Core Elements of
Anticoagulation Stewardship Programs

Administrative Oversight Gap Analysis: Hospitals and Skilled Nursing Facilities

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Executive Summary

Background

The U.S. Department of Health and Human Services (HHS), in its National Action Plan for Adverse Drug Event (ADE) Prevention, identified anticoagulants as one of three classes of medications* contributing to ADEs that were sufficiently common, clinically significant, preventable, and measurable to be designated as high-priority targets for aligned action by Federal health agencies.[1] Such action is warranted, as anticoagulant-related ADEs continue to rise and this single drug class now accounts for approximately one third of all ADEs associated with Emergency Department (ED) visits among older adults, half of which result in hospitalization and half of which are considered preventable.[2]

Anticoagulants are unique among commonly prescribed drug classes and require additional safeguards, processes, and practices to minimize serious and life-threatening adverse events.

The Anticoagulation Forum (ACF) (www.acforum.org) is a multidisciplinary, non-profit professional organization of over 12,000 anticoagulation management specialists that has been educating professionals and advocating for clinical best practices for over 25 years. In 2018, ACF secured a Broad Agency Announcement contract with the U.S. Food & Drug Administration (FDA; BAA 17-00123) to develop resources to advance the concept of anticoagulation stewardship, modeled after highly successful efforts in antibiotic stewardship.[3,4]

The resources developed under the FDA contract include:

- Core Elements of Anticoagulation Stewardship Programs Guide
- Anticoagulation Stewardship Checklist
- Administrative Oversight Gap Analysis Report

Core Elements of Anticoagulation Stewardship Programs Guide

The Anticoagulation Stewardship guide defines anticoagulation stewardship as:

Coordinated, efficient, and sustainable system-level initiatives designed to achieve optimal anticoagulant-related health outcomes and minimize avoidable adverse drug events through the:

- Application of optimal evidence-based care
- Appropriate prescribing, dispensing, and administration of anticoagulants and related agents
- Provision of appropriate patient monitoring and clinical responsiveness

The *Core Elements of Anticoagulation Stewardship Programs* guide articulates seven core elements that comprise an anticoagulation stewardship program, regardless of care setting.

* Anticoagulants, diabetes agents, and opioids

Summary of Core Elements of Anticoagulation Stewardship Programs

- **Secure Administrative Leadership Commitment:** Dedicating necessary human, financial, and technology resources
- **Establish Professional Accountability and Expertise:** Appointing a single leader responsible for program outcomes, supported by at least one clinician with expertise in anticoagulation management
- **Engage Multidisciplinary Support:** Involving key specialists and disciplines to obtain perspective from all domains of the care delivery system
- **Perform Data Collection, Tracking, and Analysis:** Defining the population, objectively evaluating performance, and guiding decision-making
- **Implement Systematic Care:** Implementing sustainable, efficient, evidence-based action(s) at the system level to assure the safety and quality of anticoagulation management
- **Facilitate Transitions of Care:** Creating systems to optimize communication and ensure safe transitions between care settings
- **Advance Education, Comprehension, and Competency:** Assuring that clinicians, patients, and others have the knowledge and skills necessary to optimize outcomes

Core Elements of Anticoagulation Stewardship Checklist

The Stewardship Checklist, which accompanies the Stewardship Guide, provides a tool for health systems to evaluate their current environment and identify areas warranting action.

Gap Analysis

The Gap Analysis identifies perceived weaknesses and omissions in administrative oversight modalities (i.e. regulations, accreditation standards, and quality measures) applicable to hospitals and skilled nursing facilities. These gaps have the potential to increase the risk of harm associated with anticoagulant use or impede the evaluation and measurement of the quality and safety of related care processes.

The identification of such gaps is intended to initiate conversations and foster collaboration among organizations responsible for improving the safety and quality of health care, with the expectation that additional work will be necessary to achieve the mutual goal of providing patients with the safest, most effective, and most efficient anticoagulation-related care possible.

The gap analysis included a thorough evaluation of current regulations (Centers for Medicare & Medicaid Services' (CMS) State Operations Manuals), accreditation standards (National Patient Safety Goal [NPSG] from The Joint Commission), and specifications of quality measures for hospitals and skilled nursing facilities from the perspective of a committee of anticoagulation quality and safety specialists (Table 1). Perceived gaps were assigned to domains aligning with the Anticoagulation Forum's priorities for health system improvement, including:

- Care Transitions
- Education
- Periprocedural Management
- Quality Improvement
- Reversal and Bleeding Management
- Safety and Appropriateness of Prescribing and Clinical Monitoring
- Venous Thromboembolism (VTE) Prophylaxis

Table 1: Documents Evaluated for Gaps

Care Setting	Source Reviewed
Hospital	1. Regulations and Surveyor Guidance: State Operations Manual - Appendix A [5] 2. Quality Measures: CMS active quality programs [6] 3. Accreditation Standards: The Joint Commission NPSG 03.05.01 [7] **
Skilled Nursing Facilities	1. Regulations and Surveyor Guidance: State Operations Manual - Appendix PP [8] 2. Quality Measures: CMS Nursing Home Quality Initiative [9] 3. Minimum Data Set: CMS Long-Term Care Facility Resident Assessment Instrument (RAI) Users Manual 2018 [10] 4. MDS Frequency Report and Research Data Assistance Center (ResDAC) [11,12] 5. Beers Criteria 2019 [13]

Gap Findings

The gap analysis identified multiple weaknesses in the current oversight modalities that the Anticoagulation Forum believes increase the risk of patient harm or impede related reporting and oversight. These findings existed across the full range domains aligned with the ACF's priorities for the health care system.

The process identified a total of 74 perceived gaps, 38 of which were categorized as "high" (Tables 2 & 3). Among the high priority gaps, 20 were related to hospitals and 18 to skilled nursing facilities. High priority gaps were identified across multiple domains, including care transitions (6), education (1), periprocedural management (2), quality improvement (10), anticoagulant reversal (1), safety (16) and VTE prophylaxis (2).

** NPSG 03.05.01 is applicable to both hospital and skilled nursing settings

Table 2: High Priority Hospital Gaps*

Domain	High Priority Gaps
Care Transitions	**Regulations and Surveyor Guidance** Patients receiving anticoagulation are not identified as "high risk" and requirements for care planning and inter-provider communication lack the structure needed to assure patients' needs are met immediately upon discharge [Gaps #9, 10, 11] **Accreditation Standards** The NPSG does not address the quality and safety of care transitions involving anticoagulants [Gap #19]
Periprocedural Management	**Regulations and Surveyor Guidance** Standards do not address important factors relating to anticoagulation in advance of or immediately following invasive medical procedures; Standards for anesthesia do not address neuraxial interventions among patients using anticoagulants [Gaps #5, 12]
Quality Improvement	**Regulations and Surveyor Guidance** Absence of standards requiring quality assurance and performance improvement (QAPI) activities relating to anticoagulant use, as is required of other important drug classes (e.g. antibiotics) and specialties (e.g. anesthesia) [Gaps #3, 8, 13] **Quality Measures** Measures do not reflect current best practices for the use of anticoagulants or account for trends towards outpatient surgery and thrombosis management [Gaps #15, 16, 17]
Reversal	**Regulations and Surveyor Guidance** Requirements for the safe administration of blood products do not address the use of clotting factors utilized to reverse the effects of anticoagulants [Gap #6]
Safety	**Regulations and Surveyor Guidance** Standards do not explicitly identify anticoagulants as "high-alert medications" or require explicit safeguards against medication errors or to assure timely clinical responses to errorsor ADEs involving anticoagulants [Gaps #4, 7, 14] **Accreditation Standards** The NPSG does not address the combined use of anticoagulants and antiplatelet drugs or address the importance of weight assessment in anticoagulant dosing decisions [Gaps #18, 20]
VTE Prophylaxis	**Regulations and Surveyor Guidance** Standards do not adequately address the importance of VTE prophylaxis for patients at risk due to surgery or medical illness [Gaps #1, 2]

