APPENDIX

A

Key Partnerships in Development of the National ADE Action Plan

Table A–1. Roles and Activities of U.S. Department of Health and Human Services (HHS) Operating Divisions and Other Federal Agencies Involved in Development of the National Action Plan for ADE Prevention

HHS Operating Division/ Federal Agency	Role/Activity
Bureau of Prisons	
BOP	▪ Provides medical, dental, and mental health to Federal inmates in Bureau facilities, including health care delivery, infectious disease management, and medical designations.
Department of Defense	
DOD	▪ Ensures health care to active duty members, retired service members, National Guard/Reserve members, families, survivors, and others entitled to DOD medical care.
Department of Health and Human Services	
AHRQ	▪ Supports research to identify root causes of threats to patient safety, inform decisions, and improve the quality of health care services. ▪ Manages systems to collect patient safety data.
ACL	▪ Provides resources/programs to support care coordination and consumer and caregiver activation.
CDC	▪ Conducts national surveillance to identify magnitude of and risk factors for health care-related harms. ▪ Collaborates with partners to identify effective prevention strategies and provide public health leadership.
CMS	▪ Leverages payment policies and data transparency to enhance delivery of quality care. ▪ Implements traditional and innovative quality improvement programs.

Table A–1. Roles and Activities of U.S. Department of Health and Human Services (HHS) Operating Divisions and Other Federal Agencies Involved in Development of the National Action Plan for ADE Prevention (continued)

HHS Operating Division/Federal Agency	Role/Activity
Department of Health and Human Services (continued)	
FDA	▪ Involved in risk mitigation. ▪ Supports ADE surveillance.
HRSA	▪ Improves health and achieves health equity of uninsured, isolated, and medically vulnerable populations through access to quality services, a skilled health workforce and innovative programs.
IHS	▪ Ensures that comprehensive, culturally acceptable personal and public health services are available and accessible to American Indian and Alaska Native people.
NIH	▪ Conducts and supports research into the causes, diagnosis, prevention, and cure of human diseases, and in directing programs for the collection, dissemination, and exchange of information in medicine and health.
OS/ASPE	▪ Advises on policy development, and is responsible for major activities in policy coordination, legislation development, strategic planning, policy research, evaluation, and economic analysis.
OS/ONC	▪ Supports the adoption of health information technology and the promotion of nationwide health information exchange to improve health care.
SAMHSA	▪ Provides information, education, and outreach on medication misuse/abuse.
Department of Veterans Affairs	
VA	▪ Provides health care to eligible Veterans, partners with other Federal departments and Agencies to measure the frequency and impact of ADEs. ▪ Supports surveillance.

Abbreviations: AHRQ = Agency for Healthcare Research and Quality; ACL = Administration for Community Living; ASPE = Assistant Secretary for Planning and Evaluation; BOP = Bureau of Prisons; CDC = Centers for Disease Control and Prevention; CMS = Centers for Medicare & Medicaid Services; DOD = Department of Defense; FDA = Food and Drug Administration; HRSA = Health Resources and Services Administration; IHS = Indian Health Services; NIH = National Institutes of Health; ONC = Office of the National Coordinator for Health IT; OS = Office of the Secretary; VA = U.S. Department of Veterans Affairs

APPENDIX B

Overview of Federal Systems That Conduct ADE Surveillance

Table B–1. Federal Systems for Conducting ADE Surveillance—National Surveillance Systems

Agency	AHRQ	AHRQ	AHRQ	CDC	FDA	FDA
System Name	HCUP-Nationwide Inpatient Sample (NIS); State Inpatient Databases	HCUP-NEDS	MPSMS*	NEISS-CADES	FAERS	Sentinel Initiative Mini-Sentinel Pilot
Active or Passive?	Active	Active	Active	Active	Passive (voluntary)	Active
Surveillance Population	Patients in U.S. short-term, acute-care, non-Federal hospitals	Visits to U.S. emergency departments in short-term, acute care, non-Federal hospitals	U.S. (all payors)	Visits to U.S emergency departments in short-term, acute-care hospitals	U.S. and Foreign	Enrollees in 18 large health plans including: (currently) Aetna, HealthCore, Humana, Optum, HMORN (partial) Kaiser (partial), Vanderbilt University (TN, WI Medicaid data)
System Focus	Research and statistical reporting on utilization and costs of care provided in U.S. hospitals	Research and statistical reporting on utilization and costs of care provided in U.S. emergency departments	Hospital complications from select medications (e.g., anticoagulants, insulin, digoxin)	Monitoring acute harms from commonly used medications in ambulatory care	Signal detection and assessment	Signal assessment

