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1. PURPOSE
This paper will provide an environmental scan of the use of pharmacogenomic coding by the health care industry. The information in this paper is current as of June 1, 2015.

GOALS
• Review the literature including, research articles, presentations, papers, and resources around the use of coding of pharmacogenomics (PG) by the health care industry.
• Review examples of organizations integrating patient specific pharmacogenomic information into their practices and how these organizations incorporate this information into the electronic health record (EHR).
• Review the major pharmacogenomics databases and resource guidelines currently available.
• Summarize challenges with storing pharmacogenomic information in the electronic medical record (EMR).
• Identify SNOMED CT codes currently available to document pharmacist’s involvement with pharmacogenomic interventions and those that may be needed as the field of pharmacogenomics continues to grow.

The contribution of pharmacists to the integration of PG into the EMR may include:
• Integration of pharmacogenomic information into electronic health records.
• Designing clinical decision support tools utilizing PG information to optimize medication therapy for patients.

RECOMMENDATIONS FOR ACTION
• Draft a pharmacogenomic value set of codes that will be used to document pharmacogenomic information in the electronic health record.
2. Overview
Pharmacogenomics has become an important part of the medical conversation. Pharmacogenomics is the study of the role of inherited and acquired genetic variations on a patient’s response to a medication. Pharmacogenomic information allows us to identify which patients may respond to specific treatments or predict which may have increased toxicity, while optimizing drug efficacy and minimizing morbidity and mortality. Pharmacogenetics is a term often interchanged with pharmacogenomics. Pharmacogenetics is the study of how a single gene variation influences the response to a single drug, while pharmacogenomics is a broader based term that encompasses all genes that may impact a medication’s response. In order to effectively use this valuable information we must develop methods to incorporate it into the electronic health record to assist with therapeutic decision-making. This information should be easily accessible to all medical providers, including pharmacists, as they are evaluating appropriateness and safety of drug therapy.1, 2, 3

The concept of the medical utility of pharmacogenomics is of significant debate. Widespread efforts are under way, determining which pharmacogenomic biomarkers are actionable and may result in clinically meaningful outcomes. More than 150 medications include pharmacogenetic information in their package labeling information. The labeling information includes genes which influence drug exposure and clinical response variability, risk for adverse events, genotype-specific dosing, mechanism of drug action, polymorphic drug target, and disposition genes. The speed of the discovery of genetic biomarkers far outpaces the understanding of corresponding clinical significance, as well as the incorporation of this data into current clinical practice. 1, 2, 4

There are significant challenges in translating pharmacogenomic information into clinical practice, as well as integrating this information in a meaningful way into the electronic health records. We will discuss many of these challenges and describe health systems currently integrating pharmacogenomic information into clinical practice. Various groups throughout the country are playing vital roles in the study and implementation of this information into current practice. In this paper, we will provide an overview of some of these programs, highlighting the processes by which they have been able to integrate pharmacogenomic information or specific pharmacogenetic information into their electronic health records to optimize patient outcomes. We will also review major databases and resource guidelines available to health care providers and researchers.

3. DISCUSSION

3.1. DATABASE/GUIDELINES OF PHARMACOGENOMIC DATA
There are various databases and guidelines available for this rapidly growing field of study to the health care community. Below, we describe some of the pharmacy-specific resources and highlight other general genomic resources available. These clinical recommendations are necessary to make the integration of pharmacogenomics information into clinical practice possible.

PHARMGKB
PharmGKB is a publicly available knowledge resource playing a critical role in connecting the link between genetic variants and drug response. They partner with various consortiums including the Clinical Pharmacogenetics Implementation Consortium (CPIC), International Clopidogrel Pharmacogenomics Consortium, and International SSRI Pharmacogenomics Consortium, among many others whose underlying aim is to collect large amounts of data to understand genetic variation and responses to specific classes or individual drugs. In addition, there are implementation partnerships,
such as the 1200 Patients Project: Studying the Implementation of Clinic Pharmacogenomic Testing at the University of Chicago, and PG4KDS at St. Jude Children’s Research Hospital, which focus on translating the genetic information into real world practice. These projects include the incorporation of this information into the electronic health record and integration into CPOE, as well as pharmacy operating systems to assist providers and pharmacists in clinical decision making.²