* Hospital types affected by the source documents may vary – see full report for complete details

Table 3: High Priority Skilled Nursing Facility Gaps[†]

Domain	High Priority Gaps
Care Transitions	**Regulations and Surveyor Guidance** Standards do not address key aspects of care transitions involving anticoagulants when patients enter or depart from skilled nursing facilities, which is of particular importance for short-term/rehabilitation stays [Gaps #21, 24]
Education	**Regulations and Surveyor Guidance** Standards do not include requirements for education of patients and families regarding anticoagulants, which is of particular importance for short-term/rehabilitation stays [Gap #23]
Quality Improvement	**Regulations and Surveyor Guidance** Absence of standards requiring QAPI activities relating to anticoagulant use, as is required of other important drug classes (e.g. antibiotics) [Gaps #26, 28] **Quality Measures** Absence of anticoagulation-related quality measures for skilled nursing facilities in the Nursing Home Quality Initiative [Gap #29] **Minimum Data Set (MDS)/ MDS Frequency Reports/ResDAC** Absence of a publicly available dataset supporting research of anticoagulation, thrombosis, and bleeding despite the systematic collection of related data fields [Gap #31]
Safety	**Regulations and Surveyor Guidance** Standards do not include direct oral anticoagulants (DOACs) among "high-risk drugs" or require facilities to implement evidence-based policies and procedures involving anticoagulants; there are no specific care plan requirements to address important aspects of anticoagulation therapy [Gaps #22, 25, 27] **MDS/MDS Frequency Reports/ResDAC** Data fields relating to anticoagulant use do not mention DOACs or distinguish among anticoagulant types, diminishing the quality and utility of related data [Gap #30] **Beers Criteria** The Criteria do not provide a sufficient characterization of appropriate anticoagulation utilization in the elderly and would benefit from multiple additions and modifications [Gaps #32-38]

[†] Skilled nursing facility types affected by source documents may vary - see full report for complete details

Dissemination and Next Steps

The completed Administrative Oversight Gap Analysis Report is intended to serve as a tool for facilitating dialogue and accelerating system changes to advance the quality and safety of anticoagulation management. It is hoped that the Gap Report will be a useful means of advancing the goals and intentions of the U.S. Department of Health and Human Services' previous multi-agency report, the National Action Plan for Adverse Drug Event Prevention.[1]

In addition, the Anticoagulation Forum intends to utilize the Gap Report and the companion *Core Elements of Anticoagulation Stewardship Programs* guide to engage professional societies, accreditation agencies, patient advocacy groups and other organizations to advance the cause of anticoagulation quality and safety.

The ACF is exceedingly grateful for the contributions from the members of the Technical Expert Panel and looks forward to continuing these productive and collegial collaborations in the future, and would also like to thank the ACF Steering Committee and Board of Directors for their contributions and guidance.

The ACF is fully committed to engaging all entities interested in advancing the cause of anticoagulation-related quality and welcomes comments, criticisms, and suggestions from all parties engaged in this important work.

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Acronyms

ACF	Anticoagulation Forum
ADE	Adverse Drug Event
AF	Atrial Fibrillation
CMS	Centers for Medicare & Medicaid Services
CoP	Conditions of Participation
DOAC	Direct Oral Anticoagulant
DVT	Deep Vein Thrombosis
ED	Emergency Department
EP	Element of Performance
FDA	U.S. Food & Drug Administration
HAC	Hospital-Acquired Condition Reduction Program
HHS	U.S. Department of Health and Human Services
HRRP	Hospital Readmission Reduction Program
INR	International Normalized Ratio
IQR	Hospital Inpatient Quality Reporting Program
LOS	Length of Stay
LTC	Long-Term Care
MDS	Minimum Data Set
NHQI	Nursing Home Quality Initiative
NPSG	National Patient Safety Goal
NSAID	Non-Steroidal Anti-Inflammatory Drug
PE	Pulmonary Embolism
QAPI	Quality Assurance and Performance Improvement
RAI	Resident Assessment Instrument
ResDAC	Research Data Assistance Center
VTE	Venous Thromboembolism

Methodology and Report Format

Upon contract award the Anticoagulation Forum established a Steering Committee consisting of members of the Board of Directors and assembled a Technical Expert Panel to provide external perspectives from a range of relevant organizations and care settings. A Gap Analysis Subcommittee was then charged to identify key administrative oversite resources applicable to hospital and skilled nursing facility settings and to oversee a systematic and iterative process to identify, categorize, and prioritize perceived gaps relating to anticoagulation management.

For both the acute care and skilled nursing settings the most recent surveyor guidance from the CMS State Operations Manual was evaluated.[5,8] Quality measures included in CMS programs for hospitals were identified through the QualityNet website and evaluated,[6] as were anticoagulation-related accreditations standards from The Joint Commission (i.e. NPSG 03.05.01).[7] For skilled nursing facilities, quality measures from the CMS Nursing Home Quality Initiative were evaluated.[9] As NPSG 03.05.01 is applicable to multiple settings, including "nursing centers", no additional evaluation of accreditation standards for this setting was performed.

A number of other important resources relating to skilled nursing facilities were evaluated. Due to their visibility and influence on prescribing practices in senior care populations and their prominent mention within the skilled nursing facility surveyor guidance, an evaluation of the most recent release of the Beers Criteria was performed and included in the final report.[13] The Resident Assessment Instrument Manual 3.0 (with MDS)[10] and the related MDS Frequency Report and ResDAC were also evaluated.[11,12] To guide future discussions, an appendix of fields potentially related to anticoagulation therapy (e.g. analysis, quality measurement) was also included in the final report (Appendix 1).

The most current versions of the source documents were acquired and reviewed to identify all potential anticoagulation-related gaps and categorized according to Anticoagulation Forum's priorities for health system improvement, including:

- Care Transitions
- Education
- Periprocedural Management
- Quality Improvement
- Reversal and Bleeding Management
- Safety and Appropriateness of Prescribing and Clinical Monitoring
- VTE Prophylaxis

The list of potential gaps was reviewed by members of the Gap Analysis Subcommittee. Through iterative discussions, and with input from members of the Steering Committee and the Technical Expert Panel, the Subcommittee came to consensus on a final binary ranking (high priority, lower priority) for each gap included in the current report. The definitions of the prioritization tiers are included in Table 4.

A section of the report was then developed for each care setting evaluated with sub-sections for each category of administrative oversight modality reviewed. Each sub-section identifies the specific source document reviewed, the settings to which the document is applicable[‡], and includes a brief description of the relevance of the source document.

For each source document reviewed, the identified gaps are listed and described in separate tables based on their final ranking. The location of the gaps within each source document is provided along with the assigned gap category. Gaps associated with a perceived omission have their location designated as "Perceived Omission", to indicate the lack of a specific existing location within the document.

Finally, a recommendation for addressing each gap is provided. These recommendations are intended to prompt constructive dialogue and collaboration among interested organizations, and are not intended to be critical of earlier efforts or to achieve immediate adoption in their current form.

By identifying perceived gaps and proposing possible remedies to which external organizations can respond, the Anticoagulation Forum believes that it can accelerate the development, implementation, and adoption of system-level improvements that reflect the collective best thinking of collaborating organizations. The ACF welcomes comments and suggestions regarding this resource and is pleased to play a positive role in meaningful advances in the safety, quality, and efficiency of anticoagulation-related care and services.

