TOTAL KNEE REPLACEMENT (TKR) MEASURES GROUP OVERVIEW

2016 PQRS OPTIONS FOR MEASURES GROUP:

2016 PQRS MEASURES IN TOTAL KNEE REPLACEMENT MEASURES GROUP:
#130 Documentation of Current Medications in the Medical Record
#226 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention
#350 Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy
#351 Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation
#352 Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet
#353 Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report

INSTRUCTIONS FOR REPORTING

- It is not necessary to submit the measures group-specific intent G-code for registry-based submissions. However, the measures group-specific intent G-code has been created for registry only measures groups for use by registries that utilize claims data.

G9234: I intend to report the Total Knee Replacement Measures Group

- Report the patient sample method:
  20 Patient Sample Method via registries: 20 unique procedures (a majority of which must be Medicare Part B FFS patients) meeting patient sample criteria for the measures group during the reporting period (January 1 through December 31, 2016).

- Patient sample criteria for the TKR Measures Group are patients regardless of age that have a specific procedure for TKR performed:
  One of the following patient procedure codes: 27438, 27442, 27446, 27447

- To satisfactorily report the TKR Measures Group requires reporting a numerator option on all applicable measures, for each patient (each isolated TKR procedure) within the eligible professional’s patient sample, a minimum of once during the reporting period.

- Measures #130 and #226 only need to be reported on patients aged 18 years and older.

- Instructions for qualifying numerator option reporting for each of the measures within the Total Knee Replacement (TKR) Measures Group are displayed on the next several pages. The following composite Quality Data Code (QDC) has been created for registries that utilize claims data. This QDC may be reported in lieu of individual QDCs when all quality clinical actions for all applicable measures within the group have been performed.

Composite QDC G9233: All quality actions for the applicable measures in the Total Knee Replacement (TKR) Measures Group have been performed for this patient

- Measure Group Reporting Calculations:

  Measures groups containing a measure with a 0% performance rate will not be counted as satisfactorily reporting the measures group. The recommended clinical quality action must be performed on at least one patient for each applicable measure within the measures group reported by the eligible professional.

  Performance exclusion QDCs are not counted in the performance denominator. If the eligible professional submits all performance exclusion QDCs, the performance rate would be 0/0 (null) and would be considered satisfactorily reporting.
If a measure within a measures group is not applicable to a patient, the patient would not be counted in the performance denominator for that measure (e.g., Preventive Care Measures Group - Measure #39: Screening for Osteoporosis for Women Aged 65-85 Years of Age would not be applicable to male patients according to the patient sample criteria). If the measure is not applicable for all patients within the sample, the performance rate would be 0/0 (null) and would be considered satisfactorily reporting.

- **NOTE:** The detailed instructions in this specification apply exclusively to the reporting and analysis of the included measures under the measures group option.
Measure #130 (NQF 0419): Documentation of Current Medications in the Medical Record --
National Quality Strategy Domain: Patient Safety

DESCRIPTION:
Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a
list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbs, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications’ name, dosage, frequency and route of administration.

NUMERATOR:
Eligible professional attests to documenting, updating or reviewing a patient’s current medications using all immediate resources available on the date of encounter. This list must include ALL known prescriptions, over-the-counters, herbs, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications’ name, dosages, frequency and route of administration.

Definitions:
Current Medications – Medications the patient is presently taking including all prescriptions, over-the-counters, herbs and vitamin/mineral/dietary (nutritional) supplements with each medication’s name, dosage, frequency and administered route.
Route - Documentation of the way the medication enters the body (some examples include but are not limited to: oral, sublingual, subcutaneous injections, and/or topical).
Not Eligible - A patient is not eligible if the following reason is documented:
• Patient is in an urgent or emergent medical situation where time is of the essence and to delay treatment would jeopardize the patient’s health status.

NUMERATOR NOTE: The eligible professional must document in the medical record they obtained, updated, or reviewed a medication list on the date of the encounter. Eligible professionals reporting this measure may document medication information received from the patient, authorized representative(s), caregiver(s) or other available healthcare resources. G8427 should be reported if the eligible professional documented that the patient is not currently taking any medications.