CLINICAL PHARMACOGENETICS IMPLEMENTATION CONSORTIUM (CPIC)

One of the limitations with pharmacogenetic information is the ability to convert a patient’s individual genotype into a clinically meaningful phenotype. There is limited guidance for clinicians regarding dose adjustment of medications based off of genotypes/phenotypes and understanding what the clinical impact a patient’s phenotype will have on a medication. The CPIC was formed with PharmGKB and the Pharmacogenomics Research Network to provide peer-reviewed, continually updated guidelines that center on how to assign phenotypes to clinical genotypes, dosing recommendations, and standardized system for grading each recommendation.² The CPIC formal working group focuses on the informatics aspects of CPIC guidelines and implementation into EHR with clinical decision support. The initial focus is to create comprehensive tables to translate genotype information of phenotypes to clinical recommendations and developing recommendations for decision support in the electronic health records.³

Currently twenty-four different CPIC guidelines have been published on eleven different genes (as of 9/2014):

<table>
<thead>
<tr>
<th>GENE</th>
<th>GUIDELINES</th>
</tr>
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<tbody>
<tr>
<td>HLA-B</td>
<td>CPIC Dosing Guideline for abacavir and HLA-B</td>
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<tr>
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<td>CPIC Dosing Guideline for allopurinol and HLA-B</td>
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<td>CPIC Dosing Guideline for boceprevir, peginterferon alfa-2a, peginterferon alfa-2b, ribavirin, telaprevir and IFNL3</td>
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<td>CPIC Dosing Guideline for capecitabine and DPYD</td>
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</tr>
<tr>
<td>VKORC1</td>
<td>CPIC Dosing Guideline for warfarin and CYP2C9, VKORC1</td>
</tr>
</tbody>
</table>

**THE DUTCH PHARMACOGENETIC WORKING GROUP (DPWG)**

The DPWG is a multidisciplinary group made of pharmacists, physicians, clinical pharmacologists, chemists, epidemiologists, and toxicologists, whose objectives are to develop pharmacogenetic-based therapeutic (dose) recommendations and to assist drug prescribers and pharmacists by integrating the recommendations into computerized systems for drug prescription and automated medication surveillance.27

**ELECTRONIC MEDICAL RECORDS AND GENOMICS (eMERGE)**

The Electronic Medical Records and Genomics (eMERGE) Network is a National Institutes of Health (NIH) organized and funded consortium of the U.S. medical research institutions. Phase I of eMERGE was completed in 2011 with the primary goals to develop, disseminate, and apply approaches to research that combine DNA biorepositories with electronic medical record systems for large-scale, high-throughput genetic research. A fundamental question that arose was whether EMR systems could serve as a resource for such complex genomic analysis of disease susceptibility and therapeutic outcomes across diverse patient populations. Phase II will be completed in 2015 with a primary goal to explore the best avenues to incorporate genetic variants into EMRs for use in clinical care, such as improvement of genetic risk assessment, prevention, diagnosis, treatment, and accessibility of genomic medicine.79

**IMPLEMENTING GENOMICS IN PRACTICE (IGNITE) CONSORTIUM**

The NIH’s Implementing Genomics in Practice (IGNITE) consortium is developing methods for incorporating genomic information in diverse clinical settings. The University of Florida’s Personalized Medicine Program is part of this consortium and will be described in greater detail in the next section. The field of pharmacogenomics is continually changing, and it will be important for pharmacists to be abreast of new guidelines and recommendations for clinical practice.8

**3.2. PROJECTS: HEALTH SYSTEMS LEADING THE WAY**

Some organizations have programs supporting the use of pharmacogenomics and incorporating this information into the EMR. The following projects are highlighted because of their collaboration with the Pharmacogenomics Research Network, funding by the National Institutes of Health, or having been identified by various national pharmacy organizations (e.g. ASHP, ACCP) for their cutting edge work in the field.

