SECTION 4

Incentives and Oversight Opportunities

The U.S. Department of Health and Human Services (HHS)—specifically, the Centers for Medicare and Medicaid Services (CMS)—has a variety of tools within its statutory and regulatory authority to support the prevention of ADEs [**Appendix D**]. These tools can be broadly classified as

- Regulatory oversight activities (including Conditions of Participation (COPs), accreditation, and survey and certification)
- Value-based purchasing (VBP) programs and other financial incentives
- Transparency and associated incentives
- Medicare and Medicaid initiatives

This section discusses in detail the various ways in which these tools and initiatives are being used to support the Nation's efforts to prevent ADEs.

Regulatory Oversight

The CMS developed Conditions of Participation (CoPs), Conditions for Coverage (CfCs),[i] and long-term care facility (LTCF) requirements[ii] that hospitals and other providers and suppliers must meet to participate in the Medicare and Medicaid programs. These Federal health and safety requirements are intended to ensure that high-quality care is provided to all patients and residents. All Medicare- and Medicaid-participating providers and suppliers for which there are CoPs/CfCs are required to be in compliance at all times. Compliance is assessed by CMS Federal surveyors, State Survey Agencies (SAs), federally contracted surveyors, and national accreditation organizations (AOs) having CMS-approved

[i] More information on the CoPs and CfCs is available at: http://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/index.html

[ii] More information on the requirements for LTCFs is available at: http://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/LTC.html

Medicare accreditation programs. CMS has regulatory requirements and interpretive guidelines related to the prevention of ADEs for numerous health care providers and suppliers. The following section describes some of these ADE-related regulations and guidelines.

Regulations and Interpretive Guidelines

Hospitals

The hospital CoPs address ADEs in two ways. First, in accordance with accepted standards of practice, the CoPs address the establishment and implementation of policies and procedures to minimize errors related to drugs and to internally report errors when they occur. Second, the CoPs address the hospital's internal quality assessment and performance improvement process to track adverse events, including ADEs; to analyze their causes; and implement preventive actions, including feedback and learning throughout the hospital. In addition, the CMS survey and certification interpretive guidelines provide a vehicle for a more specific discussion of best practices in ADE prevention and tracking.

Critical Access Hospitals

The critical access hospital (CAH) CoPs focus on internal reporting of adverse drug reactions and drug administration errors in a manner similar to that required for traditional acute care hospitals.

Long-Term Care (LTC)

The LTC regulations that apply to institutional settings such as nursing homes contain many drug-related requirements. Specifically, the regulations state that an LTC facility must ensure that it is free of medication error rates of 5 percent or greater and that residents do not experience any significant medication errors. The LTC facility regulations also require that each resident's drug regimen be free from unnecessary drugs, and focus on the adverse consequences associated with the use of a wide variety of drugs. CMS provides extensive background and clinical information to improve the body of knowledge surrounding the prescription and administration of drugs in the LTC setting. In particular, CMS provides specific use and monitoring guidelines for anticoagulants, diabetes medications, and opioids.

CMS requires that LTC facility residents be free from unnecessary drugs and, to minimize adverse consequences related to drug therapy to the extent possible, the regulations also require that the drug regimen of each resident be reviewed at least once a month by a licensed pharmacist. Furthermore, the regulations require that any irregularities be reported to the attending physician and the director of nursing, and that facility staff act on these reports. The interpretive guidelines also discuss the drug-

related risks that are involved in care transitions, a period when drugs are often added, discontinued, omitted, or changed, and how these increased risks necessitate the need for safeguards, such as drug regimen review.

Home Health Agencies

The home health agency CoPs seek to prevent ADEs by ensuring that each patient receives a drug regimen review as part of a comprehensive assessment that is conducted at the time the patient begins home health care. The drug regimen review is updated at least once every 60 days. The review has a particular focus on identifying potential adverse effects, drug interactions, duplicate drugs, and issues related to patient noncompliance with the prescribed drug regimen. The interpretive guidelines for this section state that, if any potential adverse effects and/or reactions are identified, the physician must be notified. Because orders change frequently, the home health agency staff must be aware of any and all changes as they occur, constantly reevaluating medications, compliance, interactions, and effectiveness of the drug regimen.

