



# Adverse Drug Events and Data: A Work in Progress

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Quality Improvement  
Organizations

Sharing Knowledge. Improving Health Care.  
CENTERS FOR MEDICARE & MEDICAID SERVICES



Quality  
Insights

# Learning Objectives

- Identify the structure and goals of the QIN-QIO program
- Present overview of QIN-QIO initiatives
- State the definition of an adverse drug event (ADE)
- Recognize the three classes of drugs frequently associated with adverse drug events (anticoagulants, anti-diabetic drugs and opioids)
- Identify challenges and barriers associated with measuring and reducing ADEs in the community setting

# Learning Objectives

- State the rate of adverse drug events in NJ associated with anticoagulants, diabetes drugs and opioids
- Describe the “top 10” types of events associated with anticoagulant, diabetes drug and opioid ADEs
- Discuss how ADE data can be applied to quality improvement/prevention initiatives
- Describe outpatient quality measures that address ADEs
- Identify opportunities for pharmacists to get involved in quality improvement activities



# Who is Quality Insights?

- Quality Insights is a “QIN-QIO” – Quality Innovation Network – Quality Improvement Organization
- QIN-QIOs are healthcare consultants funded by CMS\* to work with providers (and in some cases beneficiaries) across the continuum of care to help meet health care quality goals targeted towards FFS Medicare beneficiaries
- Focus on national and local quality priorities

\*Centers for Medicare & Medicaid Services

# The QIN-QIO Program's Approach to Clinical Quality

## Aims



### Foundational Principles

- Enable innovation
- Foster learning organizations
- Eliminate disparities
- Strengthen infrastructure and data systems

Make care safer

Strengthen person and family engagement

Promote effective communication and coordination of care

Promote effective prevention and treatment

Promote best practices

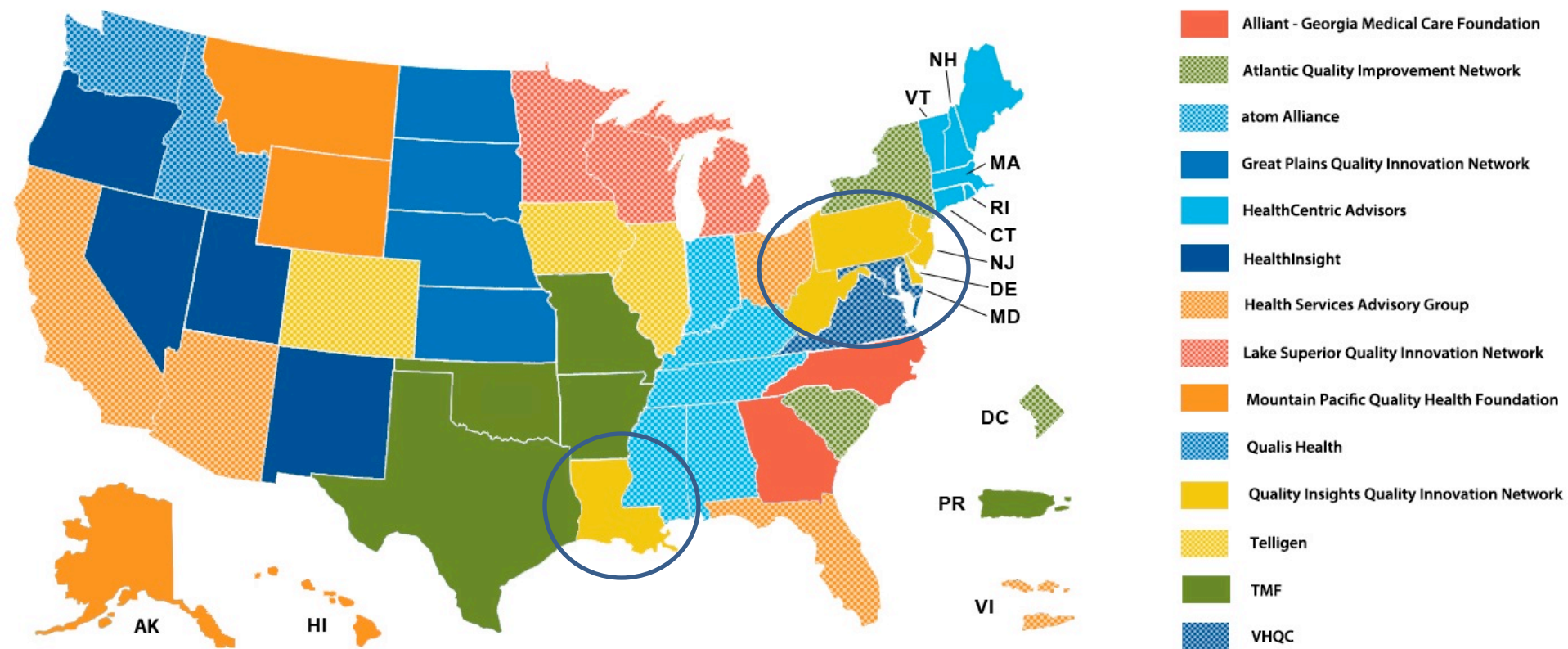
Make care affordable

# QIN-QIO: Quality Insights

- Five-year contract with CMS under its 11th Scope of Work (SoW)
- Includes Delaware, Louisiana, New Jersey, Pennsylvania and West Virginia



# QIN-QIO Map





# Four Key Roles of QIN-QIOs



- **Facilitate Learning and Action Networks (LANs)**
  - Creating an “all teach, all learn” environment
  - Placing motivation for improvement at the bedside level – e.g., handwashing
- **Teach and advise as technical experts**
  - Teach so learning is never lost
- **Champion local-level, results-oriented change**
  - Improve data
  - Active engagement of patients; convene community partners
  - Spread innovation and best practices that “stick”
- **Communicate effectively**
  - Sustain clinician, provider and patient/family behavior change



# Examples of Quality Insights Initiatives

- **Care Coordination**
  - Develop community coalitions with providers from all levels of care working together to reduce avoidable hospital readmissions
  - Support coalition activities
- **Medication Safety**
  - Work with post-acute providers, pharmacies, etc. across the state to reduce preventable ADEs with three groups of high risk medications; conduct ADE surveillance
  - Anticoagulants, diabetes drugs, opioids
- **Opioid misuse and diversion**

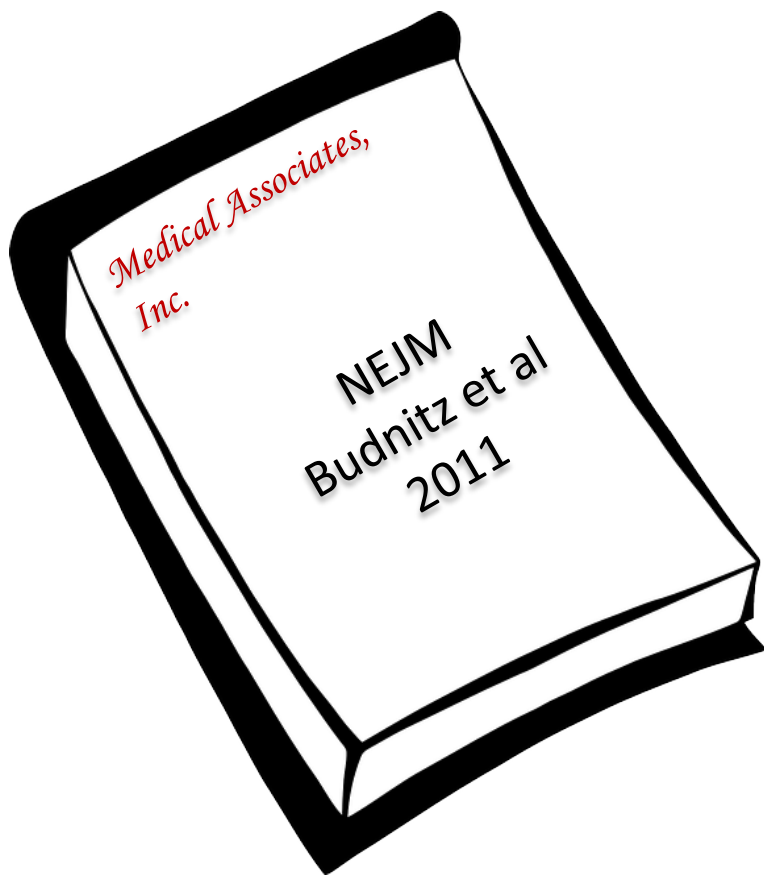
# Definition of Adverse Drug Event

- Adverse Drug Event (ADE): An injury resulting from medical intervention related to a drug.<sup>1</sup>



1. Kohn, LT, et al. (Institute of Medicine). To err is human: building a safer health system. Washington, DC: National Academy Press, 2000.