Numerator Options:
Performance Met:
Eligible professional attests to documenting in the medical record they obtained, updated, or reviewed the patient’s current medications (G8427)

OR

Other Performance Exclusion:
Eligible professional attests to documenting in the medical record the patient is not eligible for a current list of medications being obtained, updated, or reviewed by the eligible professional (G8430)

OR

Performance Not Met:
Current list of medications not documented as obtained, updated, or reviewed by the eligible professional, reason not given (G8428)
**Measure #226 (NQF 0028): Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention -- National Quality Strategy Domain: Community/Population Health**

**DESCRIPTION:**
Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user.

**NUMERATOR:**
Patients who were screened for tobacco use at least once within 24 months **AND** who received tobacco cessation intervention if identified as a tobacco user.

**Definitions:**
- **Tobacco Use** – Includes use of any type of tobacco.
- **Tobacco Cessation Intervention** – Includes brief counseling (3 minutes or less), and/or pharmacotherapy.

**NUMERATOR NOTE:** In the event that a patient is screened for tobacco use and identified as a user but did not receive tobacco cessation intervention report 4004F with 8P.

**Numerator Options:**

- **Performance Met:** Patient screened for tobacco use AND received tobacco cessation intervention (counseling, pharmacotherapy, or both), if identified as a tobacco user (4004F)

- **OR**
- **Performance Met:** Current tobacco non-user (1036F)

- **OR**
- **Medical Performance Exclusion:** Documentation of medical reason(s) for not screening for tobacco use (eg, limited life expectancy, other medical reasons) (4004F with 1P)

- **OR**
- **Performance Not Met:** Tobacco screening OR tobacco cessation intervention not performed, reason not otherwise specified (4004F with 8P)

**DESCRIPTION:**
Percentage of patients regardless of age or gender undergoing a total knee replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy (e.g., non-steroidal anti-inflammatory drug (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure.

**NUMERATOR:**
Patients with documented shared decision-making including discussion of conservative (non-surgical) therapy (e.g. NSAIDs, analgesics, weight loss, exercise, injections) prior to the procedure.

**Numerator Options:**

- **Performance Met:** Patients with documented shared decision-making including discussion of conservative (non-surgical) therapy (e.g., NSAIDs, analgesics, weight loss, exercise, injections) prior to the procedure (G9296)

- **Performance Not Met:** Shared decision-making including discussion of conservative (non-surgical) therapy (e.g. NSAIDs, analgesics, weight loss, exercise, injections) prior to the procedure not documented, reason not given (G9297)

DESCRIPTION:
Percentage of patients regardless of age or gender undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g. history of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke)

NUMERATOR:
Patients who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g., history of DVT, PE, MI, arrhythmia and stroke)

Numerator Options:

**Performance Met:**
Patients who are evaluated for venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g. history of DVT, PE, MI, arrhythmia and stroke) (G9298)

**Performance Not Met:**
Patients who are not evaluated for venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure including (e.g. history of DVT, PE, MI, arrhythmia and stroke), reason not given (G9299)

DESCRIPTION:
Percentage of patients regardless of age or gender undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet

NUMERATOR:
Patients who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet (tourniquet around the proximal thigh)

Numerator Options:

- **Performance Met:**
  Patients who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet
  (G9301)

- **Medical Performance Exclusion:**
  Documentation of medical reason(s) for not completely infusing the prophylactic antibiotic prior to the inflation of the proximal tourniquet (e.g., a tourniquet was not used)
  (G9300)

- **Performance Not Met:**
  Prophylactic antibiotic not completely infused prior to the inflation of the proximal tourniquet, reason not given
  (G9302)

**DESCRIPTION:**
Percentage of patients regardless of age or gender undergoing a total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of the prosthetic implant and the size of each prosthetic implant.