Survey and Certification[iii]

The survey and certification (S&C) program is designed to ensure that providers and institutional suppliers comply with the CoPs/CfCs. When surveyors identify a deficiency, the provider or supplier is required to take prompt action to ensure compliance, typically involving a plan of correction, which must be reviewed and found acceptable by CMS, either through the survey agency or the accreditation organization, if applicable, and then appropriately implemented.

Value-Based Purchasing Financial Incentives

Value-based purchasing is a mechanism that uses financial incentives to encourage all levels of health care providers to improve quality of care.

Hospital Pay-for-Reporting[iv]

The Hospital Inpatient Quality Reporting (Hospital IQR) Program requires subsection (d) hospitals paid under the Inpatient Prospective Payment System (IPPS) to report on different quality measures,

[iii] More information on the S&C program is available at: http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/index.html?redirect=/surveycertificationgeninfo/

[iv] More information on the Hospital IQR program is available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalRHQDAPU.html

including process, structure, outcome, patients' experience of care, efficiency, and cost efficiency measures. Performance on quality measures is publicly reported on the CMS Hospital Compare Web site.[v] In implementing the Hospital IQR Program, CMS expects the measure set to continue to evolve on the basis of factors such as program needs and high-priority areas. Through the Hospital IQR Program, CMS has the authority to adopt quality measures addressing ADEs. Measures adopted for the Hospital IQR Program may also be adopted for use in other CMS initiatives linking quality to payment, such as the Hospital Value-Based Purchasing and the Hospital-Acquired Condition Reduction Programs.

CMS Demonstration Projects and Models

The CMS Innovation Center develops and tests innovative payment and service delivery models. Within this center, there are at least five programs that address ADEs; they are described in the following sections.

Health Care Innovation Awards (HCIA)[vi]

The Health Care Innovation Awards provide funding to organizations that are implementing the most compelling new ideas designed to deliver better health, improved care, and lower costs to people enrolled in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). Of the 107 currently funded projects, 48 include a focus on medication reconciliation or medication management services.

Pioneer Accountable Care Organizations (ACO) Model[vii]

The Pioneer Accountable Care Organizations (ACO) Model is designed to work in coordination with private payers by aligning provider incentives to improve quality and health outcomes, while achieving cost savings. The Pioneer ACO Model supports measuring and reducing ADEs, including efforts to standardize decision support for safe medication management (e.g., medication reconciliation, allergy checks, drug interaction checks, and checks for duplicate or contraindicated therapy). Specifically, one Pioneer ACO measured and reported safety events of all types via safety reporting systems at each site within its network. In regard to measurement approaches, system process measures (e.g.,

[v] http://www.medicare.gov/hospitalcompare/search.html

[vi] More information on the Health Care Innovation Awards is available at: http://innovation.cms.gov/initiatives/Health-Care-Innovation-Awards/

[vii] More information on the Pioneer ACO Model is available at: http://innovation.cms.gov/initiatives/Pioneer-ACO-Model/

implementation of barcoding, computerized order entry, electronic prescribing, and anticoagulation management services) were a primary focus.

Multi-Payer Advanced Primary Care Practice (MAPCP)[viii]

The Multi-Payer Advanced Primary Care Practice (MAPCP) demonstration includes multipayer reform initiatives that eight States are conducting to make advanced primary care practices more broadly available. Two participating States include a focus on medication safety. In one State, networks of community-based practices focus on medication safety through the provision of clinical pharmacy and care management services. The focus is on high-risk patients, including those with multiple co-morbid conditions and those at risk for complications from polypharmacy. Nurse care managers and clinical pharmacists conduct medication reviews and reconciliations to identify and rectify expired, duplicate, or incorrectly dosed medications. These providers also are tasked to identify reasons why patients might not be taking their medicines as prescribed and to counsel patients taking multiple medications.