Table 4: Definitions of Priority Ranking

High Priority Gaps	**Weaknesses or omissions in administrative oversight modalities that:** • Increase the risk of suboptimal clinical outcomes for patients or impede optimal evaluation and measurement of anticoagulation-related quality and safety and; • Are amenable to discrete, evidence-based modifications in the parent documents or related processes and; • Are sufficiently important to warrant immediate advocacy for resolution through appropriate channels
Lower Priority Gaps	**Weaknesses or omissions in administrative oversight modalities that:** • May contribute to suboptimal clinical outcomes or impede optimal evaluation and measurement of anticoagulation-related quality and safety and; • Do not warrant immediate advocacy for resolution and; • May be resolved through the resolution of other high-priority gaps or at later dates in alignment with other opportunities to introduce system improvements

‡ While the review was focused on acute care and skilled nursing facilities, oversight modalities may apply to or exclude additional care settings

High Priority Gaps

Hospital Setting

Regulations and Surveyor Guidance

Source Reviewed: State Operations Manual - Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals (Version 183, October 12, 2018)[5§]

Description: This document provides explicit, authoritative guidance to surveyors of hospitals across the country. Hospitals are required to be in compliance with the Federal requirements set forth in the Medicare Conditions of Participation (CoP) in order to receive Medicare/Medicaid payment. The goal of a hospital survey is to determine if the hospital is in compliance with Medicare CoP.

Certification of hospital compliance with the CoP is accomplished through observations, interviews, and document/record reviews. The survey process focuses on a hospital's performance of patient-focused and organizational functions and processes. The hospital survey is the means used to assess compliance with Federal health, safety, and quality standards that will assure that the beneficiary receives safe, quality care and services.

High Priority Gaps Identified in Hospital Regulations and Surveyor Guidance

Gap No. / Location	Category	Gap Description	Recommendation
1. Perceived Omission	VTE Prophylaxis	Standards do not require that hospitals have policies and procedures in place for evaluating patients for medical risk of VTE and assuring the provision of evidence-based prophylaxis.	Update standards to require that hospitals implement evidence-based policies, procedures, and guidelines for evaluating patients at risk of VTE due to medical conditions and the administration of appropriate prophylaxis (pharmacological or non-pharmacological).[14]
2. Perceived Omission	VTE Prophylaxis	Standards do not require that hospitals have policies and procedures in place for evaluating patients for surgical risk of VTE and assuring the provision of evidence-based prophylaxis.	Update standards to require that hospitals implement evidence-based policies, procedures, and guidelines for evaluating patients at risk of VTE due to surgical procedures and the administration of appropriate prophylaxis (pharmacological and non-pharmacological).[15,16]

§ Additional survey modules may be applicable to facilities with swing beds, psychiatric and rehabilitation services; Excludes critical access hospitals

High Priority Gaps Identified in Hospital Regulations and Surveyor Guidance

Gap No. / Location	Category	Gap Description	Recommendation
3. §482.21 Condition of Participation: Quality Assessment and Performance Improvement Program	Quality Improvement	Survey team instructions and regulations relating to QAPI do not explicitly require a focus on anticoagulant-related care as required for other therapeutic areas (e.g. infection/antimicrobial, anesthesia).	Revise standards to require that survey team instructions and hospital QAPI processes specifically include the quality of anticoagulation-related care and services as a high priority.[17]
4. §482.23(c)(2) Assessment/ Monitoring of Patients Receiving Medications	Safety	Requirements for alerting of practitioners immediately upon the identification of adverse patient reactions do not explicitly mention adverse events relating to anticoagulants therapy (but do include opioid-induced respiratory depression as an example).	Update standards to require that hospitals employ specific policies, procedures, and guidelines regarding the response to identified cases of bleeding among patients receiving anticoagulant therapy.[17-19]
5. §482.23(c)(4) Monitoring Patients Receiving High-Alert Medications, Including IV Opioids	Periprocedural	Requirements for policies and procedures related to the use of high-alert medications in post-operative setting include opioids, but do not explicitly mention post-operative assessment of patients receiving anticoagulant therapy (e.g. hemostasis) or requiring initiation of VTE prophylaxis.	Revise standards to require that hospitals have comprehensive evidence-based policies and procedures regarding the periprocedural management of anticoagulants, including the post-operative assessment of patients receiving or requiring anticoagulant therapy.[20,21] Consider alignment with NPSG.03.05.01 EP3 (i.e. periprocedural management of anticoagulants)
6. §482.23(c)(4) Blood Components and Blood Administration Procedures	Reversal	Specific requirements are described for safe practices regarding the administration of blood transfusions, but it is unclear whether these apply equally to the administration of clotting factors derived from blood products used to correct clotting disorders and reverse the effects of anticoagulant agents.	Revise standards to include safe practices for the administration of clotting factors and require hospitals to establish evidence-based policies and procedures regarding the use of blood products and other agents to reverse the effects of anticoagulants for bleeding and other clinical scenarios.[18] Consider alignment with NPSG.03.05.01 EP2 (i.e. reversal of anticoagulants)

High Priority Gaps Identified in Hospital Regulations and Surveyor Guidance

Gap No. / Location	Category	Gap Description	Recommendation
7. §482.25 Policies and Procedures for Minimizing Drug Errors	Safety	Standards state that high alert medications "may" include a variety of drug classes, but do not explicitly require that facilities identify anticoagulants therapy as high-alert medications nor require specific safeguards against medication errors involving anticoagulants (e.g. avoidance of dangerous abbreviations, use of order sets, clinical decision support features, etc.)	Modify standards to explicitly identify anticoagulant medications and other agents identified in the National Action Plan for Adverse Drug Event Prevention (i.e. opioids and hypoglycemic agents) as “high alert” and require safeguards against errors involving their use.[17]
8. §482.42 Condition of Participation: Infection Control	Quality Improvement	Standards include entire section describing requirements for infection control, including the requirement for an "active program" for the prevention, control and investigation of infections, the designation of a qualified infection control officer, and reporting to the QAPI program, but no parallel requirements are articulated to assure the systematic oversight of anticoagulant therapy.	Revise standards to require hospitals to include an active program (i.e. stewardship) to assess and improve the quality and safety of anticoagulation-related care, including the designation of a qualified anticoagulation stewardship officer and reporting to the facility’s QAPI program.[17]
9. §482.43 Condition of Participation: Discharge Planning	Care Transitions	Standards for the discharge planning process do not specifically identify patients using anticoagulant therapy as being inherently "at risk of adverse health consequences post-discharge if they lack discharge planning" and warranting "evaluation of the post-discharge needs" relating to their anticoagulant use.	Revise standards to require that hospitals establish a systematic approach to identify patients receiving anticoagulants and other high-risk drugs (e.g. those identified in the National Action Plan for Adverse Drug Event Prevention) prior to discharge, assessing their needs for related post-discharge support or services.[22-24]
10. §482.43(a) Identification of Patients in Need of Discharge Planning	Care Transitions	Standards require that "any pertinent" information is in the patient's medical record upon transfer to another hospital, but do not explicitly require that comprehensive anticoagulant-related information be included and communicated in a timely manner to support the effective continuation of appropriate therapy.	Revise standards to explicitly require that hospitals establish processes for assuring the effective communication of all information relating to anticoagulation to downstream providers.[22-24]