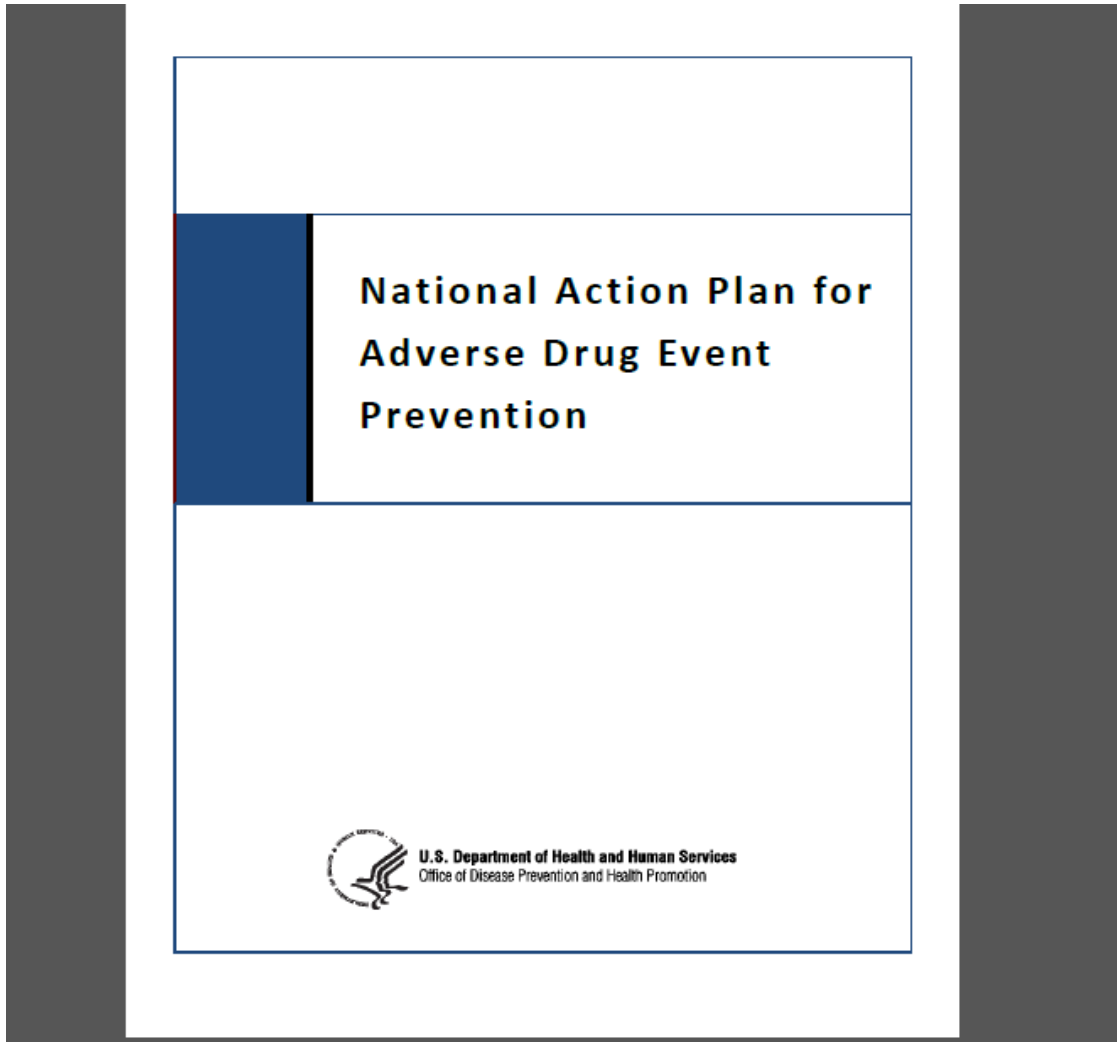
# Application to Consultant Pharmacists?



Emergency Hospitalizations for  
Adverse Drug Events in Older  
Americans

Four medication classes were  
implicated in  
67 percent of events  
(95 percent CI 60.0 to 74.1)

- Oral hypoglycemics (11%)
- Oral antiplatelets (13%)
- Insulins (14%)
- Warfarin (33%)



<http://www.health.gov/hai/ade.asp#action-plan>

# Messages from the National Action Plan

- Reduce adverse drug events at the community/population level
- Identify events that are common, preventable and measurable

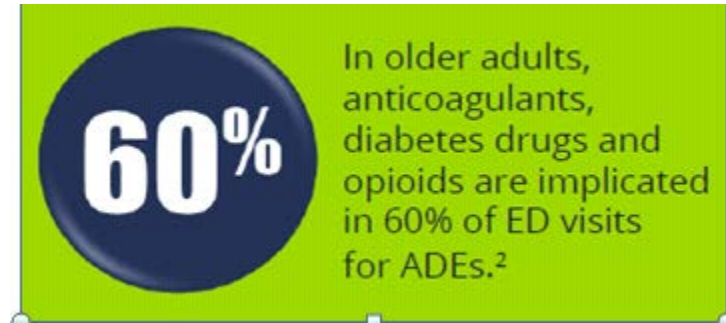
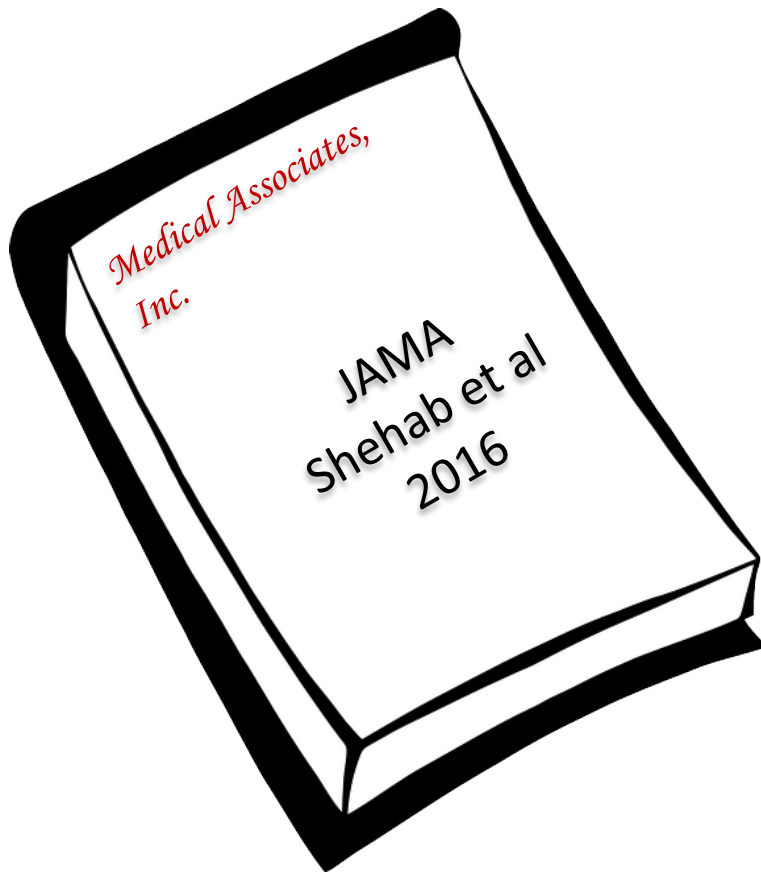
Diabetes drugs:  
hypoglycemia



Anticoagulants:  
Bleeding

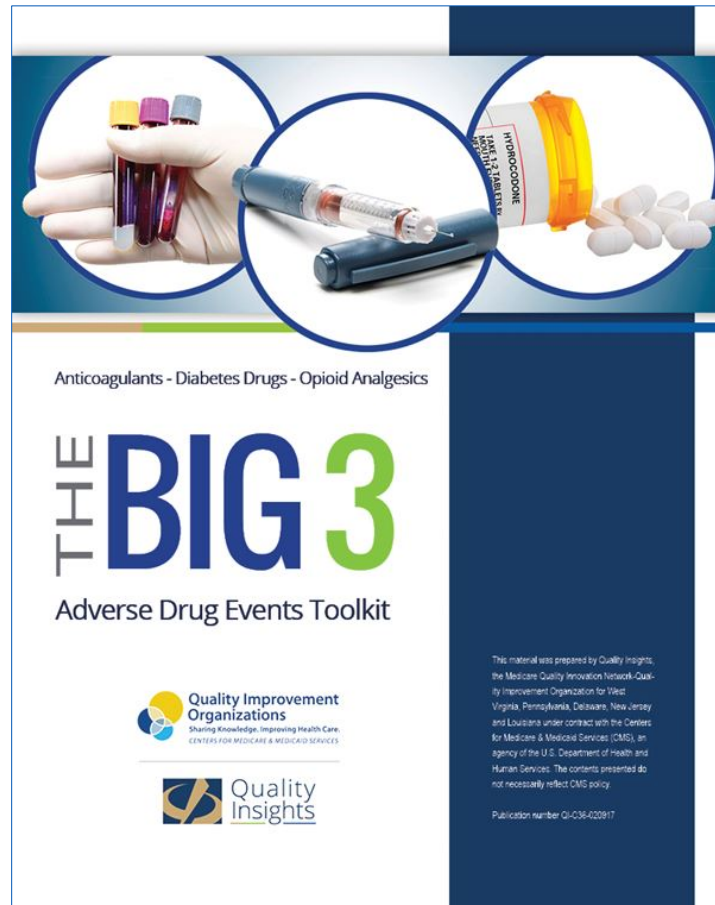
Opioids: accidental overdose,  
oversedation, respiratory  
depression

# Which Drugs Cause ADEs?



- Update to original Budnitz study
- ED visits related to outpatient ADEs
- Data set 2013-2014
- DOACs (Direct Acting Oral Anticoagulants) included

# The Big Three of Adverse Drug Events



Available to project participants only – reach out to your state contact



# Measuring Community ADEs

## Measurement

- Limited/no definitions or validated measures
  - Some on the way?
- Limited/no data sources
  - Claims, self-reported
- Limited ability to gather/report self-reported data/resistance to reporting
  - Community pharmacy, home health, physician practice, urgent care, ED?
- ???

# Preventing Community ADEs

- Identify proven best practices & interventions (BP&Is)
  - Anticoagulation clinic, chronic disease management, MTM, diabetes self-management educations?
- Identify settings to implement BP&Is
  - Varies by intervention
- Implement BP&Is
  - Barriers – lack of reimbursement, scope of work limitations, patient factors (engagement, health literacy)
- Measure results
- ???