The other State uses an advanced health IT system that provides patient-level information on pharmacy claims and medication history for point-of-care activities. The system also can generate population-based reports to identify patients who may benefit from clinical pharmacy and care management services. This system captures descriptions of clinical pharmacists' activities and findings, previously identified drug–drug interactions, expired medications, reconciled medications, suggested formulary medications, and changes to lower cost medication. In addition, providers at practices with advanced electronic health records (EHRs) receive alerts for patients who need refills, in order to keep track of patients' medications and to identify duplications and drug–drug interactions.

Community-Based Care Transitions Program[ix]

The goals of the Community-Based Care Transitions Program (CCTP) are to improve transitions of high-risk Medicare beneficiaries from the inpatient hospital setting to other care settings, including home. All the CCTP sites provide medication reconciliation, and two are providing a separate pharmacy intervention, whereby a pharmacist meets with the beneficiary, reviews the current medication regimen, and attempts to optimize the regimen.

[viii] More information on the Multi-Payer Advanced Primary Care Practice is available at: http://innovation.cms.gov/initiatives/Multi-Payer-Advanced-Primary-Care-Practice/

[ix] More information on the Community-based Care Transitions Program is available at: http://innovation.cms.gov/initiatives/CCTP/

Partnership for Patients[x]

The Partnership for Patients is a public–private partnership working to improve the quality, safety, and affordability of health care for Medicare, Medicaid, and CHIP beneficiaries—and, by extension, all Americans. The Partnership involves physicians, hospitals, employers, patients and patient advocates, and the Federal and State Governments to achieve two main goals:

1) Making care safer by reducing hospital-acquired conditions
2) Improving care transitions by decreasing preventable complications during transitions from one health care setting to another

The Partnership has identified 10 core safety areas of focus, including adverse drug events. Working with more than 3,700 hospitals across the United States, the program aims to eliminate approximately 1.8 million avoidable injuries.

Medicare-Medicaid Beneficiaries

The Medicare-Medicaid Coordination Office (MMCO), partnered with the Center for Medicare & Medicaid Innovation (CMMI), has launched the "Initiative To Reduce Avoidable Hospitalizations Among Nursing Facility Residents."[xi] One goal of this initiative is to improve beneficiary safety by better coordinating the management of prescription drugs, to reduce the risk of polypharmacy, improve medication reconciliation, and prevent adverse drug events.

Hospital Value-Based Purchasing and the Affordable Care Act[xii]

With the 2010 passage of the Affordable Care Act, CMS launched the Hospital Value-Based Purchasing (HVBP) Program, which provides powerful incentives, both financial and nonfinancial, to improve quality of care. CMS is considering whether to propose ADE measures for future updates to the program to reward high-quality performance.

[x] More information on the Partnership for Patients is available at: http://partnershipforpatients.cms.gov/

[xi] More information on the Initiative to Reduce Avoidable Hospitalizations Among Nursing Facility Residents is available at: http://innovation.cms.gov/initiatives/rahnfr/

[xii] More information on the Hospital Value-Based Purchasing Program is available at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html?redirect=/hospital-value-based-purchasing

Medicare and Medicaid EHR Incentive Programs[xiii]

The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 authorized CMS to establish the Medicare and Medicaid EHR Incentive Programs for meaningful use of certified EHR technology (Meaningful Use). In order to qualify for Meaningful Use incentive payments, each provider category (eligible professionals, eligible hospitals, and critical access hospitals) must meet different functional objectives.

Providers must report four measures related to ADEs:

- Maintain active medication list
- Maintain active medication allergy list
- Implement drug–drug and drug–allergy interaction checks
- Implement clinical decision support rules

Also, there are specific measures that address the prevention or reduction of ADEs related to the three main drug classes (anticoagulants, opioids, and diabetes agents). In the future, additional measures can be developed and electronically specified for a more diverse range of ADE prevention and monitoring measures.