Table B–1. Federal Systems for Conducting ADE Surveillance—National Surveillance Systems (continued)

Agency	AHRQ	AHRQ	AHRQ	CDC	FDA	FDA
Setting of Drug Exposure	Inpatient or outpatient (can distinguish between exposure setting when the data system provides information on whether diagnoses were present on admission [POA]—this information is available for a subset of States contributing to HCUP)	Emergency department (no POA information is provided for ED visits)	Select adult inpatient populations (those with hospital discharge diagnosis of HF, AMI, or pneumonia)	Outpatient (all ages)	All settings	Drug exposure in any setting ▪ Inpatient (including, procedures) ▪ Outpatient (including, procedures)
Geographic Scope	▪ National (~1,000 hospitals) ▪ Regional stratification ▪ State estimates for some States	▪ National (~1,000 hospitals) ▪ Regional stratification ▪ State estimates for some States	▪ National (~800 of ~3,400 hospitals) ▪ No regional stratification	▪ National (~63 hospitals) ▪ No regional stratification	Foreign and domestic	Varying with data partners/sources; Currently Sentinel covers > 125 million lives (does not constitute a nationally representative sample)
Data Source(s)	Hospital billing data	ED billing data	Hospital discharge medical records	ED medical records	▪ (Primarily) post-marketing, spontaneous AE reports ▪ (Some) clinical trial AE reports	▪ Insurance claims ▪ Public and private administrative claims

Table B–1. Federal Systems for Conducting ADE Surveillance—National Surveillance Systems (continued)

Agency	AHRQ	AHRQ	AHRQ	CDC	FDA	FDA
Data Collection Method	▪ NIS is a stratified sample of about 1,000 hospitals; all discharge records (~8 million) are retained in the dataset. ▪ SIDs are based on discharge data collected by statewide data organizations and shared with AHRQ through voluntary agreements.	NEDS is based on ED data collected by statewide data organizations and shared with AHRQ through voluntary agreements. NEDS is a stratified sample of about 1,000 hospital-based EDs; all records of stays (~25—30 million) are retained in the dataset.	Random national sample	National stratified probability sample	Voluntarily submitted reports	Database queries
Case Identification Method	▪ Algorithmic detection using ICD-9-CM codes	▪ Algorithmic detection using ICD-9-CM codes	Algorithmic detection based on chart abstraction of *select* ADEs (select anticoagulants, antibiotic-related CDI, insulin, oral diabetes agents, digoxin)	Algorithmic detection based on chart abstraction using clinician diagnosis as it appears in medical record narrative (not ICD-9-CM coding)	MedDRA Preferred Terms (PTs) or Standardized MedDRA Queries (SMQs)	Algorithm detection using drug exposure codes (dispensing), ICD-9-CM codes (diagnosis), and CPT (procedure) codes

* In 2015, MSPMS will be replaced by the Quality and Safety Review System (QSRS) for Health Systems, and AHRQ Common Formats utilized as the primary data collection method.

Table B–2. Federal Systems for Conducting ADE Surveillance—Federal Health Systems

Agency	BOP	DOD	DOD	IHS	VHA	VHA
System Name	N/A	Pharmacovigilance Defense Application System	Patient Safety Reporting System	Resource and Patient Management System (RPMS-EHR)	VA ADERs	Department of VA Integrated Databases
Active or Passive?	Passive (voluntary)	Active	Passive (voluntary)	Passive (voluntary)	Passive (voluntary)	Active
Surveillance Population	Inmates in facilities under the supervision of BOP	DOD (active duty, family members and retirees and family members)	DOD (active duty, family members and retirees and family members)	Federally recognized American Indians and Alaska Natives	VHA	VHA
System Focus	Quality improvement	▪ Signal generation ▪ Signal refinement ▪ Signal evaluation ▪ Quality improvement	▪ Signal detection ▪ Quality improvement	▪ Signal detection ▪ Quality improvement ▪ Patient care	▪ Signal detection ▪ Quality improvement	▪ Signal detection ▪ Quality improvement
Setting of Drug Exposure	▪ Inpatient ▪ Outpatient	▪ Inpatient (all ages) ▪ Outpatient (all ages)	▪ Inpatient (military treatment facilities) ▪ Outpatient (military treatment facilities)	▪ Inpatient ▪ Outpatient	▪ Inpatient (VHA facilities) ▪ Outpatient (VHA facilities)	▪ Inpatient ▪ Outpatient
Geographic Scope	▪ Regional BOP ▪ Facility	▪ National DOD ▪ Facility ▪ Service	▪ National DOD-run facilities ▪ Facility level ▪ Service level	▪ National IHS ▪ Regional area office ▪ Facility ▪ Individual patient care	▪ National VHA ▪ Regional VHA ▪ VHA network ▪ Facility	▪ National VHA ▪ Regional VHA ▪ VHA network ▪ Facility