High Priority Gaps Identified in Hospital Regulations and Surveyor Guidance

Gap No. / Location	Category	Gap Description	Recommendation
11. §482.43 Standard: Discharge Planning Evaluation	Care Transitions	Standards require that the hospital's discharge planning evaluation consider whether the "patient's care needs will be met immediately upon discharge" and the hospital consider the "availability of such services", but do not explicitly identify anticoagulation-related needs or assurances that related needs can be met immediately following discharge.	Revise standards to require that hospital discharge planning processes assess patient need for anticoagulation-related support services and assure that related needs can be met immediately following discharge.[22-24]
12. §482.51(b) Standard: Delivery of Services (Surgical Services)	Quality Improvement	Standards for surgical services require policies and procedures relating to “pre-operative workup”, but without explicit mention of the timing and content of anticoagulant therapy evaluation or care planning.	Revise standards to require that patients utilizing anticoagulant therapy who undergo elective or non-elective invasive procedures receive a thorough evaluation and corresponding anticoagulation management plan for the periprocedural period.[20,21] Consider alignment with NPSG.03.05.01 EP3 (i.e. periprocedural management of anticoagulants)
13. §482.52 Condition of Participation: Anesthesia Services	Quality Improvement	Standards require hospitals that provide any degree of anesthesia services comply with explicit CoP, including the designation of a single, qualified individual to serve as director of anesthesia, whereas there are no parallel requirements to oversee the safety and quality of anticoagulant therapy in institutions that utilize such agents.	Revise standards to require hospitals to include an active program (i.e. stewardship) to assess and improve the quality and safety of anticoagulation-related care, including the designation of a qualified anticoagulation stewardship officer and reporting to the facility’s QAPI program.[17,25]
14. §482.52(b) Standard: Delivery of Services (Anesthesia)	Safety	Standards require that anesthesia services be "consistent with needs and resources" and articulate a number of topics that must be addressed (e.g. infection control and safety practices), but do not explicitly mention or describe relevant aspects of anticoagulant care (e.g. administration of neuraxial anesthesia in patients receiving anticoagulant therapy, control of bleeding among patients receiving anticoagulants, etc.)	Revise standards to address the provision of anesthesia services to patients receiving anticoagulants, including but not limited to the administration of neuraxial injections and the management of acute bleeding events.[17,25] Consider alignment with NPSG.03.05.01 EP3 (i.e. periprocedural management of anticoagulants)

Quality Measures

Sources Reviewed:

- Hospital Inpatient Quality Reporting Program (IQR) – Fiscal Year 2021[6]
- Hospital Acquired Condition Reduction Program (HAC) – Fiscal Year 2019[6]
- Hospital Value Based Purchasing Program (HVBP) – Fiscal Year 2018-2024[6]
- Hospital Readmission Reduction Program (HRRP) – Fiscal Year 2019[6]
- The Core Quality Measure Collaborative[26]

Description: As the nation's largest payer for acute care medical services, CMS has been empowered by a number of legislative actions and has leveraged regulatory authority to drive improvements in the safety and quality of hospital services. For the purposeof this gap analysis, the most prominent and wide-reaching programs were included, with the technical specifications of all quality measures included in the indicated program years being evaluated from the perspective of anticoagulation quality and safety. Through the IQR Program CMS pays hospitals that successfully report designated quality measures a higher annual update to their regular payment rates. Under the Program, CMS collects quality data from hospitals paid under the Inpatient Prospective Payment System, with the goal of driving quality improvement through measurement and transparency by publicly displaying data to help consumers make more informed decisions about their health care.

The HAC Reduction Program is a Medicare pay-for-performance program that supports CMS's long-standing effort to link Medicare payments to healthcare quality in the inpatient hospital setting. Beginning with Fiscal Year FY 2015 discharges, the HAC Reduction Program requires the Secretary of Health and Human Services (HHS) to reduce payments to hospitals that rank in the worst-performing 25 percent of all hospitals with respect to HAC quality measures.

The HVBP Program is part of the ongoing work to structure Medicare's payment system to reward providers for the quality of care they provide. This program adjusts payments to hospitals under the Inpatient Prospective Payment System, based on the quality of care they deliver. The HVBP Program rewards acute care hospitals with incentive payments for the quality of care they give to people, not just the quantity of services they provide.

The HRRP is a Medicare value-based purchasing program that reduces payments to hospitals with excess readmissions. The program supports the national goal of improving healthcare for Americans by linking payment to the quality of hospital care.

Measures included in the Core Quality Measure Collaborative were selected through collaboration between CMS, commercial plans, Medicare and Medicaid managed care plans, purchasers, physician and other care provider organizations, and consumers with the goal of establishing broadly agreed upon core measure sets that could be harmonized across both commercial and government payers. While all of the core measures were reviewed as part of the gap analysis, not all of the measures are currently included or active in CMS programs for hospitals.

High Priority Gaps Identified in Hospital Quality Measures

Gap No. / Location	Category	Gap Description	Recommendation
15. Perceived Omission	Quality Improvement	Emerging evidence has identified a trend in clinical practice to use inappropriate, "off-label" and purposeful under-dosing of DOACs, and data suggests that such practices are associated with significantly increased risk of adverse patient outcomes.	Explore the development of measure(s) that assess the quality of DOAC dosing in inpatient and outpatient care settings.[27,28]
16. IQR, STK-03 (Anticoagulation Therapy for Atrial Fibrillation/Flutter)	Quality Improvement	List of anticoagulant agents counted in numerator is broad and includes agents not typically used for atrial fibrillation/stroke or associated with high quality care, potentially inflating performance; Specifications may not include all available agents.	Update measure specifications to reflect available agents and narrow numerator to include only agents recommended for use in stroke with AF. Consider modification of inclusion criteria or timing of drug initiation, as immediate initiation of anticoagulation may not be appropriate for all patients.[28,29]
17. IQR, COMP-HIP-Knee (Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA))	Quality Improvement	Denominator only includes inpatient elective hip procedures; Specifications only include PE as a complication (i.e. not DVT) in numerator. Specifications require that PE require hospitalization to count in numerator.	Explore measure and program development that evaluates quality of surgical outcomes and adverse events across care settings and reflects current practices for VTE prophylaxis (i.e. outpatient DOAC therapy).[28,30]

Accreditation Standards

Sources Reviewed: National Patient Safety Goal 03.05.01 (Effective July 1, 2019)[7**]

Description: The Joint Commission is an independent, not-for-profit organization that currently accredits approximately 82 percent of hospitals in the United States. To earn and maintain The Joint Commission's Gold Seal of Approval™, an organization must undergo an on-site survey by a Joint Commission survey team at least every three years. Survey components and accreditation standards are continually updated to reflect current medical evidence and recognized best practices.

The Joint Commission establishes National Patient Safety Goals (NPSGs) in order to help accredited organizations address specific areas of concern in regard to health care safety, and to focus on how to solve them. The gap analysis evaluated NPSG 03.05.01, which specifically targets priority issues relating to the safe and effective use of anticoagulants.

High Priority Gaps Identified in Hospital Accreditation Standards

Gap No. / Location	Category	Gap Description	Recommendation
18. Perceived Omission	Safety	Standard does not require evidence-based processes to assure the appropriate use of antiplatelet drugs in combination with anticoagulants.	Expand the Standard to require processes to assure evidence-based policies and procedures regarding the appropriate combined use of anticoagulants and antiplatelet medications.[31,32]
19. Perceived Omission	Care Transitions	Standard does not include an EP requiring that organizations proactively solicit explicit information regarding anticoagulant use upon admission/intake or have practices in place to send necessary anticoagulant-related information to downstream providers in a timely and cohesive manner upon discharge or transfer.	Expand Standard to include an EP that characterizes requirements or anticoagulation-related communication in the intervals including patient admission and discharge or transfer.[22-24]
20. EP1 (The [hospital/ organization] uses approved protocols and evidence-based practice guidelines for the initiation and maintenance of anticoagulant therapy)	Safety	Standard does not require the inclusion of patient current weight as a specific component of protocols for the initiation and management of anticoagulants; Patient weight is a key variable in the management of multiple anticoagulant medications.	Modify Standard to include patient weight as a required component of protocols guiding the initiation and management of anticoagulants.[30,33]

**Applicable to The Joint Commission-accredited hospitals, critical access hospitals, nursing care centers, and medical centers (accredited under the ambulatory health care program)

Skilled Nursing Facility Setting

Regulations and Surveyor Guidance

Sources Reviewed: State Operations Manual Appendix PP – Guidance to Surveyors of Long-Term Care Facilities (Rev. 11-22-17)[8]

Description: This document provides explicit, authoritative guidance to surveyors of skilled nursing facilities across the country. Nursing home surveys are conducted in accordance with survey protocols and Federal requirements to determine whether a citation of non-compliance is appropriate. The requirements for participation were recently revised to reflect the substantial advances that have been made over the past several years in the theory and practice of service delivery and safety.

The survey protocols and interpretive guidelines serve to clarify and/or explain the intent of the regulations. All surveyors are required to use them in assessing compliance with Federal requirements. Deficiencies are based on violations of the regulations, which are to be based on observations of the nursing home's performance or practices.

