or both. Statistical test comparisons with present sample were not performed for insurance coverage or race because of differences in definitions. Pearson  $\chi 2$  tests: diabetes  $\chi 2[1] = 62.92$ , p < .001; hypertension  $\chi 2[1] = 158.3$ , p < .001; percentage female  $\chi 2[1] = 90.55$ , p < .001 <sup>b</sup>Excluding lisdexamfetamine. Statistical significance test comparisons with present sample were not performed because *N* in the study by Fairman et al. (2018) was 91,588. <sup>c</sup>Rate shown for the study by Fairman et al. (2018) includes all patients in sample, not just the patients treated with stimulants.

## Appendix H: Initial Assessments of Statistical Reliability of Logistic Regression

		Scenario A: patients with ADHD				Scenario B: patients with CVD or SUD			
Cases in mod	lel $(\overline{n})$	669 <sup>a</sup>				8,685 <sup>a</sup>			
Predictor	Reference	<u>β</u>	SE of	Number p	otentially	<u>β</u>	SE of	Number p	otentially
	<u>group</u>		<u>β</u>	<u>unsafe</u>			<u>β</u>	<u>unsafe</u>	
				<u>Dummy</u>	Reference			<u>Dummy</u>	Reference
Male	Female	0.487	.305	48	29	0.370	.253	83	54
Age (years)		-0.006	.010	Not appli	cable	-0.040	.009	Not appli	cable
White or	Black or	1.100	.626	72	5	1.022	.532	130	7
Hispanic	other race								
race									
Medicaid	Other or no insurance	-0.539	.587	12	65	-0.627	.365	16	121
Urban	Nonurban	-0.722	.707	69	8	-0.075	.439	127	10
Depression	No depression	0.560	.383	30	47	0.251	.302	54	83
Anxiety	depression	-1.003	.419	16	61	-0.686	.326	23	114
Cardiology	Neither			nodel; $n = 3$		-0.765	.567	9	128
Psychiatry	cardiology	1.231	.431	41	36	1.904	.364	56	81
	nor								
CCI of $\geq 1$	psychiatry CCI = 0	0.041	.614	6	71	-0.011	.398	24	113
CDS	No CDS	-0.607	.741	53	24	-1.409	.776	100	37
BBW	No BBW			ple size ade		-0.225	.729	100	30
BBW ×	No			ple size ade		0.605	.770	76	61
CDS	interaction	Remove	a m sam	pie size due	quuey test	0.005	.770	70	01
Meaningful	No	1.619	.772	52	25	1.053	.418	104	33
use	meaningful	11017		02		11000		101	20
	use								
Theory-base	d terms, first								
stage of theor									
modeling									
PCP, $\geq 4$	Not PCP	0.040	.607	13	64	-0.436	.518	20	117
visits									
PCP, <u>&lt;</u> 3	Not PCP	-0.264	.635	12	65	0.488	.453	23	114
visits									
Patient	No patient	-0.968	.454	67	10	0.133	.372	118	19
revenue	revenue								
Continued	New	-0.258	.287	64	13	Remove	d in sam	ple size ade	quacy test
prescription	prescription								

#### Coefficients

Note. ADHD = attention-deficit hyperactivity disorder; BBW = black-box warning; CCI = Charlson comorbidity index; CDS = computerized decision support; CVD = cardiovascular disease; PCP = primary care provider; SE = standard error; SUD = substance use disorder.

<sup>a</sup>Excludes cases with missing values on any predictor in either the theory-based or atheoretical models. In Scenario A, this exclusion criterion includes 108 visits in which no medication was prescribed, because the theory-based model includes a predictor of whether the medication was new or continued.

### Appendix I: Atheoretical Models, Scenarios A and B, Complex Samples Logistic

Regression Analyses of U.S. Office-Based Physician Visits Made by Adults, 2014–2016

		S	Scenario A: patients with ADHD			Scenario B: patients with CVD or SUD				
		Potentially unsafe prescription versus any other			Potentially unsafe prescription versus no					
		treatmer	treatment (safer medication or psychotherapy)			potentially unsafe prescription				
Unweighted nu				669				8,685		
	ysicians (strata)			301 (101)				1,659 (130	))	
"c" (concordar				.572				.870		
Nagelkerke R <sup>2</sup>				.099				.243		
Model $\chi^2$ (critidf), <i>p</i>	ical $\chi 2, \alpha = .05;$	-	31.03 (16	.92; $df = 9$	), <i>p</i> < .001	30	6.59 (21	.03; df = 1	12), <i>p</i> < .001	
Predictor	Reference group	<u>β</u>	<u>SE</u>	<u>OR</u>	<u>95% CI</u>	ß	<u>SE</u>	<u>OR</u>	<u>95% CI</u>	
Male	Female	0.511	.301	1.667	[0.921, 3.017]	0.371	.253	1.449	[0.882, 2.380]	
Age (years)		-0.003	.009	0.997	[0.978, 1.015]	-0.040	.009	0.961	[0.945, 0.977]	
White or	Black or	1.121	.632	3.068	[0.883, 10.661]	1.028	.534	2.794	[0.981, 7.960]	
Hispanic race	other race									
Medicaid	Any other payment source	Not included in model; removed in statistical -0.619 .366 0.539 [0.26 reliability assessment						[0.262, 1.105]		
Urban	Nonurban	-0.582	.713	0.559	[0.137, 2.277]	Not inclu reliabilit			noved in statistical	
Depression	No depression	0.551	.407	1.735	[0.777, 3.871]	0.250	.299	1.284	[0.714, 2.307]	
Anxiety	1	-0.960	.413	0.383	[0.169, 0.865]	-0.685	.328	0.504	[0.265, 0.959]	
Cardiology	Neither	Not inclu	ded in mo	odel; $n = 3$		-0.768	.564	0.464	[0.153, 1.403]	
Psychiatry	cardiology nor psychiatry	1.214	.424	3.367	[1.459, 7.771]	1.900	.357	6.688	[3.321, 13.468]	
BBW	No BBW	Not inclu adequacy		odel; remov	ved in sample size	-0.224	.726	0.800	[0.192, 3.324]	
CDS	No CDS	-0.620	.733	0.538	[0.127, 2.284]	-1.406	.782	0.245	[0.053, 1.137]	
BBW × CDS	No interaction	Not inclu adequacy		odel; remov	ved in sample size	0.608	.777	1.836	[0.400, 8.428]	
Meaningful use	No meaningful use	1.602	.753	4.961	[1.124, 21.898]	1.053	.417	2.865	[1.265, 6.488]	