**1200 PATIENT PROJECT AT THE UNIVERSITY OF CHICAGO**

The University of Chicago’s 1200 Patient Project is a system designed to eliminate practical barriers of implementation of pharmacogenetic information into the EHR through use of preemptive genotyping of patients and assessment of integration of an interactive informatics portal. The 1200 Patient Project evaluated whether providers consider pharmacogenomic information during an office visit and the impact of this information on prescribing patterns. Patients had preemptive comprehensive genotyping conducted for a large number of germline polymorphisms with established impact on efficacy or toxicity of commonly used medications. Each patient’s specific genotypes
were incorporated into a Genomic Prescribing System (GPS). The GPS presents an interpretation of the complex pharmacogenomic data for specific medications in a quick concise summary, including the nature of the genetic association, clinical impact of the patient specific variant, and supporting literature. The pharmacogenomics information was presented as color-coded alerts correlating with the clinical severity of those alerts. Over 350 pharmacogenomic alerts have been developed within the GPS on over 600 adult patients. O’Donnell discusses how this model addresses three critical areas of implementing PG information into practice: “information dissemination, instantaneous availability of results, and clinical interpretation and guidance.”

PG4KDS AT ST. JUDE CHILDREN’S RESEARCH HOSPITAL
PG4KDS is a program at St. Jude Children’s Research Hospital with a goal to determine which pharmacogenetic information should be integrated into the EHR and to establish processes to integrate this information into EHR to improve safe and appropriate prescribing. The program was initiated in 2005 and focuses on specific clinical pharmacogenetic tests based on commercially available genotyping tests and medications that are used within their patient population, including thiopurine methyltransferase (TPMT) and cytochrome P450 2D6. Priority genes added to their protocol and now being investigated include cytochrome P450 2C19, dihydropyrimidine dehydrogenase (DPYD), and SLCO1B1, in addition to TPMT and CYP2D6. Not all information identified is integrated into the EHR. Rather, PG4KDS has developed a system to prioritize gene/drug pair placement into the EHR. Criteria used to evaluate what information should be integrated into the EHRs include establishment of CPIC or other organization guidelines, FDA labeling recommendations, evidence of reimbursement for specific drugs and genetic testing, the availability of a CLIA-approved test for the specific gene, and other publications demonstrating the effect of pharmacogenetic markers and drug response.

St. Jude has a developed a process by which the genetic information makes its way from the patient into the electronic health record. Once the samples are collected and processed, a gene-specific diplotype translation report is sent to St. Jude via Secure File Transfer Protocol (SFTP). The diplotypes are stored in a research database, a custom web-based applications (DMET Tracker and Consult Builder). The tracker controls the transfer of results into the EHR, as only results for selected genes are made available for review. Pharmacists manually review results and approve or reject the transfer into the EHR, and with approval, each diplotype is coupled with an interpretive consult and clinical significance. There is a second pharmacist verification built into the process. There are predetermined interpretive consults for each result, which are prebuilt within the “Consult Builder” application (providing templates, reusable text, and versioning to produce consistent consults).

While most phenotypes are not incorporated into the EHR, certain high-risk phenotypes that are likely to have a significant impact on medication prescribing are incorporated. The system produces a gene-specific problem list for the selected genes that is incorporated into clinical decision support to provide point of care alerts with specific dosing recommendations. An automated email is also sent to the health care providers when a phenotype is added to the gene specific problem list. Patient education is critical in PG4KDS, and patients are provided letters explaining their high-risk phenotype. There have been twelve medications that have been implemented, with four different genes and phenotypes. Hoffman, et al discuss how the current EHR vocabularies do not adequately differentiate between various phenotypes for priority (high vs. low risk results); therefore, an internal nomenclature was created.

PREDICT AT VANDERBILT UNIVERSITY
Pharmacogenomic Resource for Enhanced Decisions in Care and Treatment or PREDICT is a program designed to establish the infrastructure for preemptive incorporation of patient-specific genomic data into the electronic medical record. Initiation focused on CYP2C19 genotypes and the impact on prescribing of clopidogrel. The program has expanded to include warfarin, simvastatin, tacrolimus,
and thiopurines. Both internal and CPIC guidelines are used to design which specific genotypes will be targeted. The genotypes are stored in a separate database and archived in a secure database. A service layer API is built on top of the database to provide information within clinical applications. If a patient has an actionable genotype, it is converted into a standardized notation and interpretation. This combined genotype, phenotype, and clinical interpretation is stored in an internally developed EHR as a molecular laboratory result and found within a “drug-genome” interaction section of the patient summary page. PREDICT uses a homegrown database for coding pharmacogenomic information into the electronic health record. Intensive collaboration among members of the PREDICT initiative agreed upon clinical recommendations for dosing adjustments (consider alternative therapy) based on the genotype (e.g., CYP2C19*2/*2) and phenotype (e.g., poor metabolizer). This information is presented during ordering/prescribing to the providers. Pharmacists and other clinicians have access to this information, but their system does not encourage providers to consult pharmacists or integrate pharmacists into this service. The information is integrated into CPOE and provides an alternative drug therapy with the alert. 26, 28