High Priority Gaps Identified in Skilled Nursing Facility Regulations and Surveyor Guidance

Gap No. / Location	Category	Gap Description	Recommendation
21. §483.20(a) Physician Orders for Immediate Care	Care Transitions	Guidance does not require specific information to be requested or obtained by facilities to support the safe management of patients prescribed anticoagulants upon admission to nursing facilities.	Expand guidance to include the receipt of specific clinical information necessary to support safe, high-quality care for newly admitted patients utilizing high-risk drugs such as anticoagulants, opioids, and hypoglycemic agents, as identified in the National Action Plan for Adverse Drug Event Prevention.[1,22,24,34-36]
22. §483.21 Comprehensive Person-Centered Care Planning	Safety	Guidance does not require that anticoagulation be a formal, distinct component of the resident care plan.	Expand guidance to require specific care plan components for patients prescribed anticoagulants including but not limited to: anticoagulant drug name(s), indication(s), dose(s), route(s), frequency of administration, desired intensity (e.g. INR target), anticipated changes in dose intensity and applicable dates (e.g. step-down dose with DOAC and PE treatment), monitoring plan (physical and laboratory), duration of therapy, risk avoidance (e.g. NSAID use, key drug interactions), education of patient/family, and explicit treatment goals (e.g. stroke prevention with absence of bleeding, rehabilitation from surgery without VTE).[37,38]

High Priority Gaps Identified in Skilled Nursing Facility Regulations and Surveyor Guidance

Gap No. / Location	Category	Gap Description	Recommendation
23. §483.21(b)(2)(ii)(E) Comprehensive Care Plans	Education	Guidance does not require that patients/family receive education and guidance specific to an anticoagulation care plan during the facility stay, in the peri-procedural period, or at discharge or transfer.	Expand guidance to include requirement for appropriate anticoagulant-related education for patients and families as a component of a comprehensive care plan (see care plan recommendation in Gap #22).[39,40]
24. §483.21(c)(2) Information Conveyed to Receiving Provider	Care Transitions	Guidance does not require specific information be effectively communicated by facilities to downstream providers, patients and family to assure the safe and effective continuation or completion of the anticoagulation regimen upon discharge or transfer from nursing facilities.	Expand guidance to include the communication of specific clinical information necessary to support safe, high-quality care for patients discharged or transferred from nursing facilities utilizing high-risk drugs such as anticoagulants, opioids, and hypoglycemic agents, as identified in the National Action Plan for Adverse Drug Event Prevention.[1,22,24,34-36]
25. §483.45 Pharmacy Services	Safety	Guidance does not require that the facility develop and implement evidence-based policies and procedures to support the provision of safe and effective therapy with anticoagulants.	Expand guidance to require the development, implementation and maintenance of comprehensive evidence-based policies and procedures regarding the use of anticoagulants including but not limited to: drug selection, drug dosing, dose adjustment based on relevant factors (age, sex, renal and hepatic function, weight, laboratory results, comorbidities, contraindications), consideration of risk factors for thrombosis and bleeding, periprocedural management, drug interactions, duration of therapy, management strategies for bleeding or out of range laboratory values, processes to assure timely and effective communication between facility, prescribers, and pharmacists involved in anticoagulation management. Consider similar requirements for other drug classes included in the National Action Plan for Adverse Drug Event Prevention.[32]

High Priority Gaps Identified in Skilled Nursing Facility Regulations and Surveyor Guidance

Gap No. / Location	Category	Gap Description	Recommendation
26. §483.75(c) Program Feedback, Data Systems and Monitoring	Quality Improvement	Guidance does not explicitly mention adverse event documentation and reporting involving anticoagulation therapy or the necessary inclusion of anticoagulant-related ADEs in QAPI program.	Expand documentation, reporting and QAPI requirements to include adverse events involving anticoagulants (bleeding and thrombosis).[17,28]
27. §483.75(g)(2)(ii) High Risk, High Volume, Problem-Prone	Safety	Guidance does not include DOACs among high-risk drugs.	Revise guidance to explicitly include all commercially available DOACs among high-risk drugs.[32]
28. §483.80(a) Infection Control	Quality Improvement	Guidance does not require facilities to develop, implement, and maintain a viable stewardship program for anticoagulants.	Expand guidance to include requirements for anticoagulation stewardship programs.[41,42]

Quality Measures

Sources Reviewed:

- CMS Nursing Home Quality Initiative (NHQI) (Accessed May 2, 2019)[9]
- Skilled Nursing Facility Quality Reporting Program Measure Calculations and Reporting User's Manual, Version 2.0 (October 1, 2018)[43]
- Nursing Home Compare Claims-Based Quality Measure Technical Specifications (April, 2019)[44]

Description: In November 2002, the Centers for Medicare & Medicaid Services (CMS), an agency of the HHS, began a national NHQI. The program allows consumers, providers, states and researchers to compare information on nursing homes. Further, efforts such as the Post-Acute Care Payment Reform Demonstration (PAC-PRD) have been initiated to promote stronger associations between the quality of patient care provided and payments received by LTC facilities. The measures and supporting specifications are therefore highly relevant to nursing home administrators and others, and modifications to the program have the potential to influence patient outcomes in priority areas such as anticoagulation quality and safety.

High Priority Gaps Identified in Skilled Nursing Facility Quality Measures

Gap No. / Location	Category	Gap Description	Recommendation
29. Perceived Omission	Quality Improvement	Despite the fact that the elderly are significantly more prone to have indications for anticoagulation and are at greater risk of experiencing serious and avoidable anticoagulation-related ADEs, there are no anticoagulation-related quality measures for LTC facilities in the NHQI.	Develop and implement quality measures targeting key areas of anticoagulation management using available data sources (e.g. MDS, Medicare Part A and D, clinical laboratory data), including but not limited to ED visits and hospitalization for thrombosis and bleeding-related events among patients prescribed anticoagulants, and appropriateness of dosing of oral anticoagulants.[27,28,41,42,45,46]

Long-Term Care Facility Resident Assessment Instrument (RAI)

Source Reviewed: Centers for Medicare & Medicaid Services' Long-Term Care Facility Resident Assessment Instrument (RAI) User's Manual October 2018[10]

Description: This document provides clear, comprehensive, and authoritative guidance about how to use the Resident Assessment Instrument (RAI) correctly and effectively to help provide appropriate care in skilled nursing facility settings. It encompasses three basic components: the MDS Version 3.0, the Care Area Assessment (CAA) process, and the RAI Utilization Guidelines. The three components of the RAI yield information about a resident's functional status, strengths, weaknesses, and preferences, as well as offering guidance on further assessment once problems have been identified. This process and resultant data and reports serve as the basis of CMS' national quality oversite program for care provided in skilled nursing facilities.

In addition to the standardized review of the Manual, currently available data reports and repositories related to the data collected in the MDS process were also reviewed.[11,12] Perceived gaps in these sources were identified and included in this report.

High Priority Gaps Identified in Long-Term Care Facility Resident Assessment Instrument (RAI) User's Manual and ResDac

Gap No. / Location	Category	Gap Description	Recommendation
30. RAI Manual, N0410E	Safety	This field describing anticoagulant use does not mention DOACs or distinguish among anticoagulant type used (vitamin K antagonist, heparin, DOAC); Reviewers unfamiliar with DOACs may not code properly; Failure to capture data discriminating between drug classes is a missed opportunity to evaluate and compare important outcomes in this high-risk population; DOACs are now among drugs most frequently associated with ED visits among the elderly.	Revise question to make distinction between type(s) of anticoagulants utilized by the patient in the evaluation interval (i.e. DOACs, heparins, warfarin).[47]
31. ResDAC	Quality Improvement	Although multiple fields collected in the MDS instrument relate to anticoagulation, thrombosis and related factors (see Appendix), there is no publicly available dataset to support research and quality assessment for SNF setting using the available data; Making data on such a large and important population of patients available to researchers would stimulate necessary research and improvements in care.	Create and make available to researchers a dataset including fields relating to anticoagulant use, bleeding and thrombosis. Integrate data from other relevant government data sources characterizing drug prescribing, ED use, and hospitalization.[47]

Beers Criteria

Source Reviewed: American Geriatrics Society 2019 Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults[13]

Description: The American Geriatrics Society's Beers Criteria are an explicit list of Potentially Inappropriate Medications that are considered best to be avoided by older adults in most circumstances or under specific circumstances, such as in certain diseases or conditions. Originally published by geriatrician Dr. Mark Beers in 1991, the publication has been updated and disseminated by the American Geriatrics Society every 3 years since 2011.