Table B–2. Federal Systems for Conducting ADE Surveillance—Federal Health Systems (continued)

Agency	BOP	DOD	DOD	IHS	VHA	VHA
Data Source(s)	Spontaneous AE reports	▪ DOD EHRs ▪ DOD administrative claims	Patient Safety Reporting System Submitted Reports	▪ RPMS-EHR ▪ Adverse Reaction Tracking System ▪ Administrative datasets (Webcident)	▪ Spontaneous AE reports	▪ VHA EHRs ▪ VHA administrative claims
Data Collection Method	EHR review	Database queries (automated and ad hoc; updated quarterly)	Electronically submitted reports	Database queries	Database queries	Database queries
Case Identification Method	Review of cases with prescribed medication (anticoagulants)	▪ Algorithmic detection using combination of drug exposure/J-code and ICD-9-CM/ CPT, LOINC codes ▪ Clinic visits, ED visits, hospitalizations, and procedures following drug exposure	Patient Safety Reporting System collections on both ADE and ADRs.* ADE are classified as: death, severe permanent harm, permanent harm, temporary harm, additional treatment, emotional distress or inconvenience, no harm, near miss (did not reach patient), unsafe condition	▪ Algorithmic detection using ICD-9-CM codes ▪ Clinic visits, ED visits, hospitalizations following drug exposure	MedDRA codes	▪ Algorithmic detection using ICD-9-CM codes ▪ Clinic visits, ED visits, and hospitalizations following drug exposure

* Adverse drug reaction (ADR): A subtype of an ADE that stems directly from taking an appropriate dose of the drug. ADEs also may be caused by a medication error, intentional overdose, or other inappropriate use (of an otherwise appropriate drug).

Abbreviations

ADE	adverse drug event
AE	adverse event
AMI	acute myocardial infarction
AHRQ	Agency for Healthcare Research and Quality
BOP	Bureau of Prisons
CDC	Centers for Disease Control and Prevention
CDI	Clostridium difficile infection
CPT	Current Procedural Terminology
DOD	Department of Defense
ED	emergency department
EHR	electronic health record
FDA	Food and Drug Administration
FAERS	FDA Adverse Event Reporting System
HCUP-NEDS	Healthcare Cost and Utilization Project—Nationwide Emergency Department Sample
HCUP-NIS	Healthcare Cost and Utilization Project—Nationwide Inpatient Sample
HF	heart failure
ICD-9-CM	International Classification of Diseases (ICD), Ninth Revision, Clinical Modification
IHS	Indian Health Service
LOINC	Logical Observation Identifiers Names and Codes
MPSMS	Medicare Patient Safety Monitoring System
NEISS-CADES	National Electronic Injury Surveillance System—Cooperative Adverse Drug Events Surveillance System
POA	present on admission
PTs	MedDRA Preferred Terms
RPMS	Resource and Patient Management System
SID	State Inpatient Database
SMQs	Standardized MedDRA Queries
VA ADERs	VA Adverse Drug Event Database
VHA	Veterans Health Administration

APPENDIX C

Affordable Care Act Health Care Delivery Models Relevant to ADE Prevention

Table C–1. Affordable Care Act Health Care Delivery Models Relevant to ADE Prevention