# Adverse Drug Event Rates – Claims Experiment

- Medicare Fee for Service Claims
  - Inpatient, emergency department claims
  - ICD9/ICD10 codes associated with drug related events (no official list – several versions)
  - **Medicare Part A, D claims for anticoagulants, diabetes drugs and opioids\***
  - Not validated measure, ADEs considered “possible or potential”
  - Serves as a guide or starting point

\*Intentional overdose and addiction related codes excluded

# Quality Insights Data Portal

## QUALITY INSIGHTS LOGIN

Welcome to the Quality Insights login area for registered users. Below are t



### My Quality Insights

Community training and resources.



### Report Data

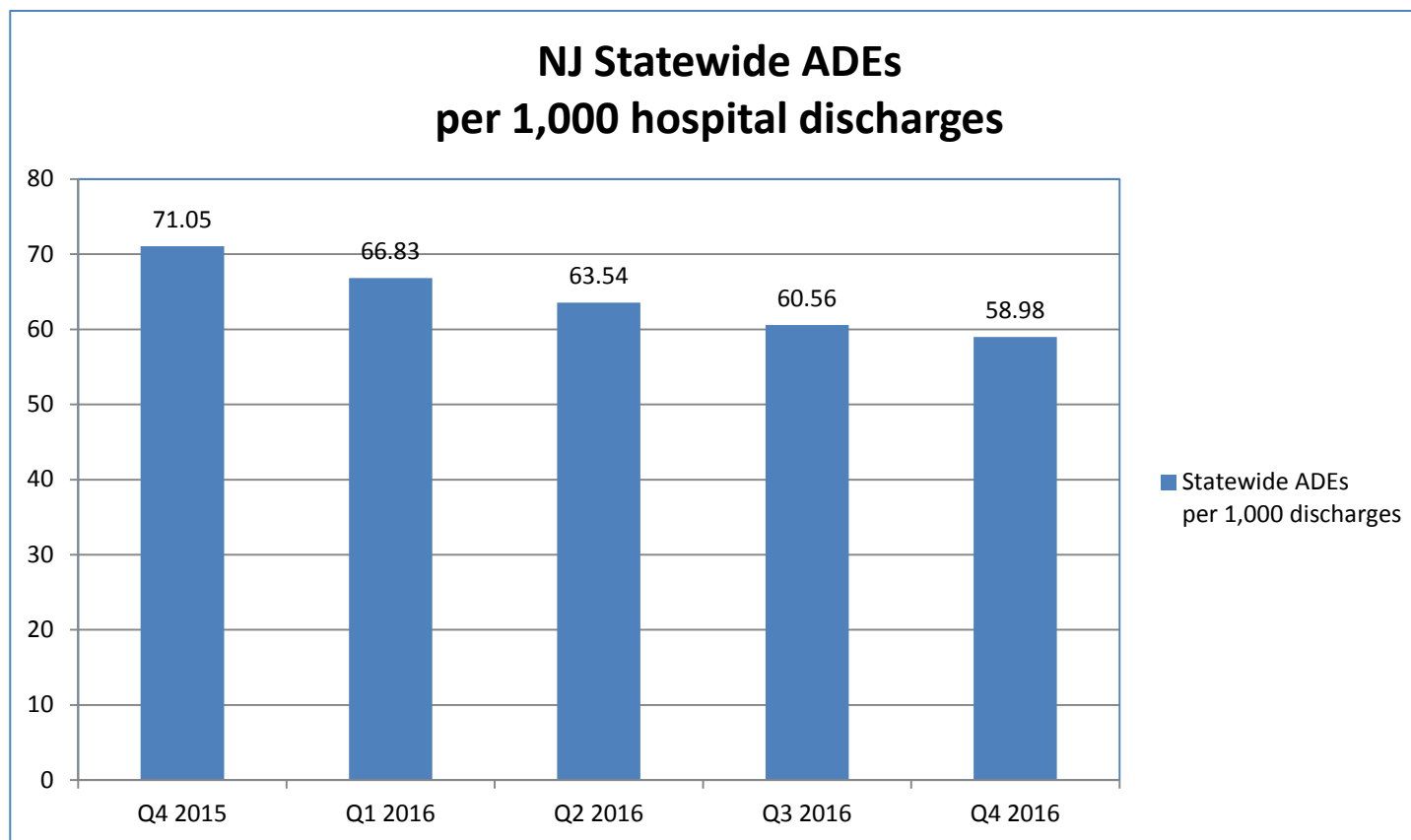
Participant monitoring reports

#### MyQI References

Introducing the *My Quality Insights* Learning Platform Webinar Handout

- Hospital specific readmission and ADE report
- Community level ADE reports
- Nursing home reports
- Physician practice reports
- Home health reports
- And more...