PERSONALIZED MEDICINE PROGRAM AT THE UNIVERSITY OF FLORIDA

The University of Florida’s Health Personalized Medicine Program is working to connect genomic information into clinical practice (IGNITE; http://www.genome.gov/27554264). The primary focus of the Personalized Medicine Program is looking at the use of genetic information to help identify which medication or dose of medications is likely to work best for an individual patient. The university has started screening patients for genetic variations of CYP2C19 that may impact how a patient responds to clopidogrel. It is also testing for TPMT variants that affect thiopurine metabolism and IL28B to help in decision making for the use of interferon alpha in hepatitis C patients. The Personalized Medicine Program consists of an interdisciplinary subcommittee of the university’s Health Pharmacy & Therapeutics Committee that addresses challenges to clinical implementation. Responsibilities of this committee include identification of robust drug-gene pairs for clinical use, creation of clinical decision support tools, storage of the genomic data in the clinical care setting, and reimbursement associated with testing.

The university developed internal translational software that converts single nucleotide polymorphism (SNP) results into the “star allele” nomenclature (i.e., CYP2C19*1/*2). A patient’s entire genome sequence is not loaded into the electronic health record (EPIC 2012), but rather the star nomenclature is available for specific genes as discrete laboratory values. Phenotype interpretation (e.g., normal metabolizer) accompanies the laboratory report as descriptive text. Clinical interpretation and recommendations are provided through clinical pharmacists and clinical decision support (Best Practice Advisories) for relevant gene/drug pairs. A PGY-2 pharmacogenetics pharmacy resident is alerted when pharmacogenetic tests and results are available and interacts with the clinical team to adjust medications as needed. The resident is available for consultations regarding appropriateness of genetic testing, explaining how the results would translate into patient care decisions, and obtaining insurance authorization. 8, 29

RIGHT DRUG, RIGHT DOSE, RIGHT TIME AT THE MAYO CLINIC

Through NIH funding, the Mayo Clinic in collaboration with the PGRN and eMERGE piloted Right Drug, Right Dose, Right Time – Using Genomic Data Individualize Treatment Protocol (RIGHT Protocol) project. This project focuses on the preemptive sequencing of selected patients with integration of clinically actionable pharmacogenetic variants into the EMR to avoid adverse drug reactions, maximize efficacy, and optimize drug selection based on patient genetic profiles. Patients were identified to have preemptive sequencing if there was a high risk of initiating statin therapy within the next three years. They captured eighty-four clinically relevant pharmacogenes, as well as CYP2D6 genotyping for 1,013 patients. At the Mayo Clinic, an internal committee oversees the selec-
tion of and clinical implementation of drug-gene pairs into the EHR and corresponding CDS. These decisions are based on drug toxicity or drug non-response risk, strength of evidence and literature support, scope and volume of drug usage, and existence of CPIC guidelines. Through their CDS program, the selected actionable pharmacogenetic variants are converted into a standard notation with interpretation within the molecular diagnostic laboratory results of the EMR. The CDS rules are available for laboratory review and medication order entry. Mayo Clinic has approved CDS rules for four specific drug-gene pairs (carbamazepine-HLA-B*1502, abacivir-HLA-B*5701, thiopurines-TPMT, and interferon-IFNL3) and ongoing efforts include CYP2D6, CYP2C19 and SLCO1B1.

Pharmacists leading the way in pharmacy informatics and pharmacogenomics will need to collaborate and determine the optimal method of presenting this “new age” data about patients to enhance their medication therapy outcomes.