Term	Definition
Patient-centered medical home (PCMH)	Patient-centered medical home is a care delivery model designed to improve quality of care through better coordination, treating the many needs of the patient at once, increasing access, and empowering the patient to be a partner in his/her own care. Central attributes of PCMH models of care include enhanced patient access to a regular source of primary care; stable and ongoing relationships with a personal clinician who directs a care team; and timely, well-organized health services that emphasize prevention and chronic care management. An important feature of medical homes is enhanced payment in recognition of the infrastructure needed to provide more services. Evidence suggests that, on the whole, PCMHs improve patient experiences and outcomes by increasing access to care, encouraging the receipt of recommended preventive services, and facilitating better management of chronic conditions. Source: Davis K et al. How the Affordable Care Act Will Strengthen the Nation's Primary Care Foundation. 2011. J Gen Intern Med, 26(10): 1201–1203.
Accountable Care Organization (ACO)	An ACO refers to a group of providers and suppliers of services (e.g., hospitals, physicians, and others involved in patient care) that will work together to coordinate care for the patients they serve with Original Medicare (that is, those who are not in a Medicare Advantage private plan). The goal of an ACO is to deliver seamless, high-quality care for Medicare beneficiaries. The ACO would be a patient-centered organization in which the patient and providers are true partners in care decisions. The Affordable Care Act specifies that an ACO may include the following types of groups of providers and suppliers of Medicare-covered services: ▪ ACO professionals (i.e., physicians and other practitioners meeting the statutory definition) in group practice arrangements ▪ Networks of individual practices of ACO professionals ▪ Partnerships or joint venture arrangements between hospitals and ACO professionals ▪ Hospitals employing ACO professionals ▪ Other Medicare providers and suppliers, as determined by the Secretary Source: Centers for Medicare & Medicaid Services. Medicare Learning Network. Summary of Final Rule Provisions for Accountable Care Organizations under the Medicare Shared Savings Program. Available at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO_Summary_Factsheet_ICN907404.pdf. Accessed January 7, 2014.

Table C–1. Affordable Care Act Health Care Delivery Models Relevant to ADE Prevention (continued)

Term	Definition
Team-based health care	Implemented through ACOs and can be defined as: The provision of health services to individuals, families, and/or their communities by at least two health providers who work collaboratively with patients and their caregivers to the extent preferred by each patient—to accomplish shared goals within and across settings to achieve coordinated, high-quality care. Source: Mitchell P, Wynia M, Golden R et al. Core Principles & Values of Effective Team-Based Health Care. Institute of Medicine of the National Academies. Available at: http://www.iom.edu/global/perspectives/2012/teambasedcare.aspx. Accessed January 7, 2014.

APPENDIX

D

Overview of CMS Programs/Initiatives With Potential To Advance ADE Prevention

Table D–1. Overview of CMS Programs and Initiatives That Support ADE Prevention

Program/Initiative	Description	General ADEs Addressed	ADE Targets (Anticoagulants, Diabetes Agents, Opioids) Specifically Addressed?	Opportunities
Regulatory Oversight				
Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and long-term care facility (LTCF) requirements	▪ Federal health and safety requirements for hospitals and other providers and suppliers ▪ All Medicare- and Medicaid-participating providers to be in compliance	*Hospital CoPs* ▪ Policies/procedures to minimize errors related to drugs ▪ Report errors ▪ Require internal process to track adverse events (including ADEs), analyze cause, and implement preventive actions *Critical Access Hospital CoPs* ▪ Report adverse drug and drug administration errors *Long-Term Care CoPs* ▪ Free of medication errors >5% ▪ Free of ALL significant medication errors ▪ Drug regimens not include unnecessary drugs *Home Health Agency CoPs* ▪ Drug regimen review ▪ Focus on adverse effects, drug interactions, duplicate drugs, noncompliance	*Long-term Care* ▪ Specific use/guidelines for – Anticoagulants – Diabetes agents – Opioids	Opportunity for improving ADE prevention practices

Table D–1. Overview of CMS Programs and Initiatives That Support ADE Prevention (continued)

Program/Initiative	Description	General ADEs Addressed	ADE Targets (Anticoagulants, Diabetes Agents, Opioids) Specifically Addressed?	Opportunities
Regulatory Oversight				
Survey & Certification	▪ Assess compliance with CoPs and CfCs	▪ Guidelines and policy memos related to prevention of ADEs	No	Opportunity for improving ADE prevention practices
Value-Based Purchasing Financial Incentives				
Hospital Inpatient Quality Reporting Program	▪ Hospitals required to report quality measures or subject to payment reduction ▪ Measures are publicly reported on CMS Web site	No	No	Opportunity for development of quality measures specific to the ADE targets
Value-Based Purchasing Financial Incentives				
Physician Quality Reporting System	▪ Eligible professionals receive incentive payment for meeting satisfactory reporting criteria for quality measures. ▪ Beginning in 2015, eligible professionals who do not meet satisfactory reporting criteria of quality measures will be subject to payment adjustment.	Measure #46—Medication Reconciliation Measure #130—Documentation of Current Medications in the Medical Record Measure #176—Rheumatoid Arthritis: Tuberculosis Screening Measure #238—Use of High-Risk Medications in the Elderly Measure #271—Inflammatory Bowel Disease: Preventive Care: Corticosteroid-Related Iatrogenic Injury–Bone Loss Assessment	Measure #380—ADE Prevention and Monitoring: Warfarin Time in Therapeutic Range	Opportunity for development of quality measures specific to the ADE targets