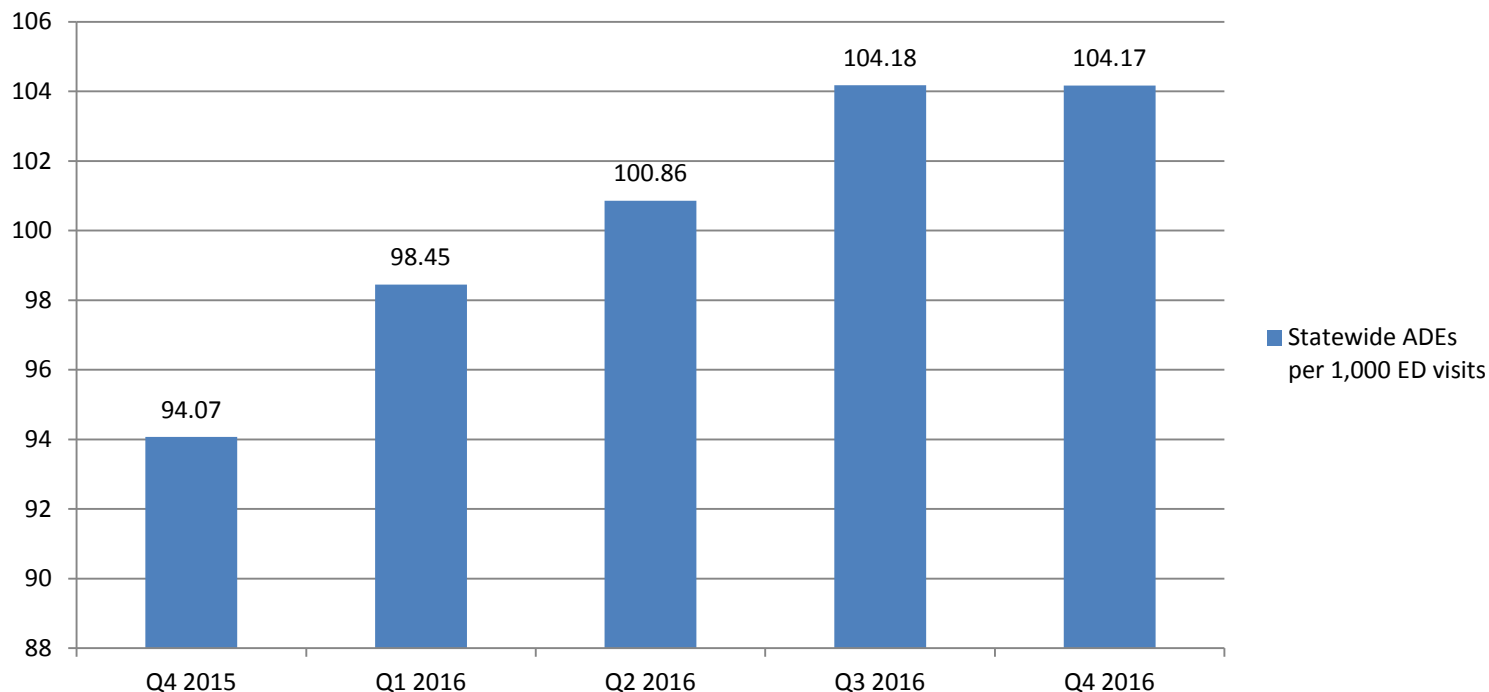
# NJ - ADE Rates per 1000 Discharges



Medicare FFS part A and D claims, ICD10 codes available upon request

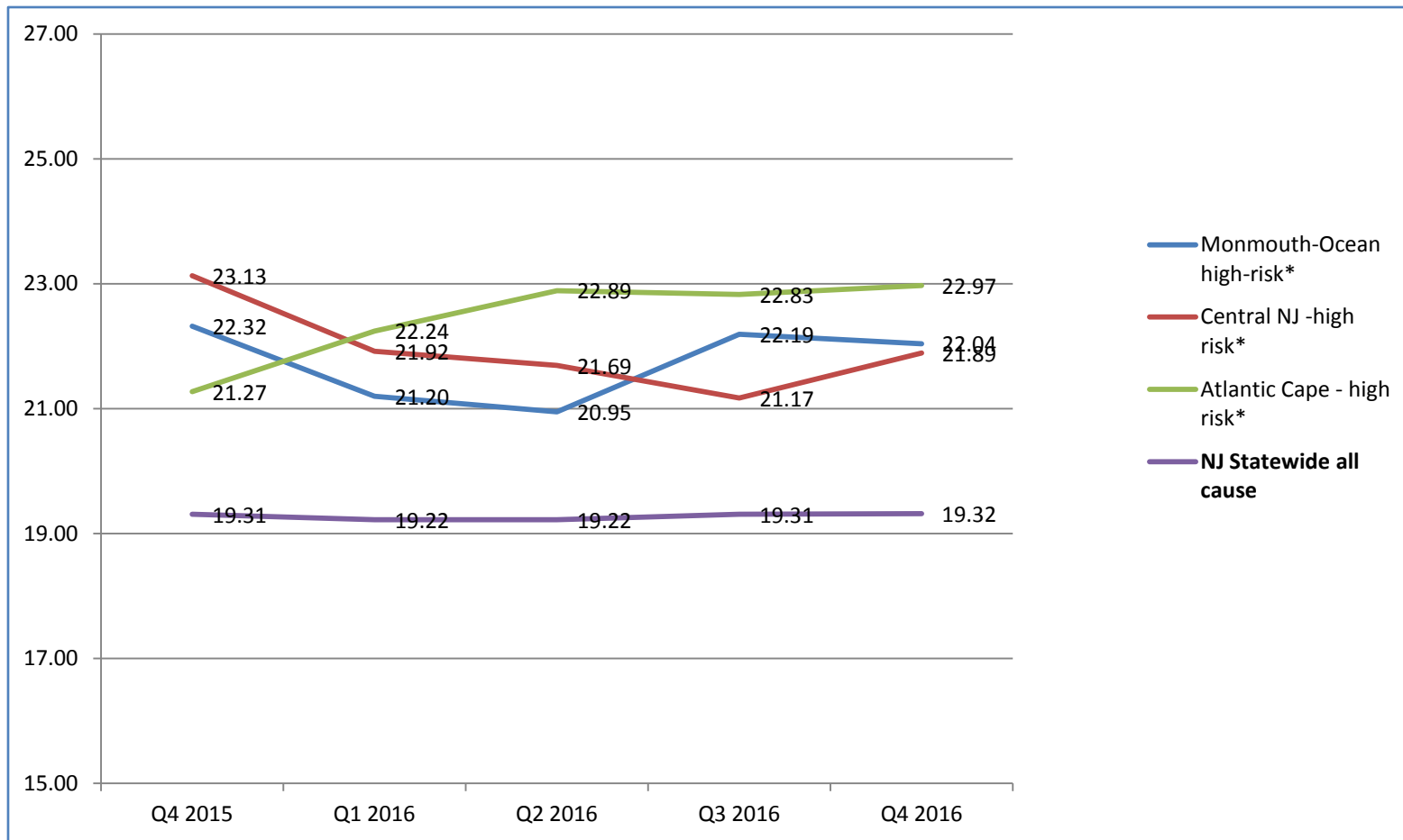
# NJ – ADE rates per 1000 ED Visits

**NJ Statewide ADEs  
per 1,000 ED visits**



Medicare FFS part A and D claims, ICD10 codes available upon request

# NJ Readmission Rates (%)- Big Three



\*High risk – defined as FFS beneficiary with Medicare D on 3 or more chronic medications with 1 or more anticoagulant, diabetes drug or opioid.



# Most Common ICD-10 Codes – Anticoagulants\*

ICD10	# of events	Percentage	Potential Anticoagulant Events - Inpatient	ICD10 ED	# of events ED	Percentage %	Potential Outpatient Events - Emergency Dept Visits
K922	646	28.66	Gastrointestinal hemorrhage, unspecified	R040	1015	44.58	Epistaxis
K921	185	8.21	Melena	R319	225	9.88	Hematuria, unspecified
D62	126	5.59	Acute posthemorrhagic anemia	R791	204	8.96	Abnormal coagulation profile
D649	114	5.06	Anemia, unspecified	D649	186	8.17	Anemia, unspecified
R310	97	4.3	Gross hematuria	K625	83	3.65	Hemorrhage of anus and rectum
K254	88	3.9	Chronic or unspecified gastric ulcer with hemorrhage	K922	75	3.29	Gastrointestinal hemorrhage, unspecified
K648	82	3.64	Other hemorrhoids	R310	61	2.68	Gross hematuria
K625	81	3.59	Hemorrhage of anus and rectum	R042	58	2.55	Hemoptysis
D500	70	3.11	Iron deficiency anemia secondary to blood loss (chronic)	R58	40	1.76	Hemorrhage, not elsewhere classified
K264	66	2.93	Chronic or unspecified duodenal ulcer with hemorrhage	H1131	34	1.49	Conjunctival hemorrhage, right eye
				H1132	30	1.32	Conjunctival hemorrhage, left eye

\*CY 2016 Medicare FFS claims only, ICD10 codes available on request

# Most Common ICD-10 Codes – Diabetes Drugs\*

ICD10	# of events	Percentage	Potential Diabetes Drug Events - Inpatient	ICD10 ED	# of events ED	Percentage ED	Potential Diabetes Events - Emergency Dept Visits
R55	457	66.72	Syncope and collapse	R55	650	51.22	Syncope and collapse
R4182	138	20.15	Altered mental status, unspecified	R4182	297	23.4	Altered mental status, unspecified
T383X1A	49	7.15	Poisoning by insulin and oral hypoglycemic [antidiabetic] drugs, accidental	E162	193	15.21	Hypoglycemia, unspecified
E160	21	3.07	Drug-induced hypoglycemia without coma	R410	50	3.94	Disorientation, unspecified
R410	11	1.61	Disorientation, unspecified	T383X1A	40	3.15	Poisoning by insulin and oral hypoglycemic [antidiabetic] drugs, accidental
E162	9	1.31	Hypoglycemia, unspecified	E160	15	1.18	Drug-induced hypoglycemia without coma
				T383X5A	14	1.1	Adverse effect of insulin and oral hypoglycemic [antidiabetic] drugs
				E161	6	0.47	Other hypoglycemia
				E08649	4	0.32	Diabetes mellitus due to underlying condition with hypoglycemia without coma

\*CY 2016 Medicare FFS claims only, ICD10 codes available on request

# Most Common ICD-10 Codes – Opioids\*

ICD10	# of events	Percentage	Potential Opioid Events - Inpatient	ICD 10 ED	# of ED events	Percentage %	Potential Opioid Events - Emergency Dept Visits
R55	321	20.62	Syncope and collapse	R55	511	44.86	Syncope and collapse
J9601	284	18.24	Acute respiratory failure with hypoxia	R4182	229	20.11	Altered mental status, unspecified
F1123	278	17.85	Opioid dependence with withdrawal	F1123	107	9.39	Opioid dependence with withdrawal
T402X1A	136	8.73	Poisoning by other opioids, accidental (unintentional)	R410	58	5.09	Disorientation, unspecified
J9602	115	7.39	Acute respiratory failure with hypercapnia	T402X1A	45	3.95	Poisoning by other opioids, accidental (unintentional)
J9600	114	7.32	Acute respiratory failure, unspecified whether with hypoxia or hypercapnia	T40601A	35	3.07	Poisoning by unspecified narcotics, accidental (unintentional)
R4182	109	7	Altered mental status, unspecified	R0902	19	1.67	Hypoxemia
T40601A	62	3.98	Poisoning by unspecified narcotics, accidental (unintentional)	R440	16	1.4	Auditory hallucinations
R410	15	0.96	Disorientation, unspecified	R404	11	0.97	Transient alteration of awareness
T404X1A	14	0.9	Poisoning by other synthetic narcotics, accidental (unintentional)	R443	10	0.88	Hallucinations, unspecified

\*Intentional overdose and addiction related codes excluded; CY 2016 Medicare FFS claims only, ICD10 codes available on request

# Other Uses of Claims Data

- Identifying trends within a specific population
  - Rates of hypo/hyperglycemia
  - Combined use of opioids and benzodiazepines
  - Bleeding in patients on oral anticoagulants
  - Use of transitional care management (TCM) office visits
  - Utilization of Medicare Annual Wellness Visits (AWV)
  - Healthcare utilization (readmissions, primary care visits, ED visits) in diabetes self-management education workshop participants

# National Outpatient ADE Measures

- Developed by Federal Office of Disease Prevention and Health Promotion (ODPHP) in collaboration with other agencies
  - Outcomes-based rather than process-based
  - Derived from surveillance systems that (a) are nationally-representative, (b) can provide baseline estimates from which to measure progress on prevention, and (c) use consistent and stable ADE measurement methodology for the foreseeable future
  - Align ADE measurement with other departmental medication safety measures and goals (e.g., [Partnership for Patients](#), [Healthy People 2020](#))

<https://health.gov/hcq/ade-measures.asp>

# “Big Three” High Risk Medications

- Reduce U.S. emergency department visits for adverse drug events (unintended measurable harm or injury) from anticoagulants
- Reduce U.S. emergency department visits for adverse drug events (unintended measurable harm or injury) from diabetes agents
- Reduce U.S. emergency department visits for adverse drug events (unintended measurable harm or injury associated with therapeutic use) from opioid analgesics

<https://health.gov/hcq/ade-measures.asp>

Measure <sup>1</sup>	Numerator	Denominator	Target Reduction	Departmental Measure Alignment
Rate of visits to U.S. hospital EDs for injury from oral anticoagulants	Number of visits to U.S. hospital EDs for injury from oral anticoagulants	Number of patients receiving dispensed oral anticoagulants in U.S. retail outpatient settings	10%	HHS <a href="#">Healthy People 2020</a> Medical Product Safety Objective 5.1 <sup>2</sup>
Rate of visits to U.S. hospital EDs for injury from insulin	Number of visits to U.S. hospital EDs for injury from insulin	Number of patients receiving dispensed insulin in U.S. retail outpatient settings	10%	HHS <a href="#">Healthy People 2020</a> Medical Product Safety Objective 5.2 <sup>3</sup>
Rate of visits to U.S. hospital EDs for injury associated with therapeutic use of opioid analgesics	Number of visits to U.S. hospital EDs for injury associated with therapeutic use of opioid analgesics	Number of patients receiving dispensed opioid analgesics in U.S. retail outpatient settings	10%	HHS <a href="#">Healthy People 2020</a> Medical Product Safety Objective 2.3 <sup>4</sup>

<https://health.gov/hcq/ade-measures.asp>

[https://www.healthypeople.gov/2020/topics-objectives/topic/medical-product-safety/objectives?\\_ga=2.51327146.2090885034.1509327740-1066437703.1484063261](https://www.healthypeople.gov/2020/topics-objectives/topic/medical-product-safety/objectives?_ga=2.51327146.2090885034.1509327740-1066437703.1484063261)