This publication was included in the current gap analysis because it is referred to directly in CMS regulations as a source of "information on safely prescribing medications for older adults" (§483.45(d)),[8] is the basis for multiple quality measures targeting the quality of prescribing among seniors[48,49] and is widely utilized by consultant pharmacists as a reference for making therapy-related recommendations to prescribers in senior care facilities and other settings.

High Priority Gaps Identified in Beers Criteria

Gap No. / Location	Category	Gap Description	Recommendation
32. Table 4: Drugs to use with caution in older adults	Safety	Table implies that among available oral anticoagulants only dabigatran and rivaroxaban need to be used with caution in older adults.	Revise recommendation to state that all anticoagulants are to be used with caution in older adults.[32,41,42]
33. Table 4: Drugs to use with caution in older adults	Safety	Table appears to recommend warfarin over dabigatran and rivaroxaban for VTE and AF based solely on relative rates of gastrointestinal bleeding, whereas major guidelines recommend DOACs over warfarin for VTE and AF in all age groups due to significant net reduction in stroke and major and fatal bleeding.	Revise recommendation to state that drug and dose selection should be based upon net clinical benefit and evidence-based guidelines, with DOACs generally being preferredover warfarin for AF and VTE.[29,32,50-52]
34. Table 4: Drugs to use with caution in older adults	Safety	Table identifies rivaroxaban and dabigatran as having higher gastrointestinal bleeding rates than other available DOACs, yet does not clearly recommend preferential use of the alternate agent(s) when appropriate.	Revise recommendation to state that, among patients who have indications for DOAC therapy and are at high risk of bleeding, apixaban may be preferred over other agents.[32,51 53-55]

High Priority Gaps Identified in Beers Criteria

Gap No. / Location	Category	Gap Description	Recommendation
35. Table 5: Drug-drug interactions to be avoided	Safety	The list of drugs interacting with warfarin excludes a number of well-documented interacting agents (e.g. fluconazole, rifampin, carbamazepine) and does not prompt readers to consider other possible interacting agents or clinical factors that may also affect INR control (e.g. infection, diarrhea).	The list of potential drug-drug interactions involving warfarin should be expanded to include other well-documented agents and health-related factors.[56-61]
36. Table 5: Drug-drug interactions to be avoided	Safety	Table informs readers to avoid use of NSAIDs with warfarin but neglects to make similar mention with DOACs.	Readers should be informed of the risks of use of NSAIDs and other drugs that affect hemostasis with all anticoagulants in the elderly.[32,62-64]
37. Table 5: Drug-drug interactions to be avoided	Safety	Table makes no mention of avoidance of strong P-glycoprotein/Cytochrome P450-3A4 inducers and inhibitors with DOACs.	Readers should be informed of the risks of all significant drug interactions with DOACs.[33,65-68]
38. Table 5: Drug-drug interactions to be avoided	Safety	Table makes no mention of the dangers associated with combining aspirin and anticoagulant therapy, a practice that doubles major bleeding risk without decreasing risk of thrombosis (e.g. myocardial infarction, stroke, VTE) for most patients.	Readers should be informed of the risks of use of aspirin with anticoagulants, particularly where medical evidence does not support such combinations.[64]

Lower Priority Gaps

The following tables include gaps that, in comparison to the previously identified high priority gaps, do not warrant focused action or advocacy in the immediate near-term. However, these gaps should be considered for resolution when the underlying source documents and related programs undergo updates or revisions or when efforts to address high priority gaps are undertaken.

Detailed descriptions of the individual source documents are included in their respective High Priority Gaps sections and the criteria for gap categorization and ranking may be found in the Methodology and Report Format section.

Lower Priority Gaps Identified in Hospital Regulations and Surveyor Guidance[5]

Gap No. / Location	Category	Gap Description	Recommendation
39. Introduction – Task 2 – Sample Size and Selection	Quality Improvement	Survey team instructions repeatedly state requirements or suggestions for sampling of patient records and performance of patient interviews to evaluate, but do not explicitly require evaluation of records of patients receiving or requiring anticoagulant therapy at key points in the hospital care process (e.g. admission, surgery, etc.)	Update surveyor processes to require review of records of patient(s) prescribed anticoagulant therapy.[17]
40. Introduction – Task 3 – Survey Locations	Quality Improvement	Survey team instructions and regulations relating to outpatient surgery locations and other facility-owned patient care and service locations (e.g. laboratories, etc.) do not explicitly require evaluation of anticoagulant-related care or processes.	Update surveyor processes to require evaluation of anticoagulation-related care and processes within and between facility-owned service locations.[17]
41. §482.23(c) Nursing Services – Preparation and Administration of Drugs- Missed or Late Administration of Medications	Safety	Requirements for hospital policies and procedures regarding actions to be taken when medications are not administered within their permitted time window do not explicitly address the handling of missed or delayed doses of anticoagulants, including documentation and notification of medical care providers.	Modify standards to require that hospitals have policies and procedures in place to adequately respond to situations in which scheduled anticoagulant doses are not administered within the permitted time window.[17]

Lower Priority Gaps Identified in Hospital Regulations and Surveyor Guidance[5]

Gap No. / Location	Category	Gap Description	Recommendation
42. §482.23(c)(5) Reporting Transfusion Reactions	Reversal	Requirements include processes for the documentation and reporting of transfusion reactions that occur during or after a blood transfusion, but it is unclear whether these apply equally to the administration of clotting factors derived from blood products and administered to correct clotting disorders and reverse the effects of anticoagulants.	Update the standards to encompass documentation of adverse reactions relating to other blood products, such as clotting factors used to reverse the effects of anticoagulant agents.[18] Consider alignment with NPSG.03.05.01 EP2 (i.e. reversal of anticoagulation).
43. §482.23(c)(6) Required Elements of a Self-Administration Program	Safety	Requirements for patient self-administration of medications brought from home to the hospital do not include policies and procedures to assure that patients are informed of and implement changes to anticoagulant regimens when ordered by practitioner.	Modify standards to require that patients who utilize anticoagulant medications from home are informed when changes to their medication regimen are ordered by practitioners during the hospital stay.[17]
44. §482.23(c)(6) Required Elements of a Self-Administration Program	Safety	Standards regarding documentation of administration of medications brought into the hospital do not explicitly specify that the documentation of such medications (and anticoagulants in particular) is in the same location and format as other administered medications, including the ability to generate reports and electronic clinical decision support prompts on utilization where such automated processes are in place for other medications.	Modify standards to require that medications used from patient homes are documented in manner similar to medications provided by the hospital and that such medications are also subject to the same degree of automated clinical decision support and quality assurance processes (e.g. checks for drug-drug interactions).[17]
45. §482.24(c)(4)(iv) Documentation of Unfavorable Reactions to Drugs.	Quality Improvement	Standards require medical records document all hospital-acquired infections and "unfavorable reactions to drugs", without explicitly requiring documentation and reporting of bleeding events involving anticoagulant therapy or VTE occurring under the care of the hospital and outpatient care centers.	The inability of a facility to systematically document and report bleeding and thrombotic events will impede QAPI efforts, resulting in delayed system improvements and suboptimal patient outcomes.[17]

Lower Priority Gaps Identified in Hospital Regulations and Surveyor Guidance[5]