Table D–1. Overview of CMS Programs and Initiatives That Support ADE Prevention (continued)

Program/Initiative	Description	General ADEs Addressed	ADE Targets (Anticoagulants, Diabetes Agents, Opioids) Specifically Addressed?	Opportunities
		Measure #274—Inflammatory Bowel Disease: Testing for Latent Tuberculosis Before Initiating Anti-Tumor Necrosis Factor Therapy Measure #275—Inflammatory Bowel Disease: Assessment of Hepatitis B Virus Status Before Initiating Anti-Tumor Necrosis Factor Therapy Measure #337—Tuberculosis Prevention for Psoriasis and Psoriatic Arthritis Patients on a Biological Immune Response Modifier		
Hospital-Based Value Purchasing	▪ Increased payment for hospitals demonstrating high quality ▪ Penalties for hospitals demonstrating poor quality	No	No	Opportunity to include ADE measures in future years
Value-Based Purchasing Financial Incentives				
Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs	▪ Incentive payments for hospitals and eligible professionals that demonstrate meaningful use of a certified EHR technology	▪ Providers must maintain active medication list, implement drug–drug and drug–allergy interaction checks, and implement clinical decision support rules. ▪ EHR Stage 2 Meaningful Use Clinical Quality Measure: Use of high-risk medications in older adults ▪ Use of high-risk medications in older adults	▪ Specific clinical quality measures related to ADEs: – Warfarin Time in Therapeutic Range VTE discharge instructions for patients on warfarin	Opportunity for incorporation of quality measures specific to the ADE targets as part of EHR requirements and tools (e.g., Clinical Decision Support)

Table D–1. Overview of CMS Programs and Initiatives That Support ADE Prevention (continued)

Program/Initiative	Description	General ADEs Addressed	ADE Targets (Anticoagulants, Diabetes Agents, Opioids) Specifically Addressed?	Opportunities
Physician Feedback Program and Value-Based Payment Modifier	▪ Produce annual physician feedback reports ▪ Physician Fee Schedule payment modified based on quality of care compared with costs	No	No	Opportunity for development of quality measures specific to the ADE targets
Value-Based Purchasing Financial Incentives				
Health Care Innovation Awards	▪ Supports organizations using new ideas to enhance quality and reduce cost to Medicare, Medicaid, CHIP recipients.	▪ 47 projects provide medication reconciliation or management services.	No	Opportunities to address ADEs in future rounds of funding
Pioneer Accountable Care Organizations (ACOs)	▪ Shared savings payment model focusing on population-based health	▪ Many ACOs have participated in efforts to enhance drug safety, including use of barcoding, computerized provider order entry (CPOE), medicine decision support, public reporting.	No	Opportunities to enhance Pioneer ACO efforts to reduce ADEs
Multi-Payer Advanced Primary Care Practice	▪ State-level multi-payer reforms to expand advanced primary care practices ▪ Primary Care Medical Homes (PCMHs) receive monthly care management fees for Medicare.	▪ Two States focus on medication safety through clinical pharmacy, case management, efforts to reduce medication errors and complications, use of electronic data system for managing pharmacy care.	No	Opportunities to expand ADE efforts into additional States

Table D–1. Overview of CMS Programs and Initiatives That Support ADE Prevention (continued)

Program/Initiative	Description	General ADEs Addressed	ADE Targets (Anticoagulants, Diabetes Agents, Opioids) Specifically Addressed?	Opportunities
Community-Based Care Transitions Program	▪ Models to improve care transitions ▪ Goals: reduce readmissions, improve quality, save cost	▪ All sites provide medication reconciliation.	No	Opportunities to enhance focus on ADEs
Transparency and Associated Incentives				
Hospital Compare	▪ Consumer-oriented Web site providing information on hospital quality	▪ Some hospitals voluntarily report data on ADEs.	No	Opportunities to include measures related to ADEs
Physician Compare	▪ Consumer-oriented Web site providing information on physician quality and patient experience ▪ Quality measures including those reported under the Physician Quality Reporting System (PQRS)	No	No	Opportunities to include measures related to the specific ADE targets

Table D–1. Overview of CMS Programs and Initiatives That Support ADE Prevention (continued)