*Note.* **Bold text** denotes a statistically significant predictor. Sampling-design degrees of freedom were 200 for Scenario A and 1,529 for Scenario B. ADHD = attention-deficit hyperactivity disorder; BBW = black-box warning; CDS = computerized decision support; CI = confidence interval; CVD = cardiovascular disease; df = degrees of freedom; LL = log likelihood; NA=not applicable; OR = odds ratio (exponentiated  $\beta$ ); SE = standard error; SUD = substance use disorder.

## Appendix J: Theory-Based Models, Scenarios A and B, Logistic Regression Analyses of

	Scenario A: patients with ADHD				Scenario B: patients with CVD or SUD				
Binary Outcome		Potentially unsafe prescription versus another treatment (safer medication or psychotherapy)				Potentially unsafe prescription versus no potentially unsafe prescription			
Unweighted number of visits		669				8.685			
						- )			
Number of physicians (strata)		301 (101)				1,659 (130) .871			
"c" (concordance) Statistic		.587							
Nagelkerke $\mathbb{R}^2$		.116				.243			
Model $\chi^2$ (critical $\chi^2$ , $\alpha = .05$ ;		36.41 (21.03; df = 12), <i>p</i> < .001				305.68 (22.36; df = 13), <i>p</i> < .001			
df), <i>p</i>	<b>D</b> (	0	ar	0.5	0.544 .07	0	<b>aF</b>	0.7	0.504 67
Predictor	Reference	<u>β</u>	<u>SE</u>	<u>OR</u>	<u>95% CI</u>	<u>β</u>	<u>SE</u>	<u>OR</u>	<u>95% CI</u>
	group								
Male	Female	0.501	.293	1.650	[0.925, 2.941]	0.361	.264	1.435	[0.855, 2.407]
Age (years)		-0.001	.010	0.999	[0.979, 1.018]	-0.040	.009	0.961	[0.945, 0.977]
White or	Black or	1.163	.647	3.199	[0.893, 11.466]	1.020	.536	2.774	[0.970, 7.937]
Hispanic race	other race								
Medicaid	Any other	Not inclu							[0.263, 1.146]
	payment source	reliability assessment							
Urban	Nonurban	-0.630	.699	0.533	[0.134, 2.113]	Not included in model; removed in statistical reliability assessment			
Depression	No depression	0.596	.393	1.814	[0.837, 3.935]	0.238	.303	1.269	[0.701, 2.299]
Anxiety	No anxiety	-0.958	.393	0.384	[0.177, 0.832]	-0.684	.323	0.505	[0.268, 0.951]
Cardiology	Neither cardiology	Not included in model; $n = 3$				-0.743	.657	0.476	[0.131, 1.724]
Psychiatry	nor psychiatry Neither	1.163	.549	3.200	[1.085, 9.441]	1.936	.415	6.928	[3.069, 15.639
	cardiology nor psychiatry								
BBW	No BBW	Not included in model; removed in sample size adequacy test				0.287	.452	1.333	[0.549, 3.236]
CDS	No CDS	-0.563	.756	0.570	[0.128, 2.531]	-0.913	.410	0.402	[0.180, 0.898]
Meaningful use	No meaningful use	1.398	.807	4.046	[0.823, 19.884]	1.072	.423	2.922	[1.275, 6.698]
Patient-derived revenue	No revenue on this basis	-0.941	.465	0.390	[0.156, 0.976]	0.113	.374	1.119	[0.538, 2.330]
РСР	Physician is not the PCP	-0.136	.564	0.873	[0.287, 2.656]	0.085	.423	1.088	[0.475, 2.495]
Continuing prescription	New prescription	-0.257	.289	0.773	[0.438, 1.366]	Not included in model; removed in sample size adequacy test			

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*Note.* **Bold text** denotes a statistically significant predictor. Sampling-design degrees of freedom were 200 for Scenario A and 1,529 for Scenario B. ADHD = attention-deficit hyperactivity disorder; BBW = black-box warning; CDS = computerized decision support; CI = confidence interval; CVD = cardiovascular disease; df = degrees of freedom; LL = log likelihood; OR = odds ratio (exponentiated  $\beta$ ); PCP = primary care provider; SE = standard error; SUD = substance use disorder.