Gap No. / Location	Category	Gap Description	Recommendation
46. §482.24 (c)(4)(v) Medical Record Services – Informed Consent Forms	Education	Standards for patient consent do not specifically include the requirement that, for patients utilizing anticoagulant therapy that must be modified to allow them to undergo an invasive procedure (i.e. discontinued, reduced or otherwise modified), the patient be informed of the competing risks of thrombosis and bleeding.	Update standards to include patient education and informed consent in situations in which invasive procedures require interruption or alteration of existing (e.g. chronic) anticoagulation therapy.[20,21] Consider alignment with NPSG.03.05.01 EP3 (i.e. periprocedural management).
47. §482.23(c)(4)(vii) Discharge Summary	Care Transitions	Standards require the discharge summary include provisions for follow-up care, but do not explicitly mention the details of anticoagulation therapy.	The risk of thrombosis is often elevated following hospitalization and surgical procedures, and patients are at increased risk for medication omissions and errors during care transitions. The lack of systematic processes for documenting and communicating how anticoagulant-related care needs are to be addressed after hospital discharge increases the risk of thrombosis and bleeding complications.[22-24]
48. §482.25(b)(5) Drugs and biologicals not specifically prescribed as to time or number of doses	Safety	Standards require that drugs not prescribed for a specific duration or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff, but do not specifically require policies and procedures regarding anticoagulant therapy.	Modify standards to require that hospitals have clear policies and procedures regarding continuation or discontinuation of anticoagulant medications that are not ordered for a specific duration of time or explicit number of doses.[17]
49. §482.25(b)(6) Drug Administration Errors	Safety	Standards allow staff administering medications to use their clinical judgment regarding the immediate notification of practitioners when drug administration errors occur that result in "no or insignificant harm to the patient", and the example of a missed nighttime analgesic dose is provided. However, the standards do not include specific provisions regarding how medication errors or missed doses involving anticoagulant therapies are to be handled.	Modify standards to require that hospitals have policies and procedures in place to adequately respond to situations in which administration errors occur involving anticoagulant medications.[17]

Lower Priority Gaps Identified in Hospital Regulations and Surveyor Guidance[5]

Gap No. / Location	Category	Gap Description	Recommendation
50. §482.25(b)(6) QAPI Program	Quality Improvement	Standards state that hospitals must identify the types of events that must be reported to the QAPI program, but do not explicitly require that anticoagulant therapy-related events be reported to the QAPI.	The lack of a facility-wide QAPI program that identifies all relevant antithrombotic-related events increases the risk of suboptimal patient outcomes and deters the implementation of effective anticoagulant stewardship principles.[17]
51. §482.24(b)(6) Steps to Identify Medication Errors and ADRs	Quality Improvement	Standards require proactive efforts (e.g. observation of medication passes) to identify medication errors and to guide system improvements (i.e. QAPI) regarding high-alert medications, but anticoagulants are not specifically identified as a required focus of such efforts.	The sole reliance upon the evaluation of documented errors and adverse patient events is an insufficient means of safeguarding patients receiving anticoagulant therapy and increases the risk of suboptimal patient outcomes and catastrophic bleeding and thrombotic events.[17]
52. §482.43(d) Transfer with Necessary Medical Information	Care Transitions	Standards require that necessary medical information be sent within 7 days to providers to whom the patient has been referred or by the time of the first post-discharge appointment, an interval that may be too long to assure proper support of anticoagulant utilization among patients requiring such services.	Patients requiring post discharge support services for anticoagulant use may experience medication omissions or errors if the practitioners/services providing post-discharge support do not receive complete information regarding the regimen at the time of discharge or before, increasing the risk of catastrophic bleeding and thrombotic events.[20-24]
53. §482.51 Surgical Services	Quality Improvement	Standards state that a hospital's inpatient and outpatient surgical services must be integrated into its hospital-wide QAPI program but does not explicitly require the inclusion of anticoagulant therapy into said program.	The migration of surgical services from the inpatient to the outpatient setting without commensurate oversight and safeguards regarding anticoagulant therapy may increase the incidence and prevalence of ADEs and catastrophic bleeding and thrombotic events.[17] Consider alignment with NPSG.03.05.01 EP3 (i.e. periprocedural management of anticoagulants).

Lower Priority Gaps Identified in Hospital Regulations and Surveyor Guidance[5]

Gap No. / Location	Category	Gap Description	Recommendation
54. §482.52(b)(1) Pre-Anesthesia Evaluation	Periprocedural	Standards require a pre-anesthesia evaluation of the patient within 48 hours of procedures requiring anesthesia services, but this time interval does not allow adequate time to make necessary adjustments to anticoagulant therapy.	Consider revising standards to assure that all patients undergoing invasive medical procedures are evaluated for the use of anticoagulants at least 7 days prior to the procedure (and receive evidence-based periprocedural management).[20,21] Consider alignment with NPSG.03.05.01 EP3 (i.e. periprocedural management of anticoagulants).
55. §482.52(b)(3) Post-Anesthesia Evaluation	Periprocedural	Standards list the components of an adequate post-anesthesia evaluation (including assessment of pain, nausea, vomiting, etc.) but does not require definitive assessment of post-procedural hemostasis.	The presence or absence of post-procedural hemostasis has implications for the timing and appropriateness of post-procedural anticoagulant therapy (VTE prophylaxis and re-initiation of chronic anticoagulant therapy), and the lack of systemic processes to identify and respond to hemostatic status in the post-anesthesia period increases the risk of bleeding and thrombosis.[20,21]

Lower Priority Gaps Identified in Hospital Quality Measures[6]

Gap No. / Location	Category	Gap Description	Recommendation
56. IQR, STK-02 (Discharged on Antithrombotic Therapy)	Quality Improvement	The list of antithrombotic agents counted in numerator is broad and includes agents not typically used for stroke or associated with high quality care.	Update measure specifications to narrow numerator to include only antithrombotic agents recommended for use in stroke.[28]
57. IQR, STK-05 (Antithrombotic Therapy by the End of Hospital Day Two)	Quality Improvement	The list of antithrombotic agents counted in numerator is broad, and includes agents not typically used for stroke or associated with high quality care.	Update measure specifications to narrow numerator to include only antithrombotic agents recommended for use in stroke.[28]
58. IQR, STK-08 (Stroke Education)	Quality Improvement	Measure concept (i.e. provision of written materials) is insufficient to assure patient comprehension and cohesive care post-discharge.	Include patient comprehension of anticoagulation regimen and timely/ effective communication of key clinical data to post-acute care providers in measures.[22,23]
59. IQR, PSI-04 (Death Rate among Surgical Inpatients with Serious Treatable Complications)	Quality Improvement	Denominator only includes inpatient elective procedures.	Explore measure and program development that evaluates quality of surgical outcomes and adverse events across care settings and reflects current practices for VTE treatment (i.e. outpatient DOAC therapy).[28]
60. HAC, PSI-12 (Perioperative Pulmonary Embolism or Deep Vein Thrombosis Rate)	Quality Improvement	Numerator only includes events that occur during index stay; Inclusion of only events that occur during index stay creates opportunity to miss events that occur after discharge (e.g. most VTE); Measure does not capture events associated with outpatient/ ambulatory surgery (in absence of counterpart measure).	Explore measure and program development that evaluates quality of surgical outcomes and adverse events across care settings and reflects current practices for VTE treatment (i.e. outpatient DOAC therapy).[28]

Lower Priority Gaps Identified in Hospital Accreditation Standards[7]