# Data Sources ODPHP Measures

- Numerator: NEISS-CADES (CDC): Data sampling from inpatient and ED medical record review.
  - Jhung MA, et al. [Evaluation and overview of the national electronic injury surveillance system-cooperative adverse drug event surveillance project \(NEISS-CADES\) \[PDF - 434 KB\]](#). *Medical Care* 2007;45 (10 Suppl 2):S96–S102
- Denominator: Total Patient Tracker<sup>®</sup>, IMS Health<sup>™</sup> data – obtained through FDA
  - Estimates total number of unique patients across all drugs and therapeutic classes in the retail outpatient setting over time. (Data from Vector One<sup>®</sup> database- prescription activity from a sample received from payers, switches, and other software systems)

# QPP/MIPS/MACRA Connections

**Many services require documentation of current medications and/or completion of medication reconciliation:**

- Annual Wellness Visit
- Chronic Care Management
- Initial Preventive Physical Exam
- Transitional Care Management

# QPP/MIPS/MACRA Connections, cont.

**Medication management and medication reconciliation are required for new quality measures and MACRA Improvement Activities:**

- NQF #0419 Documentation of Current Medications in the Medical Record
- NQF #0097 Medication Reconciliation Post-Discharge
- NQF #0022 Use of High-risk Medications in the Elderly
- ACI\_HIE\_3 Clinical Information Reconciliation
- IA\_PM\_16 Implementation of Medication Management Practice Improvements
- **Chronic Stable Coronary Artery Disease (CAD) Ischemic Vascular Disease: Antiplatelet Therapy**
- VTE prophylaxis with anticoagulant
- Stroke/Afib - anticoagulant prophylaxis
- Use of high-risk meds in the elderly (Beers list)
- Opioids – therapy follow up eval, pain agreement, screen for abuse/misuse

# Warfarin Adverse Events in Nursing Home Residents



The Washington Post

- July 12<sup>th</sup>, 2015 article
- 2011-2014 165 people in nursing homes hospitalized/died due to warfarin errors

[https://www.washingtonpost.com/national/health-science/popular-blood-thinner-causing-deaths-injuries-in-nursing-homes/2015/07/12/be34f580-1469-11e5-89f3-61410da94eb1\\_story.html?utm\\_term=.313094bf77b5](https://www.washingtonpost.com/national/health-science/popular-blood-thinner-causing-deaths-injuries-in-nursing-homes/2015/07/12/be34f580-1469-11e5-89f3-61410da94eb1_story.html?utm_term=.313094bf77b5)

# Long-Term Care Guidance?

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop C2-21-16  
Baltimore, Maryland 21244-1850



**Center for Clinical Standards and Quality/Survey & Certification Group**

Ref: S&C: 15-47-NH

**DATE:** July 17, 2015  
**TO:** State Survey Agency Directors  
**FROM:** Director  
Survey and Certification Group  
**SUBJECT:** Medication-Related Adverse Events in Nursing Homes

## Memorandum Summary

- **Medication-Related Adverse Events** – Adverse events related to high risk medications can have devastating effects to nursing home residents. Proper management of high risk medications represents a serious challenge for nursing homes, and merits close attention by top management and staff throughout the facility. We are very concerned about the prevalence of adverse events involving such medications.
- **Focused Survey on Medication Safety Systems and Adverse Drug Event Trigger Tool** – The Centers for Medicare & Medicaid Services (CMS) has begun pilot testing a

**Trigger Tool:** Addresses prevention of ADEs and facility procedures and documentation for many high-risk drugs/conditions

- Change in mental status
- Psychotropics
- Hypoglycemia
- Ketoacidosis – insulin
- Thrombosis – anticoagulants
- Constipation – opioids
- Electrolytes – diuretics
- Etc.

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-47.pdf>

# CMS Survey and Certification Letter: Medication-Related Adverse Events in Nursing Homes – Trigger Tool

Adverse Drug Event	Risk Factors These increase the potential for ADEs. Multiple factors increase risk.	Triggers: Signs and Symptoms (S/S) Any of these may indicate an ADE may have occurred.	Triggers: Clinical Interventions These actions may indicate an ADE occurred.
<b>Anticoagulant/antithrombotic Bleeding and/or Thromboembolism</b>	<ul style="list-style-type: none"> <li>• Anticoagulant, antiplatelet, or thrombolytic medication use</li> <li>• Concurrent use of more than one antithrombotic medication (e.g., use of aspirin while on anticoagulants)</li> <li>• History of stroke or GI bleed</li> <li>• NSAID medication use while on anticoagulants</li> <li>• Antibiotics use while on anticoagulants</li> <li>• Amiodarone use while on anticoagulants</li> <li>• Dietary changes affecting vitamin K intake (e.g., dark leafy greens)</li> <li>• Prolonged immobility</li> <li>• Recent major surgery</li> <li>• Prior history of VTE</li> <li>• Consistently sub-therapeutic PT/INR</li> </ul>	<ul style="list-style-type: none"> <li>• Elevated PT/INR, PTT</li> <li>• Low platelet count</li> <li>• Bruising, Nosebleeds, Bleeding gums</li> <li>• Prolonged bleeding from wound, IV, or surgical sites</li> <li>• Blood in urine, feces, or vomit</li> <li>• Coughing up blood</li> <li>• Abrupt onset hypotension</li> <li>• Pain or tenderness and swelling of upper or lower extremity</li> <li>• Increased warmth, edema and/or erythema of affected extremity</li> <li>• Unexplained shortness of breath</li> <li>• Chest pain • Coughing • Hemoptysis</li> <li>• Feelings of anxiety or dread</li> </ul>	<ul style="list-style-type: none"> <li>• Stat order for PT/INR, PTT, platelet count, or CBC</li> <li>• Abrupt stop order for medication</li> <li>• Administration of Vitamin K</li> <li>• Transfer to hospital</li> <li>• Stat chest x-ray</li> </ul>
<b>Diabetic Agents Hypoglycemia</b>	<ul style="list-style-type: none"> <li>• Insulin use</li> <li>• Sliding scale insulin use</li> <li>• Oral hypoglycemic (sulfonylureas) and/or injectable hypoglycemic medication use</li> <li>• Decrease in oral intake while taking antidiabetic medication</li> </ul>	<ul style="list-style-type: none"> <li>• Hypoglycemia (e.g., &lt;50 mg/dl)</li> <li>• Falls • Headache</li> <li>• Shakiness, nervousness, anxiety</li> <li>• Sweating, chills, clamminess</li> <li>• Irritability, impatience</li> <li>• Change in mental status</li> <li>• Emotional changes (including new anger, sadness, stubbornness)</li> <li>• Lightheadedness, dizziness • Hunger, Nausea</li> <li>• Complaints of blurred or impaired vision</li> <li>• Tingling or numbness in lips and/or tongue</li> <li>• Weakness, fatigue, or somnolence</li> <li>• Incoordination • Seizures • Unconsciousness</li> <li>• Rapid heartbeat</li> </ul>	<ul style="list-style-type: none"> <li>• Stat Glucagon or IV dextrose</li> <li>• Administration of orange juice or other high sugar food or fluids in response to blood sugar reading or symptoms</li> <li>• Transfer to hospital</li> </ul>
<b>Opioid over-sedation, respiratory depression</b>	<ul style="list-style-type: none"> <li>• PRN or routine use of opioid medication</li> <li>• Opioid naïveté (someone who has not been taking opioids)</li> <li>• Opioids used in combination with sedatives or other opioids</li> <li>• History of opioid abuse • Opioid tolerance</li> <li>• Severe pain • Low fluid intake/dehydration</li> <li>• Low body weight</li> <li>• History of head injury, traumatic brain injury, or seizures</li> </ul>	<ul style="list-style-type: none"> <li>• Falls • Hallucinations • Delusions</li> <li>• Disorientation or confusion</li> <li>• Light-headedness, dizziness, or vertigo</li> <li>• Lethargy or somnolence</li> <li>• Agitation • Anxiety • Unresponsiveness</li> <li>• Decreased               <ul style="list-style-type: none"> <li>• BP</li> <li>• Pulse</li> <li>• Pulse oximetry</li> </ul> </li> <li>• Respirations</li> </ul>	<ul style="list-style-type: none"> <li>• Administration of <b>Narcan</b></li> <li>• Transfer to hospital</li> <li>• Call to physician regarding new onset of relevant signs or symptoms</li> <li>• Abrupt stop order for medication</li> </ul>

# ADE Trigger Tool

Drug Class	Surveyor Probes - These questions are designed to assist in the investigation. A negative answer does not necessarily indicate noncompliance.
Anticoagulant/Anti-thrombotic (bleeding, thromboembolism)	<ul style="list-style-type: none"><li>• Does the medical record include documentation of clinical indication?</li><li>• <b>Is there evidence the facility routinely monitors lab results of all residents on anticoagulant/antiplatelet therapy?</b></li><li>• <b>Is there a system to ensure lab results, including PT/INRs, are appropriately communicated to the physician including when panic values are obtained?</b></li><li>• Is there evidence that the facility educates caregivers on risk factors and symptoms and signs that may be indicative of excessive bleeding due to antithrombotic medications?</li><li>• Are residents/families educated regarding the risks associated with antithrombotic medication use and the signs and symptoms of excessive bleeding?</li><li>• <b>Is there evidence of system to alert prescribers and nursing staff when anticoagulants are combined with other drugs which increase the risk of bleeding?</b></li><li>• Does the resident's dietary plan include recognition of foods that interact with antithrombotic medications (e.g., is there a plan to ensure consistent intake of foods and beverages rich in Vitamin K for residents on warfarin)?</li></ul>