Because existing EHR specifications that address high-priority ADE targets were limited, at the request of the HHS Office of the National Coordinator for Health IT (ONC), the FIWs for ADEs initiated discussions among the Federal partners to identify possible requirements that the EHR Incentive Program might consider to leverage EHR capabilities to further the state of ADE prevention and monitoring. Recommendations from the three FIWs related to the potential for Meaningful Use to advance the prevention of ADEs are addressed in the drug class-specific Incentives and Oversight sections.

Physician Quality Reporting System[xiv]

The Physician Quality Reporting System (PQRS) provides a series of incentive payments to eligible professionals (including physicians, physician assistants, and nurse practitioners) for meeting satisfactory reporting criteria on quality measures. Beginning in 2015, those who do not meet the

[xiii] More information on the Medicare and Medicaid EHR Incentive Programs is available at: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Meaningful_Use.html

[xiv] More information on the Physician Quality Reporting System is available at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html

criteria will receive negative payment adjustments. In an effort to align with Meaningful Use, PQRS introduced two measures that address ADEs for the 2014 Program Year:

- CMS68 (NQF #0419)—Documentation of Current Medications in the Medical Record
- CMS179—ADE Prevention and Monitoring: Warfarin Time in Therapeutic Range

The PQRS historically held an annual call for measures during which stakeholders could submit their quality measures for consideration in the program. Beginning in 2014, PQRS will move to a rolling call for measures so that developers will be able to submit measures for inclusion in the program on an ongoing basis. Through the call for measures and continuing alignment with other quality programs, additional ADE measures could be introduced in the PQRS.

Physician Feedback Program/Value-Based Payment Modifier[xv]

The goals of the Physician Feedback/Value-Based Payment Modifier Program are to improve Medicare beneficiary health outcomes and experience of care by using payment incentives and transparency to encourage higher quality, more efficiently provided health care services. The Physician Feedback Program provides confidential, comparative performance reports to physicians and clinician groups that measure the resources involved in furnishing care and the quality of care provided to Medicare beneficiaries. Beginning in 2015, CMS is also required to apply a separate, budget-neutral, value-based payment modifier to the Physician Fee Schedule based upon a physician's or clinician group's quality of care furnished as compared to cost during a performance period. CMS utilizes PQRS measures within the quality component of the value-based payment modifier calculation. These measures may include quality measures related to patient safety and any adverse drug event. CMS anticipates continued enhancements to the quality and cost measures for the value-based payment modifier as additional quality and resource use measures become available. This also would apply to any newly developed ADE measures.

[xv] More information on the Physician Feedback/Value Based Payment Modifier Program is available at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/index.html?redirect=/PHYSICIANFEEDBACKPROGRAM. The physician compare tool is accessible at: http://www.medicare.gov/PhysicianCompare/search.html

Transparency and Associated Incentives

Public reporting of health care quality data supports transparency, encourages provider accountability, and provides consumers access to information that will help them make more informed health care decisions.

Hospital Compare[xvi]

The measures currently reported on the Hospital Compare Web site include those that are reported under the Hospital Inpatient and Hospital Outpatient Quality Reporting Programs (Hospital Pay for Reporting), those used in the calculation of incentives under the Hospital Value-Based Purchasing Program, the Hospital-Acquired Conditions Program, the Hospital Readmissions Reeducation Program, and additional measures that many hospitals voluntarily report. Some of these measures are related to reduction of ADEs.

Physician Compare[xvii]

The Affordable Care Act (2010) required CMS to establish a Physician Compare website that contains information on physicians enrolled in the Medicare program as well as other eligible professionals who participate in the Physician Quality Reporting System. The specific measures posted are addressed annually through rulemaking.