Program/Initiative	Description	General ADEs Addressed	ADE Targets (Anticoagulants, Diabetes Agents, Opioids) Specifically Addressed?	Opportunities
Related Initiatives Addressing ADEs				
Initiative To Reduce Avoidable Hospitalizations Among Nursing Facility Residents	▪ Interventions to enhance care coordination for long-stay nursing facility residents ▪ Goals: Reduce avoidable hospital transfers or readmissions, improve quality, lower costs, increase patient safety	▪ Coordinating management of prescription drugs to reduce risk of ADEs	No	Opportunity to expand focus to include specific drug classes
Related Initiatives Addressing ADEs				
Quality Improvement Organizations	▪ Network of organizations focused on improving quality of care for Medicare beneficiaries	▪ Patient Safety and Clinical Pharmacy Services Collaborative focuses on improving quality and safety among high-risk patients, increasing medication therapy management, detecting pADEs and ADEs and reporting on ADEs. ▪ Improving Care Transitions and Readmissions focuses on improving effectiveness of pharmacotherapies, increasing patient understanding of medications, detecting ADEs.	▪ Reporting on – The rate of Adverse Drug Events – The potential Adverse Drug Events – Number of beneficiaries on warfarin with International Normalized Ratio (INR) in controlled range – Rate of beneficiaries on warfarin that have INR monitored monthly – Rate of beneficiaries with HbA1c >9% – Rate of beneficiaries prescribed a potentially inappropriate antipsychotic medication	

Table D–1. Overview of CMS Programs and Initiatives That Support ADE Prevention (continued)

Program/Initiative	Description	General ADEs Addressed	ADE Targets (Anticoagulants, Diabetes Agents, Opioids) Specifically Addressed?	Opportunities
Related Initiatives Addressing ADEs				
Medicare Part D/Opioid Overutilization Policy	▪ Part D sponsors are expected to conduct retrospective drug utilization review and engage in case management for beneficiaries meeting threshold for potential opioid overutilization; Part D sponsors are also expected to employ appropriate controls on coverage of opioids (safety edits, quantity limits).	▪ Opioid overutilization in Part D	▪ Partially; Part D beneficiaries meeting threshold for potential opioid use; opioid policy not applicable to other ADEs (anticoagulants and diabetes agents)	Sponsors may employ MTM to address opioid overutilization.
Regional Chief Medical Officers	▪ Serve as CMS liaison with medical community.	▪ Provide education on identification and reduction of ADEs. ▪ Participate in intra-agency programs, including Prescription Drug Monitoring Program. ▪ Present on importance of reducing ADEs across region. ▪ Work on appropriate use of antipsychotics in nursing homes.	▪ Importance of controlled blood pressure and management of diabetes; appropriate use of antipsychotics in nursing home; and medication reconciliation ▪ Educate health care professionals about specific ADE targets on ad hoc basis.	

Table D–1. Overview of CMS Programs and Initiatives That Support ADE Prevention (continued)

Program/Initiative	Description	General ADEs Addressed	ADE Targets (Anticoagulants, Diabetes Agents, Opioids) Specifically Addressed?	Opportunities
Related Initiatives Addressing ADEs				
National Coverage Determination	▪ Determines coverage policies for Medicare services and equipment	▪ Two determinations directly relate to prevention of ADEs.	▪ Medicare coverage for home prothrombin time testing to help patients on warfarin who may be out of therapeutic range ▪ Pharmacogenomic testing to inform physicians of gene variations that might increase or decrease patient's reaction to warfarin ▪ Coverage for home blood glucose monitoring ▪ Coverage for testing blood glucose levels in pharmacy	Opportunities to expand coverage determinations to further target reduction in ADEs
State Medicaid Drug Monitoring	▪ State Medicaid agencies use electronic monitoring system to screen prescription drug claims.	▪ Drug utilization review looks for duplication, contraindications, incorrect dosage or duration.	▪ Depends on State	Opportunity to reach out to States to focus on ADEs related to specific drug classes

Abbreviations

ACO	Accountable Care Organization
ADE	adverse drug event
CfC	Condition for Coverage
CHIP	Children's Health Insurance Program
CMS	Centers for Medicare and Medicaid Services
CPOE	Computerized Provider Order Entry
CoP	Condition of Participation
EHR	electronic health record
HbA1c	Hemoglobin A1c
INR	international normalized ratio
MTM	medication therapy management
pADEs	potential adverse drug events
PCMH	Primary Care Medical Home
PQRS	Physician Quality Reporting System
VTE	venous thromboembolism