# CMS Survey and Certification Letter

Drug Class	Surveyor Probes - These questions are designed to assist in the investigation. A negative answer does not necessarily indicate noncompliance.
Diabetic Agents - hypoglycemia	<ul style="list-style-type: none"><li>• Does the care plan reflect interdisciplinary monitoring for:</li><li>• <b>Signs/symptoms of hypoglycemic episodes?</b></li><li>• <b>Changes in oral intake?</b></li><li>• Is there evidence blood glucose testing and insulin administration are coordinated with meals?</li><li>• <b>Is there evidence the facility has addressed any pharmacy recommendations?</b></li><li>• <b>If sliding scale insulin is used, does the medical record contain documentation of risk vs. benefits? Clinical rationale?</b></li><li>• If an EHR is used, are finger stick glucose testing results incorporated into it?</li><li>• <b>Is there evidence that finger stick glucose results are routinely reviewed for effectiveness as part of the care plan?</b></li><li>• Is there evidence that the facility routinely educates caregivers on risk factors and symptoms/signs of hypoglycemia?</li><li>• Is the resident and family educated regarding the signs and symptoms of hypoglycemia and regarding the resident's diabetes management plan</li><li>• Does the facility have low blood sugar protocols in place?</li><li>• <b>Is there a system to ensure lab results, including finger stick blood glucose results, are appropriately communicated to the physician and the dietician including when panic values are obtained?</b></li><li>• <b>Is there evidence that glucose monitoring equipment is maintained and that staff technique meets standards of practice?</b></li></ul>



# CMS Survey and Certification Letter

Drug Class	Surveyor Probes - These questions are designed to assist in the investigation. A negative answer does not necessarily indicate noncompliance.
Opioid – over-sedation, respiratory depression	<ul style="list-style-type: none"><li>• Is there an assessment and determination of pain etiology?</li><li>• Does the resident’s pain management regime address the underlying etiology?</li><li>• <b>For a change in mental status, is there evidence that the physician conducted an evaluation of the underlying cause, including medications?</b></li><li>• Is there evidence of a system for ensuring that residents are routinely assessed for pain, including monitoring for effectiveness of pain relief and side effects of medication (e.g., over-sedation)?</li><li>• If receiving PRN and routinely, is there consideration for the timing of administration of the PRN?</li><li>• <b>Can staff describe signs/symptoms of over-sedation?</b></li><li>• <b>Is there evidence of a system for ensuring “hand off” communication includes the resident’s pain status and time of last dose?</b></li><li>• Do the resident, family, and direct caregivers know signs and symptoms of over-sedation and steps to take if noted (e.g., alert the nurse)?</li><li>• Is there evidence the facility implements non-pharmacological pain management approaches?</li><li>• <b>Is there a system to ensure extended-release formulations are delivered correctly (e.g. meds not crushed?)</b></li></ul>

# Other Quality Initiatives



# Comprehensive Care for Joint Replacement Model

- A proposed model to support better and more efficient care for Medicare beneficiaries undergoing hip and knee replacements
  - Flat rate paid for 90 day post discharge “episode of care” covering all Medicare Part A and B charges
- <https://innovation.cms.gov/initiatives/CJR>
- ADE prevention opportunities: anticoagulation management/education, medication distribution, care coordination

# Skilled Nursing Facility Value-Based Purchasing Program

- Part of the Protecting Access to Medicare Act of 2014
- Beginning 10/1/18, 2% of Medicare reimbursement for skilled nursing facilities to be withheld
- Nursing homes with low readmission rates (based on Calendar Year 2017 data) will receive incentive payments—maybe more than 2%
- Nursing homes with the highest **all cause** readmission rates will not receive incentive payments
- **ADE prevention opportunities: medication reconciliation, patient education, discharge planning, care coordination, etc.**

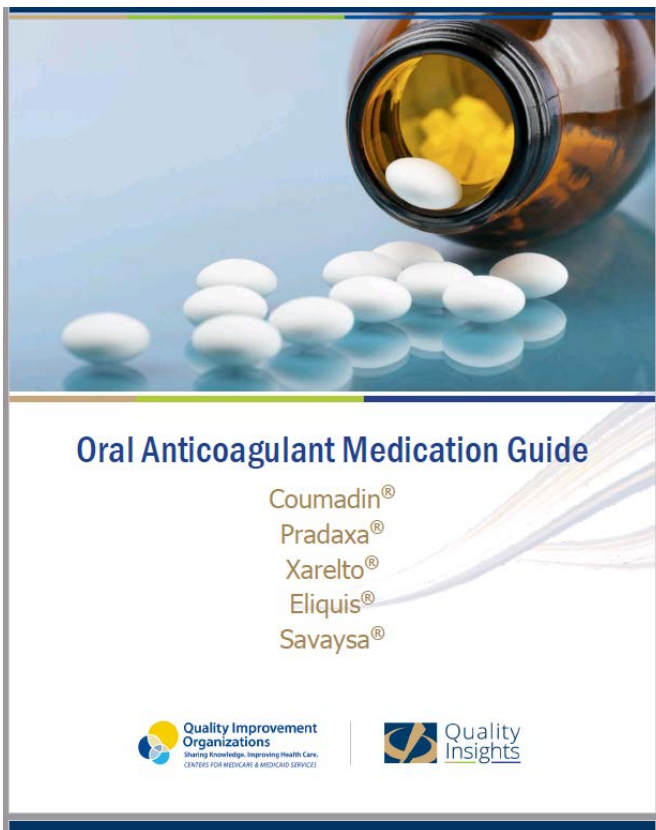
# IMPACT Act (Improving Medicare Post-Acute Care Transformation)

- Bipartisan bill passed on September 18, 2014 and signed into law by President Obama on October 6, 2014
- Requires Standardized Patient Assessment Data that will enable data element uniformity
- Quality care and improved outcomes
- Comparison of quality and data across post-acute care (PAC) settings
- Improved discharge planning
- Exchangeability of data
- Coordinated care

# IMPACT Act

- Measure Domains to be standardized:
- Skin integrity and changes in skin integrity
- Functional status, cognitive function, and changes in function and cognitive function
- **Medication reconciliation (10/2018 begin reporting)**
- Incidence of major falls
- Transfer of health information and care preferences when an individual transitions
- Resource use measures, including total estimated Medicare spending per beneficiary
- Discharge to community
- All-condition risk-adjusted potentially preventable hospital readmissions rates
- **ADE prevention opportunities: medication reconciliation, falls, cognitive function, transitions, discharge to community, readmissions**

# Anticoagulation Tools



**Oral Anticoagulant Medication Guide**

Coumadin®  
Pradaxa®  
Xarelto®  
Eliquis®  
Savaysa®

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**Warfarin SBAR Form**  
Report to a physician a SUB-therapeutic/SUPRA-therapeutic INR.

<b>S</b>	<b>SITUATION:</b> <ul style="list-style-type: none"> <li>I am calling about (name of patient).</li> <li>The patient's INR is _____.</li> <li>The patient's target INR range is (2.0 - 3.0), or (2.5-3.5), or _____ and the above reported INR is considered SUB-therapeutic/SUPRA-therapeutic.</li> <li>The patient IS/IS NOT experiencing bruising.</li> <li>The patient IS/IS NOT experiencing bleeding.</li> <li>The patient HAS/HAS NOT fallen.</li> </ul>
<b>B</b>	<b>BACKGROUND:</b> <ul style="list-style-type: none"> <li>The patient is allergic to the following medications: _____</li> <li>The patient HAS/HAS NOT had Heparin Induced Thrombocytopenia (HIT)</li> <li>The patient HAS/DOES NOT HAVE a mechanical valve (Mitral/Aortic)</li> <li>Table (I) Quick Reference Guide and Table (II) Potential Drug Interactions (see Appendix) with warfarin have been reviewed.</li> </ul>
<b>A</b>	<b>ASSESSMENT:</b> <ul style="list-style-type: none"> <li>_____The INR may be the result of a missed or held warfarin dose</li> <li>_____The INR may be the result of a potential drug interaction with warfarin</li> <li>_____The INR may be the result of a Vitamin K (dietary or supplement) source</li> <li>_____The INR may be the result of a concomitant illness such as: diarrhea, fever, hepatic disorder, nutritional status and/or CHF exacerbation</li> <li>_____Other _____</li> </ul>
<b>R</b>	<b>RECOMMENDATIONS:</b> <p>_____It is determined that a potential drug interaction may exist between warfarin sodium (Coumadin®) and _____:</p> <ul style="list-style-type: none"> <li><input type="radio"/> The new medication may ELEVATE the patients INR with the next INR to be drawn: ____/____/____</li> <li><input type="radio"/> The new medication may DECREASE the patients INR with the next INR to be drawn: ____/____/____</li> <li><input type="radio"/> The new medication is CONTRAINDICATED with warfarin and should NOT be dispensed</li> </ul> <p>_____The INR warrants administration of _____ mg of oral Vitamin K1 (phytonadione) with the next INR to be drawn: ____/____/____</p> <p>_____The INR warrants administration of Heparin or Low Molecular Weight Heparin (LMWH) 'bridge' with the next INR to be drawn: ____/____/____</p> <p>_____No change to the warfarin regimen. The next INR is to be drawn: ____/____/____.</p> <p>_____Hold the warfarin dose as follows (specify dates): _____.</p> <p>_____Change the warfarin regimen to _____ with the next INR to be drawn: ____/____/____.</p> <p>_____The situation warrants transportation to an Emergency Room for further evaluation and/or treatment.</p> <p>_____Other _____</p>

Evaluated by Nursing Supervisor: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_  
 Evaluated by Dispensing Pharmacist: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_  
 Evaluated by Physician: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