Related Initiatives Addressing ADEs

In addition to the programs detailed above, CMS also oversees a variety of additional programs that have the potential to advance nationwide efforts to prevent ADEs.

Quality Improvement Organizations[xviii]

The Quality Improvement Organization (QIO) Program is a network of organizations staffed with physicians, pharmacists, nurses, technicians, and statisticians who are experts in health care quality. Currently, each QIO

[xvi] More information on Hospital Compare is available at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalCompare.html. The hospital compare tool is accessible at: http://www.medicare.gov/hospitalcompare/search.html

[xvii] More information on Physician Compare is available at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/physician-compare-initiative/

[xviii] An overview of the Quality Improvement Organization program and the programs outlined in its current statement of work is available at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs/index.html?redirect=/qualityimprovementorgs

is responsible for a U.S. State, territory, or the District of Columbia. The current contract (also known as the 10th Statement of Work) focuses on four aims: (1) Improving individual patient care, (2) beneficiary and family-centered care, (3) integrating care for populations and communities, and (4) improving health for populations and communities. The contract also focuses on the use of learning and action networks to spread and sustain positive results. Specific QIO programs related to ADE efforts are outlined below.

Reducing Adverse Drug Events Aim

Under the current contract, CMS requires QIOs to contribute to the aim of reducing and preventing ADEs and to provide medication-related quality improvement intervention strategies to health care providers, practitioners, Medicare Advantage organizations, and prescription drug sponsors. QIOs are tasked to participate in the Patient Safety and Clinical Pharmacy Services Collaborative (PSPC) as part of this aim.

The PSPC was initiated by the Health Resources and Services Administration (HRSA) and CMS, and is now a CMS-directed initiative that integrates evidence-based clinical pharmacy services into the care and management of high-risk, high-cost, and complex patients. As part of the PSPC, QIOs recruit and form teams of community health care providers and Medicare beneficiaries to transform their health care delivery systems to reduce ADEs. The QIOs also target specific populations of focus, including beneficiaries taking diabetes agents, anticoagulants, and antipsychotics.

Nationally, the QIO program has developed innovative approaches and developed best practices to reduce ADEs across several care settings. For example, one QIO has established a multidisciplinary statewide anticoagulation coalition dedicated to improving anticoagulation quality and safety using standardized dosing algorithms, root-cause analysis of potential ADEs, and connecting outcomes such as readmissions to ADEs. Another QIO has done extensive work on measure development related to ADEs that are suitable for national programs. Measure development efforts included both process and outcome measures related to the use of anticoagulants and diabetes agents. The National Quality Foundation (NQF) has endorsed two anticoagulant-related measures (NQF 555 and NQF 556) for use in the ambulatory care setting.

In addition to implementing interventions and forming community team coalitions to reduce ADEs and improve overall medication therapy management, QIOs are required to track and report measures. Measures reported by QIOs include, across time, the overall rate of ADEs, the rate of potential ADEs,

and specific measures targeting three areas of focus: anticoagulants, diabetes agents, and antipsychotic medications.

Improve Care Transitions and Decrease Readmissions

The Integrating Care for Populations and Communities Aim (ICPCA) under the 10th Scope of Work includes interventions to improve effectiveness of pharmacotherapies that can be a driver of poor care transitions and increased readmissions. Improving the effectiveness of pharmacotherapy includes supporting a patient's understanding of appropriate medication use and potential risk for adverse events, adherence to medication regimens, and detection of adverse events and overuse or underuse. These interventions also are meant to improve transfer of patient care between providers and to improve information transfer between clinical settings.

Regional Efforts

Regional Chief Medical Officer Efforts

In response to the recommendation to enhance efforts to identify and reduce ADEs in all health care settings, the regional CMS Chief Medical Officers (CMOs) collaborate directly with their peers in other regions and key medical stakeholders in order to share and provide important information about quality improvement initiatives. The CMS CMOs also participate in State and local programs, such as the Prescription Drug Monitoring Program. As CMOs present information on Affordable Care Act provisions, the importance of reducing ADEs and medication errors is emphasized. The CMS CMOs also emphasize the importance of being a meaningful user of EHRs as a means to reduce ADEs.