3.3. CHALLENGES OF PHARMACOGENOMICS INTO ELECTRONIC HEALTH RECORDS

There are several barriers to developing a method for integrating pharmacogenomics into the EHR, many of which we are not aware. One barrier is the uniqueness of the data compared to other commonly interpreted data in the EHR. This includes its large size, the duration of applicability, and the ever-changing potential clinical application and interpretation. Determining how to code this information will require multidisciplinary collaboration that includes pharmacists. The unknown cost/benefit ratio of pharmacogenomics testing, insurance coverage restrictions, and the delay of the results, also provides a unique challenge to providers in accessing and assessing this information for their patients. Ongoing education of this rapidly growing field for providers and pharmacists and designing workflows for incorporation of this information into clinical practice presents other challenges to the leaders in pharmacogenomics.

There is a debate about how much and which pharmacogenomic data should be put into the health record. Some recommend that systems should provide genotype results for germ line polymorphisms that have been identified as affecting response or toxicity to medications. Others recommend incorporating the full genomic panel so as new information regarding clinically meaningful polymorphisms becomes available, it can be more easily applied. There is also discussion regarding importing the genotype versus phenotypic interpretation of these genotypes into the EHR. Some recommendations encourage the phenotypic information to be stored as structured data and associated with clinically relevant genomic information within the EHR and emphasize that the data must be available for use by rules-based clinical decision support. As described above, some institutions are incorporating pharmacogenomic information through clinical decision support alerts imbedded into computerized physician order entry as determined by specific internal committees. Some recommend CDS for pharmacogenomics should be institution specific, much like order sets, to allow each institution to decide on their practice and policies.

Pharmacogenomic data are massive, and current EMR systems cannot handle the extensive information for each patient. This requires data to be stored long-term, securely in a standardized format for interoperable exchange between health care setting to ensure continuity of care. Various recommendations have been made to overcome this challenge. In 2014, the Institute of Medicine convened a collaborative of several organizations to develop guiding principles for integration of genomic information into EMR systems. Point in time phenotypic interpretation can be presented via clinical decision support when a specific medication is ordered, but often the detailed genomic
result can be lost. Another commonly recommended way to store and present pharmacogenomics information is to use an external data warehouse, as is currently being done in most of the projects discussed in this paper. This preserves the original genomic data but requires the development of an interface to integrate the warehouse to the EHR.

Unlike other clinical data, which are often transient pieces of data in the patient record (e.g., blood pressure, creatinine, etc.), PG data are long-term data points that need to be accessible throughout the patient’s life. Data can become buried among all reported laboratory values. It is important to have a standardized, portable way of representing actionable pharmacogenomics data that can be easily located and interpreted consistently. Some recommend storing the information as structured data, which is standardized to allow the information to move between different EHR systems. Although the importance of portability of pharmacogenomics information is agreed upon, there is currently no formal coding language for the purpose of building phenotyping algorithms nor is there a standard approach to implementation. Developing a standard system for coding pharmacogenomic data that is accessible to all practitioners would assist in patient care and avoid duplicate orders and unnecessary costs. Although genetic information is a lifetime data point, the phenotypic interpretation changes with new evidence. With new alleles being discovered and phenotype classifications of previous ones being updated, this may pose a set of challenges for health systems to stay current and provide accurate information for patient care. The development of a unique, easily assessable location within an EHR user interface would be an ideal place to store specific pharmacogenetic information. A third party application could also store genetic information separate from but able to be integrated into the EMR.

Incorporating this new clinical information into the provider workflow is another challenge. Having pharmacogenomic information available in a timely, prospective manner that is clinically meaningful and easy to integrate into practice will be important for widespread acceptance. The EHR must be able to obtain and display the new pharmaco genomic information needed by clinicians to integrate the genotypic and phenotypic data. There are ongoing projects evaluating whether providers consider PG information during clinic visits when the information is available. These projects are studying whether this new information results in altered prescribing patterns. The portability and presentation of this information to the end user will likely have a large impact on its routine use in the future. There are projects focusing on the integration of discrete genetic results, in structured formats, to deliver actionable recommendations through existing clinical decision support systems. Work remains to be done on the proliferation of genetic data with an improved understanding of how to present succinct and actionable distillates for the busy clinician. There are significant efforts under way by various organizations working to investigate and pilot implementation of pharmacogenomic information into health records, evaluate how health care providers will use this information, and study the impact this information may have on prescribing.