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# Anticoagulation Tools


## Anticoagulant Table

	Coumadin® (Warfarin)	Pradaxa® (Dabigatran etexilate)	Xarelto® (Rivaroxaban)	Eliquis® (Apixaban)	Savaysa® (Edoxaban)
<b>Indications</b>	<ul style="list-style-type: none"> <li>Prophylaxis and treatment of venous thrombosis and its extension, pulmonary embolism (PE)</li> <li>Prophylaxis and treatment of thromboembolic complications associated with atrial fibrillation (AF) and/or cardiac valve replacement</li> <li>Reduction in the risk of death, recurrent myocardial infarction (MI), and thromboembolic events such as stroke or systemic embolization after MI</li> </ul>	<ul style="list-style-type: none"> <li>To reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation (NVAF)</li> <li>For the treatment of deep venous thrombosis (DVT) and PE in patients who have been treated with parenteral anticoagulant for 5-10 days</li> <li>To reduce the risk of recurrence of DVT and PE in patients who have been previously treated</li> <li>For the prophylaxis of DVT and PE in patients who have undergone hip replacement surgery</li> </ul>	<ul style="list-style-type: none"> <li>To reduce the risk of stroke and systemic embolism in patients with NVAF</li> <li>For the treatment of DVT</li> <li>For the treatment of PE</li> <li>For the reduction in the risk of recurrence of DVT and PE</li> <li>For the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery</li> </ul>	<ul style="list-style-type: none"> <li>Reduction of risk of stroke and systemic embolism in NVAF</li> <li>Prophylaxis of DVT following hip or knee replacement surgery</li> <li>For the treatment of DVT and PE</li> <li>Reduction in the risk of recurrent DVT and PE following initial therapy</li> </ul>	<ul style="list-style-type: none"> <li>Reduction of risk of stroke and systemic embolism in NVAF in patients with CrCl<sub>5</sub>95mL/min</li> <li>Treatment of DVT and PE following 5-10 days of initial therapy with a parenteral anticoagulant</li> </ul>
<b>Dosing/Administration</b>	<ul style="list-style-type: none"> <li>9 different tablet strengths</li> <li>Do not use more than 2 different doses at once to reduce error</li> </ul>	<p>For reduction in risk of stroke and systemic embolism in NVAF:</p> <ul style="list-style-type: none"> <li>CrCl &gt;30mL/min: 150mg twice daily</li> <li>CrCl 15-30 mL/min: 75mg twice daily</li> <li>With concomitant use with dronedarone or ketoconazole: consider reducing to 75mg twice daily</li> </ul> <p>For treatment of DVT and PE and reduction in risk of recurrence:</p> <ul style="list-style-type: none"> <li>CrCl &gt;30mL/min: 150mg twice daily</li> </ul> <p>Patients with CrCl &lt;15mL/min OR on dialysis</p> <ul style="list-style-type: none"> <li>Recommendations cannot be provided</li> </ul> <p>Prophylaxis of DVT and PE following hip replacement surgery:</p> <ul style="list-style-type: none"> <li>For patients with CrCl&gt;30mL/min: 110 mg orally first day, then 220 mg once daily</li> <li>CrCl&lt;30mL/min or on dialysis: dosing recommendations cannot be provided</li> </ul> <p>Temporarily discontinue PRADAXA before invasive or surgical procedures when possible, then restart promptly</p>	<p>For reduction in risk of stroke in NVAF</p> <ul style="list-style-type: none"> <li>CrCl &gt;50 mL/min: 20mg once daily with evening meal</li> <li>CrCl 15-50 mL/min: 15mg once daily with evening meal</li> </ul> <p>For treatment of DVT and PE</p> <ul style="list-style-type: none"> <li>For first 21 days: 15mg twice daily with food</li> <li>After 21 days: 20mg once daily with food</li> </ul> <p>For reduction in the risk of recurrence of DVT and PE</p> <ul style="list-style-type: none"> <li>20mg once daily with food</li> </ul> <p>For prophylaxis of DVT following hip/knee replacement surgery</p> <ul style="list-style-type: none"> <li>Hip replacement: 10mg once daily for 35 days</li> <li>Knee replacement: 10mg once daily for 12 days</li> </ul>	<p>For reduction of risk of stroke and systemic embolism in patients with NVAF</p> <ul style="list-style-type: none"> <li>5mg twice daily</li> </ul> <p>For prophylaxis of DVT following hip/knee replacement surgery</p> <ul style="list-style-type: none"> <li>2.5mg twice daily, with the initial dose taken 12-24 hours after surgery</li> <li>Hip replacement: treatment duration of 35 days</li> <li>Knee replacement: treatment duration of 12 days</li> </ul> <p>In patients with NVAF, 2.5mg twice daily in patients with any two of the following characteristics</p> <ul style="list-style-type: none"> <li>Age ≥80 years</li> <li>Body weight ≤60kg</li> <li>Serum creatinine ≥1.5mg/dL</li> </ul> <p>For the treatment of DVT and PE</p> <ul style="list-style-type: none"> <li>Recommended dose is 10 mg taken orally twice daily x7 days then 5mg twice daily</li> </ul> <p>Reduction in the risk of recurrent DVT and PE following initial therapy</p> <ul style="list-style-type: none"> <li>2.5mg twice daily after at least 6 months of treatment for DVT or PE</li> </ul>	<p>For reduction or risk of stroke and systemic embolism in patients with NVAF</p> <ul style="list-style-type: none"> <li>60mg once daily in patients with CrCl ≤95 and &gt;50 mL/min</li> </ul> <p>For treatment of DVT and PE</p> <ul style="list-style-type: none"> <li>60mg once daily following 5 to 10 days of initial therapy with parenteral anticoagulant</li> </ul> <p>In all patients, reduce dose to 30mg once daily if CrCl is 15-50mL/min</p> <p>In treatment of patients for DVT and PE, also use 30mg once daily if:</p> <ul style="list-style-type: none"> <li>CrCl is 15-50 mL/min</li> <li>Body weight ≤60kg</li> <li>Patient is also on certain P-gp inhibitors – clinical judgment of the medical provider must be used</li> </ul>
<b>Converting FROM warfarin</b>		<ul style="list-style-type: none"> <li>Discontinue warfarin and start Pradaxa® when INR &lt; 2.0</li> </ul>	<ul style="list-style-type: none"> <li>Discontinue warfarin and start Xarelto® as soon as the INR is &lt; 3.0</li> </ul>	<ul style="list-style-type: none"> <li>Warfarin should be discontinued and Eliquis® started when the INR is &lt; 2.0</li> </ul>	<ul style="list-style-type: none"> <li>Discontinue warfarin and start Savaysa® when INR is ≤2.5</li> </ul>




# Anticoagulation Tools

## Taking Charge of My Warfarin

 I will talk to the doctor who manages my warfarin (also called Coumadin®, Jantoven®) if I:


- **START** any new prescription drug(s) or over-the-counter product(s), including vitamins and supplements
- **STOP** any prescription drug(s) or over-the-counter product(s)
- **CHANGE** the dose of any prescription drug(s) or over-the-counter product(s) that I already take or have a major change in the foods I eat (high vitamin K-content foods)
- **EXPERIENCE bothersome bleeding**, such as:
  - Gums that won't stop bleeding
  - Severe bruises or bruises that appear for no reason


 When I call my doctor's office I will say:

1. **My name is** (state your name).
2. **The doctor who prescribed my warfarin is** (state your doctor's name).
3. **I was told to call when any of my medications change or if I have noticed bleeding.**
4. **I am calling to tell you** (describe bleeding or change to medications).
5. **Does the doctor have any new instructions for me?** (Write down and follow any new instructions.)

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I will seek immediate medical attention from my doctor, the emergency room, or 911 if I notice:

-  **Serious bleeding** I can see, including:
- Vomit that shows blood or looks like coffee grounds
  - Stool or bowel movements that show blood or are very dark and tar-like
  - Urine that is pink, red, or unusually dark
  - Phlegm (mucus) that shows blood

-  **Major changes** in how I feel, including those resulting from:
- Severe abdominal pain
  - Headaches that are severe or won't go away
  - Confusion or decreased alertness
  - Dizziness or lightheadedness
  - A serious fall or hitting my head

The doctor who manages my warfarin is:

My doctor's phone number is:

( ) \_\_\_\_\_ - \_\_\_\_\_



# Diabetes Tools

## Diabetes Medication Reference - Insulins

Generic (Brand)	Onset	Peak	Duration	Half Life	Dose Adjustments	Appearance	May it be mixed?	When to administer	Additional monitoring to HbA1c and plasma glucose	
Insulin Ispro (Humalog® U-100)  (Humalog® U-200)	Rapid	0.25-0.5hrs <sup>1</sup>	0.5-2.5hrs <sup>1</sup>	<5hrs <sup>1</sup>	~1hr <sup>1</sup>	CrCl 10-50mL/min administer 75% of dose; CrCl <10mL/min administer 50% of dose <sup>1</sup>	Clear, colorless <sup>1</sup>  U-100: Yes with NPH only and from the vial only, add rapid acting (clear) insulin to the syringe first and use immediately. <sup>1,4</sup>  U-200: Do not mix with other insulins, do not extract from pen, do not administer via continuous infusion, do not give IV <sup>2</sup>	Within 15 minutes before a meal <sup>2</sup>	Potassium (hypokalemia risk) <sup>1,2</sup>	
Insulin aspart U-100 (Novolog®)		0.2-0.3hrs <sup>3</sup>	1-3hrs <sup>3</sup>	3-5hrs <sup>3</sup>	81min <sup>3</sup>	No adjustments needed <sup>3</sup>	Clear, colorless <sup>3</sup>	Yes with NPH and from the vial only, add rapid acting (clear) insulin to the syringe first and use immediately. <sup>3</sup>	Within 5-10 minutes before a meal <sup>2</sup>	Electrolytes, potassium <sup>3</sup>
Insulin glulisine U-100 (Apidra®)		0.2-0.5hrs <sup>4</sup>	1.6-2.8hrs <sup>4</sup>	3-4hrs <sup>4</sup>	42min <sup>4</sup>	No adjustments needed <sup>4</sup>	Clear, colorless <sup>4</sup>	Yes with NPH and from the vial only, add rapid acting (clear) insulin to the syringe first and use immediately. <sup>4</sup>	:15 minutes before or within 20 minutes of starting a meal <sup>4</sup>	Electrolytes, potassium <sup>4</sup>
Insulin human Inhalation Powder (Afrezza®)		Plasma peak, 12-15 minutes <sup>20</sup>	Peak effect - 53 min <sup>24</sup>	180 mins <sup>20</sup>	28-39 mins <sup>20</sup>	Contraindicated in chronic lung disease <sup>20</sup>	N/A	N/A	Single inhalation per cartridge at beginning of a meal <sup>20</sup>	Spirometry before initiation, after 6 months and annually. See black box warning contraindicated in patients with chronic lung disease, potassium <sup>20</sup>
Insulin regular U-100 (Humulin® R, Novolin® R)  Humulin® R U-500	Short	0.5hrs <sup>5</sup>	2.5-5hrs <sup>5</sup>	U-100: 4-12hrs  U-500: up to 24hrs <sup>5</sup>	1.5hrs <sup>5</sup>	CrCl 10-50mL/min administer 75% of dose; CrCl <10mL/min administer 25-50% of dose <sup>5</sup> <b>Humulin® R U-500 should only be used with the U-500 syringe. An Rx for the U-500 syringe is required; Co-prescribe the syringe and vial/ do not switch between different types of syringes to avoid confusion<sup>5</sup></b>	Clear, colorless <sup>5</sup>  U-100: Yes from the vial only, insulin regular should be added to the syringe first <sup>5</sup>  U-500: Do not give IV or mix with other insulins. <sup>1,20</sup>	30-60 minutes before a meal <sup>1</sup>	DM <sup>5</sup> : electrolytes, potassium  DKA/HHS <sup>5</sup> : electrolytes, BUN, SCr, osmolality, venous pH, anion gap, urine output, UA, mental status	

Abbreviations:  
DM – diabetes mellitus  
DKA – diabetic ketoacidosis  
HHS – hyperosmolar hyperglycemic state

Storage of insulin products: Unopened vials and prefilled pens may be stored under refrigeration (36-46 F) until the expiration date or at room temperature (<86 F) for 14-28 days (individual products vary). Refer to individual product information for storage temperature requirements and stability of opened vials and pens. Do not freeze insulin or use insulin after it has been frozen.<sup>20</sup>

# Diabetes Tools

## Hypoglycemia

Hypoglycemia or low blood sugar is when your blood sugar is less than 70 mg/dl.

If you have these symptoms:



Check your blood sugar. If it is less than 70 mg/dl:

- 1 Eat or drink a simple sugar such as honey, sugar, fruit juice or 1/2 cup of regular soda.
- 2 Wait 15 minutes and then check your blood sugar again.
- 3 If your blood sugar is still less than 70 mg/dl have another serving of simple sugar and
- 4 Then eat a snack of complex carbohydrate such as cheese and crackers, or half of a sandwich.



If your family or friends find you "sleeping" and cannot wake you, make sure they know to call 9-1-1.

### How to Prevent Hypoglycemia

- Eat at regular times every day.
- Check your blood sugar every day.
- Do not skip meals.
- Take your medicine as directed.

If you continue to have low blood sugar, see your doctor as soon as possible.



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Illustrations by Missi Jay, Gigglebox Studios, Austin, Texas

## Your Blood Glucose Numbers

Your blood glucose number:

#

This is your blood sugar *right now*.

Good is less than 140 mg/dl.

Test regularly throughout the day.

Your # is

Your goal for next visit is



Everyone with Diabetes Counts

Illustrations by Missi Jay, Gigglebox Studios, Austin, Texas

Your A1C:

%

This is your average blood glucose for the past three months.

Good is less than 7%.

Your doctor will test your A1C at least every six months.


Your % is

Your goal for next visit is

Number	Percent
eAGmg/dl	A1C%
97	5
111	5.5
126	6
140	6.5
154	7
169	7.5
183	8
197	8.5
212	9
226	9.5
240	10
255	10.5
269	11
283	11.5
298	12

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# Opioid Tools



## OPIOID MEDICATIONS MORPHINE MILLIGRAM EQUIVALENTS (MME)

- Used to understand the potency of an opioid regimen
- Expresses cumulative daily dose of opioid in the equivalent morphine dose
- Should NOT BE USED to convert from one drug to another

**The Facts<sup>1</sup>**

- Patients on up to 50 MME per day have 2-5 times the overdose risk
- Patients on 100 MME or more per day have up to 9 times the overdose risk
- 31-61% of patients with fatal overdose were using opioids and benzodiazepines together

**Common 50 MME per day regimens:**

- Hydrocodone/acetaminophen
  - Vicodin® 5/300mg: 2 tablets every 4 hrs
  - Norco® 10/325mg: 1 tablet every 4 hrs
- Oxycontin® (oxycodone extended release) 15mg: 1 tablet every 12 hrs
- Tylenol® with Codeine #3 (acetaminophen w/ codeine 300/30mg): 2 tablets every 4 hrs
- Tramadol immediate release 50mg: 2 tablets every 6 hrs

Opioid Medications (cont.)

## Quality Insights Tools

- [Opioid Knowledge E-Learn](#) – Quality Insights login required, 1.5 nursing CEUs (scroll down to find the program)
- [Medication Teach Back Cards](#)
- Quality Insights developed an opioid tool that can be found in [Appendix C](#):
  - Opioid Overview - Morphine Milligram Equivalents

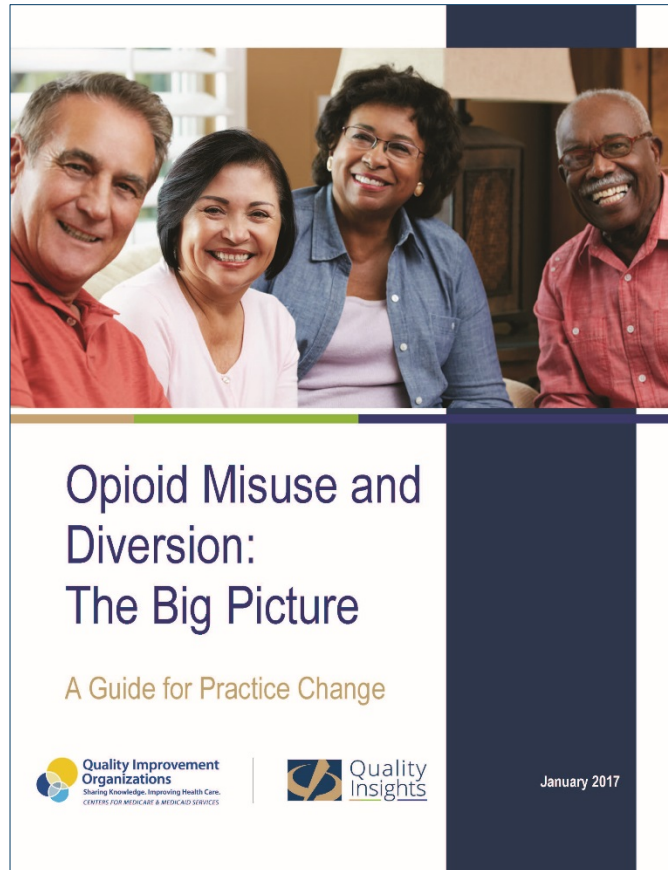


## Directory of Additional Resources

### Resources

- [Potential Adverse Drug Events for Opioid Agents](#) - drug interaction resource from TMF Quality Innovation Network
- [Pennsylvania Patient Safety Authority Opioid Knowledge Self-Assessment](#)
- [Cleveland Clinic – Six Myths About Pain Killers](#)
- [American Academy of Pain Medicine - 8 Opioid Safety Principles for Patients and Caregivers](#) - flyer for patients and caregivers
- [American Academy of Pain Medicine Controlled Substances Agreement](#) - pain contract template
- [American Academy of Pain Medicine Controlled Substances Consent for Chronic Opioid Therapy](#) - pain medication consent template
- [Current Opioid Misuse Measure](#) - brief patient self-assessment to monitor chronic pain patients on opioid therapy
- [Opioid Risk Tool](#) - brief screening tool to assess risk for opioid abuse

# Opioid Misuse and Diversion Change Package



<http://www.qualityinsights-qin.org/Initiatives/Opioid-Misuse-and-Diversion/Opioid-Physician-Change-Package.aspx>

# Upcoming Events

- Anticoagulant Safety – News You Can Use
  - Dr. Vincent Carr, Kisha Gant, PharmD
  - Thursday Nov 16th, 2017 2pm ET
  - <https://wvmievents.webex.com/wvmievents/onstage/g.php?MTID=ee71b2cbbe7ca985367423b31b1789f9a>
- Care Transitions Program for Dialysis Patients
  - Thursday Jan 25th, 2018
  - Details to come soon....
- Anticoagulant – Antibiotic Drug Interactions (in development)

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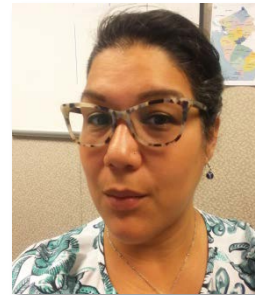
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# QUESTIONS?



## Thank You!

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