National Coverage Determinations[xix]

CMS provides coverage to expedite the diagnosis of ADEs associated with anticoagulants and diabetes agents. Coverage policies for diagnostic testing for these ADEs and other indications are explained in detail within CMS National Coverage Determinations (NCDs).

Within the limits established by statute for Medicare benefits, five NCDs provide Medicare coverage for a variety of diagnostic tests for detecting, mitigating, and preventing ADEs in beneficiaries being treated with either anticoagulants or hypoglycemic agents.

[xix] The list of all Medicare coverage determinations is available at: http://cms.hhs.gov/medicare-coverage-database/overview-and-quick-search.aspx?list_type=ncd

Two NCDs directly relate to detecting and preventing ADEs in patients receiving oral anticoagulants, like warfarin.

- NCD #190.11 provides for Medicare coverage for home prothrombin time (PT) testing, to help patients on warfarin test determine whether they may be out of therapeutic range. Home testing for PT/international normalized ratio (INR) decreases the risk of major hemorrhage and may improve warfarin compliance. This NCD was revised in 2008.
- NCD #90.1 provides for Medicare coverage under certain conditions for pharmacogenomic testing to inform physicians of gene variations that might increase or decrease a given patient's reaction to warfarin. Knowledge of the presence of gene variants may help predict the patient's ideal warfarin dose and lessen ADEs during the initial period of warfarin therapy. This NCD became available in 2009. Medicare (through the coverage with evidence development mechanism) is supporting ongoing clinical trials to determine this testing's actual benefit to patients.

Three NCDs directly relate to detection and prevention of ADEs in patients receiving diabetes agents, such as insulin.

- NCDs #40.1 and #40.2 provide Medicare coverage for home blood glucose monitoring (#40.2), as well as outpatient self-management training (#40.1). In combination, these NCDs provide a convenient way for patients with diabetes mellitus, working with their health care providers, to monitor blood glucose levels and achieve appropriate glucose control. Convenient and timely measurement of glucose levels can lead to adjustment of insulin dosage and help avoid the ADE of insufficient blood glucose.
- NCD #190.20 provides Medicare coverage for testing blood glucose levels in a clinical laboratory. Such testing confirms a patient's blood glucose level and may help physicians develop treatment plans for managing patients with abnormal glucose metabolism (e.g., as occurs with diabetes mellitus).

State Medicaid Drug Monitoring for ADEs in the Fee for Service Outpatient Pharmacy Program

Prescription drug coverage is an optional benefit under Federal Medicaid law; however, all States currently provide coverage for outpatient prescription drugs to most enrollees within their Medicaid programs. The Medicaid prescription drug programs include the management, development, and

administration of systems and data collection necessary to operate the Medicaid Drug Rebate program, the Federal Upper Limit calculation for multiple-source drugs, and the Drug Utilization Review (DUR) Program.

The Medicaid DUR Program[xx] promotes patient safety through State-administered utilization management tools and processes. The State Medicaid agency's electronic monitoring system screens prescription drug claims to identify problems such as therapeutic duplication, drug-disease contraindications, incorrect dosage or duration of treatment, drug allergy, and clinical misuse or abuse in order to minimize or eliminate ADEs. DUR involves ongoing and periodic examination of claims data to identify patterns of medically unnecessary care and implements corrective action when needed.

Summary

This Incentives and Oversight section reviewed the existing incentives and oversight opportunities that encourage reductions in ADEs. As we move toward improved standardized measurement for ADEs, there may be opportunities to take advantage of these currently existing mechanisms to promote safer medication management.

[xx] Detailed information on the Medicaid DUR program, along with reports the States submit annually on the operation of their programs, can be found at: http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Drug-Utilization-Review.html.