3.4 CODING OF PHARMACOGENOMICS INTO ELECTRONIC HEALTH RECORDS

Standardized documentation and coding of clinical information is being widely adopted across the United States thanks to the Meaningful Use of the Electronic Health Record initiative. This program sets operability standards for health information vendors and health professionals that use certified EMRs, allowing those who meet these standards to claim incentive dollars. Parts of the standards require incorporating standardized coding vocabularies for documenting clinical information within the EMR (e.g., problem list, medication list). Using standardized terminology allows this information to be packaged and sent to other health care settings using certified EMR software via Health Information Exchange (HIE). There is currently no standard vocabulary specifically designated for
documenting pharmacogenomic information. SNOMED CT is a likely candidate because it is a robust, detailed clinical documentation nomenclature used to codify many other types of clinical information.

Limited SNOMED CT codes exist for documenting clinical pharmacogenomic information. (Reference codes below).

<table>
<thead>
<tr>
<th>CODE</th>
<th>Clinical Term</th>
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<td>428931000124102</td>
<td>Pharmacogenetic consultation</td>
</tr>
<tr>
<td>38789009</td>
<td>Genetic dosage effect (finding)</td>
</tr>
<tr>
<td>422510002</td>
<td>Extensive metabolizer due to cytochrome p450 CYP2D6 variant (disorder)</td>
</tr>
<tr>
<td>424451001</td>
<td>Poor metabolizer due to cytochrome p450 CYP2C9 variant (disorder)</td>
</tr>
<tr>
<td>424500005</td>
<td>Poor metabolizer due to cytochrome p450 CYP2C19 variant (disorder)</td>
</tr>
<tr>
<td>423856005</td>
<td>Intermediate metabolizer due to cytochrome p450 CYP2D6 variant (disorder)</td>
</tr>
<tr>
<td>422681000</td>
<td>Ultrarapid metabolizer due to cytochrome p450 CYP2D6 variant (disorder)</td>
</tr>
<tr>
<td>423629005</td>
<td>Poor metabolizer due to cytochrome p450 CYP2D6 variant (disorder)</td>
</tr>
</tbody>
</table>

Health care professionals, including pharmacists, should collaborate with members of the health IT community to develop additional codes that allow detailed documentation of patient characteristics (findings, genotype information, and phenotypic interpretation) and actions (procedures) related to the clinical management of these patients and their genetic profile. Once an adequate set of codes is developed, a steward organization should be responsible for submitting codes as a value set. A value set is a set of possible values or responses. A value set often includes concepts form established vocabularies or data standards. For laboratory tests, a value set may include a range of permissible values and indicate required units. Value sets are lists of standardized codes endorsed by the National Library of Medicine (NLM) for clinical documentation in the EHR. The NLM can designate value sets to be used for documentation for meeting specific meaningful use standards. Currently, there are no meaningful use standards related to the documentation of pharmacogenomic information; however, this will likely be needed in the future.

Standardized documentation codes for the clinical management of the patient related to their genetic profile are also scarce. Clinicians may take specific action on pharmacogenomic information to optimize medication therapy. These actions and associated outcomes should be captured in the EMR to track interventions and relay information to other health professionals across the continuum of care. Similar initiatives should take place to develop standardized codes and establish value sets for the clinical management of patients related to pharmacogenomics.

4. CONCLUSION

Pharmacogenomics is an evolving field in modern medicine. New information related to drug-gene effects is continuously being discovered. There are significant challenges facing the health care community for incorporating genetic and phenotypic information in the EHR. Several demonstration projects are currently investigating this issue. It is vital that pharmacists (clinical, informatics, academics) are at the table to facilitate the incorporation of standardized pharmacogenomic information into the EHR and direct how this information is used in the clinical setting. Codifying pharmacogenomic information using standardized vocabularies would make this information sharable through health information exchanges, crossing multiple care settings and at every point of prescribing so therapy can be tailored to each unique patient. In addition, documentation codes related to the clinical management of pharmacogenomic data should be developed to describe interventions associated with optimizing medication therapy.
5. APPENDIX

18. O’Donnell, P.H.; Danahey, K.; Jacobs M.; Wadhwa, N.R.; Yuen S.; Bush, A.; Sacro, Y.; Sorrenti-


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