Gap No. / Location	Category	Gap Description	Recommendation
61. Perceived Omission	Safety	Standard does not include an EP to address appropriate ongoing reassessment of patient therapy in the context of changing medical condition(s), medication profile and other factors, particularly in the outpatient or LTC arenas.	Expand the Standard to include requirements for processes to assure the appropriate re-evaluation and modification of anticoagulation therapy in response to changes in patient medical status or risk factors.[29]
62. Perceived Omission	Education	Standard does not address the need for adequate and ongoing education of providers regarding anticoagulant management, particularly in the context of rapidly evolving medical evidence and best practices.	Modify Standard to require organizations ensure that staff involved in the care of anticoagulated patients are sufficiently knowledgeable in current anticoagulation-related best practices.[17]
63. EP2 (The [hospital/ organization] uses approved protocols and evidence-based practice guidelines for reversal of anticoagulation and management of bleeding events)	Reversal	Standard does not specifically require that protocols and evidence-based practices for the reversal of anticoagulation and bleeding address situations that involve anticoagulants but without acute bleeding (e.g. urgent or elective procedures, overdose, trauma without signs/symptoms of bleeding, etc.)[18]	Modify Standard to require that protocols and evidence-based practices regarding reversal of anticoagulation also encompass situations that involve anticoagulants but do not involve acute bleeding (e.g. urgent or elective procedures, overdose, trauma without signs/ symptoms of bleeding, etc.)[18]
64. EP6 (The [hospital/ organization] provides education to patients and families	Safety	Standard does not include that patient-provider communication include notification of anticoagulant prescriber of upcoming medical procedures, changes to medication profile (prescription and non-prescription), and clinical status changes.	Modify Standard to include that patient-provider communication is bi-directional and includes the patient notifying anticoagulant prescribers of key factors in their care, including pending medical procedures, changes to medication profile, and clinical status.[20,21]

Lower Priority Gaps Identified in Skilled Nursing Facility Regulations and Surveyor Guidance[8]

Gap No. / Location	Category	Gap Description	Recommendation
65. §483.25(c) Care Plan for Range of Motion and/or Mobility	VTE Prophylaxis	Guidance does not require that facilities implement evidence-based policies and procedures assuring the assessment of VTE risk for residents and guiding appropriate physical and pharmacological prophylaxis strategies.	Expand guidance to require that facilities develop, implement, and maintain evidence-based policies for VTE prophylaxis for sub-populations for which there exists sufficient medical evidence and recognized best practices (e.g. post-surgical prophylaxis).[14-16]
66. §483.45 Medication-Related Adverse Events	Reversal	Guidance does not require that facilities develop and implement evidence-based policies and procedures to guide the management of bleeding and out of range INRs among patients prescribed warfarin.	Include processes for the management of extreme INRs and anticoagulant-related bleeding in comprehensive anticoagulation policies and procedures.[18,61]
67. §483.45 Adverse Consequences	Periprocedural	Guidance does not require that facilities develop and implement evidence-based policies and procedures to support the safe and effective periprocedural management of anticoagulants (e.g. dental procedures).	Include processes for periprocedural management in comprehensive anticoagulation policies and procedures.[20,21]
68. §483.45(c)(1), (2), (4), and (5) Drug Regimen Review	Safety	Guidance does not require a process for the execution of medication regimen review for anticoagulated patients with anticipated length of stay <30 days (e.g. rehab).	Adopt previous recommendations for anticoagulation-related communication, care planning, and policies and procedures to minimize drug-related problems among patients prescribed anticoagulants and other high-risk drugs identified in the National Action Plan for Adverse Drug Event Prevention who have an anticipated length of stay <30 days.[41,42]
69. §483.55(a)(1) Dental Services	Periprocedural	Guidance does not require that policies and procedures regarding resident dental care or other potentially invasive services include adherence to facility processes regarding appropriate periprocedural use of anticoagulants.	Include processes for periprocedural management in comprehensive anticoagulation policies and procedures, including invasive services frequently provided to seniors (e.g. dentistry, podiatry, dermatology).[20,21]

Lower Priority Gaps Identified in Minimum Data Set for Skilled Nursing Facilities[11]

Gap No. / Location	Category	Gap Description	Recommendation
70. MDS Frequency Report	Quality Improvement	Currently available CMS reports on MDS data do not include anticoagulant field (N0410E) or other fields relevant to trending and evaluating anticoagulation use, thrombosis, and important related outcomes in this high-risk population.	Include all fields relating to anticoagulant utilization, thrombosis, and bleeding in publicly available reports (see Appendix).[47]

Lower Priority Gaps Identified in Beers Criteria[13]

Gap No. / Location	Category	Gap Description	Recommendation
71. Table 3: Potentially inappropriate due to drug-disease interactions	Safety	No mention of avoidance of DOACs or their appropriate use in various types of valvular disease.	Future releases of the Beers List should mention appropriate use of DOACs in patients with valvular disease.[33,65-68]
72. Table 3: Potentially inappropriate due to drug-disease interaction	Safety	Apixaban use in patients with Creatinine Clearance <25 mL/min is becoming accepted; Perhaps apixaban should not be singled out as a drug to avoid in this situation but should be used with caution.	Future releases of the Beers List should evaluate and describe current evidence regarding use of DOACs in patients with renal insufficiency.[69]
73. Table 4: Drugs to use with caution in older adults	Quality Improvement	Warfarin managed with unintentionally low TTR (due to poor management practices) and intentional under-dosing (i.e. targeting an INR range below what is recommended) is a problem in nursing homes nationally yet is not addressed in the Beers Criteria.	Future releases of the Beers List should include statements regarding the importance of maintaining INR within evidence-based target ranges for specific indications.[41,42]
74. Table 4: Drugs to use with caution in older adults	Quality Improvement	Emerging evidence suggests that DOACs are purposefully under-dosed in many patients, including the elderly, putting them at elevated risk of bleeding without the full benefits of proven efficacy.	Future releases of the Beers List should include statement(s) regarding the importance of using evidence-based dosing of DOACs for specific indications.[27]

Appendix 1:

MDS Fields Potentially Related to Anticoagulant Utilization, Thrombosis, and Bleeding[10]

The following MDS data fields have potential value in the evaluation of anticoagulation quality and patient safety in the long-term care setting:

MDS Item	Description
I0020A	Stroke
I0300	Atrial fibrillation and other dysrhythmias
I0400	Coronary artery disease (CAD)
I0500	Deep venous thrombosis (DVT), PE, or PTE
I0900	Peripheral vascular disease (PVD) or PAD
I1100	Cirrhosis
I1200	Gastroesophageal reflux disease (GERD) or ulcer
I1300	Ulcerative colitis, Crohn's, inflammatory bowel disease
I1500	Renal insufficiency, renal failure, ESRD
I2900	Diabetes mellitus (DM)
I3700	Arthritis
I3900	Hip fracture
I4500	Cerebrovascular accident (CVA), TIA, or stroke
J1550D	Problem conditions: internal bleeding
J2000	Prior Surgery
K0200A	Height (in inches)
K0200B	Weight (in pounds)
K0300	Weight loss
M0300A1	Stage 1 pressure ulcers: number present
M0300B1	Stage 2 pressure ulcers: number present
M0300B2	Stage 2 pressure ulcers: number at admit/reentry
M0300C1	Stage 3 pressure ulcers: number present
M0300C2	Stage 3 pressure ulcers: number at admit/reentry
M0300D1	Stage 4 pressure ulcers: number present
M0300D2	Stage 4 pressure ulcers: number at admit/reentry
M0300E1	Unstaged due to dressing: number present
M0300E2	Unstaged due to dressing: number at admit/reentry
M0300F1	Unstaged slough/eschar: number present
M0300F2	Unstaged slough/eschar: number at admit/reentry
M0300G1	Unstageable - deep tissue: number present
M0300G2	Unstageable - deep tissue: number at admit/reentry
M1030	Number of venous and arterial ulcers
M1040E	Other skin problems: surgical wound(s)
N0300	Number of days injectable medications received
N0410E	Medication received: Days: anticoagulant
N2001	Drug Regimen Review
N2003	Medication Follow-up
N2005	Medication Intervention
O0100I2	Treatment: transfusions - while resident
Q0400A	Active discharge plan for return to community
Q0600	Referral been made to local contact agency
V0200A11A	CAA-Falls: triggered

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