**NUMERATOR:**
Patients whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of the prosthetic implant and the size of each prosthetic implant.

<table>
<thead>
<tr>
<th>Numerator Options:</th>
<th>Performance Met:</th>
<th>Performance Not Met:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of the prosthetic implant and the size of each prosthetic implant (G9304)</td>
<td>Operative report does not identify the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of the prosthetic implant and the size of each prosthetic implant, reason not given (G9303)</td>
</tr>
</tbody>
</table>
MEASURE #130 – DOCUMENTATION OF CURRENT MEDICATIONS IN THE MEDICAL RECORD

RATIONALE:

In the American Medical Association’s (AMA) Physician’s Role in Medication Reconciliation (2007), critical patient information, including medical and medication histories, current medications the patient is receiving and taking, and sources of medications, is essential to the delivery of safe medical care. However, interruptions in the continuity of care and information gaps in patient health records are common and significantly affect patient outcomes. Consequently, clinical judgments may be based on incomplete, inaccurate, poorly documented or unavailable information about the patient and his or her medication.

As identified by The Agency for Healthcare Research and Quality in the National Healthcare Disparities report (2013), "different providers may prescribe medications for the same patient. Patients are responsible for keeping track of all their medications, but medication information can be confusing, especially for patients on multiple medications. When care is not well coordinated and some providers do not know about all of a patient’s medications, patients are at greater risk for adverse events related to drug interactions, overdosing, or underdosing."

In addition, providers need to periodically review all of a patient’s medications to ensure that they are taking what is needed and only what is needed. Medication reconciliation has been shown to reduce both medication errors and adverse drug events (Whittington & Cohen, 2004).

Medication safety efforts have primarily focused on hospitals; however, the majority of health care services are provided in the outpatient setting where two-thirds of physician visits result in writing at least one prescription (Stock et al., 2009). Chronically ill patients are increasingly being treated as outpatients, many of whom take multiple medications requiring close monitoring (Nassaralla et al., 2007).

Adverse drug events (ADE) prove to be more fatal in outpatient settings (1 of 131 outpatient deaths) than in hospitals (1 of 854 inpatient deaths) (Nassaralla et al., 2007). According to the first study to utilize nationally-representative data to examine annual rates of ADEs in the ambulatory care setting "Adverse Drug events in U.S. Adult Ambulatory Medical Care," ADE rates increase with age, adults 25-44 years old had a rate of 1.3 per 10,000 person per year, those 45-64 had a rate of 2.2 per 10,000 per year, and those 65 years and older had the highest rate, at 3.8 ADEs per 10,000 persons per year. This study estimates that 13.5 million ADE related visits occurred between 2005-2007, estimating that approximately 4.5 million ambulatory ADE visits occur each year. These 4.5 million visits are associated with approximately 400,000 hospitalizations annually. According to the Institute of Medicine (IOM), in the US, as many as 98,000 deaths per year are attributable to preventable adverse events that occur in the hospitals setting with annual costs of between $17 billion and $29 billion. (Sarkar et al., 2011)

Additionally, findings of The Commonwealth Fund (2010) studies identified 11% to 28% of the 4.3 million visit related ADEs (VADE) in 2001 might have been prevented with improved systems of care and better patient education, yielding an estimate of 473,000 to 1.2 million potentially preventable VADEs annually and potential cost-savings of $946 million to $2.4 billion. (Sarkar et al., 2011)

According to the AMA's published report, The Physician's Role in Medication Reconciliation, the rate of medication errors during hospitalization was estimated to be 52 per 100 admissions, or 70 per 1,000 patient days in 2005. Emerging research suggests the scope of medication-related errors in ambulatory settings is as extensive as or more extensive than during hospitalization. Ambulatory visits result in a prescription for medication 50 to 70% of the time. One study estimated the rate of ADEs in the ambulatory setting to be 27 per 100 patients. It is estimated that between 2004 and 2005, in the United States 701,547 patients were treated for ADEs in emergency departments and 117,318 patients were hospitalized for injuries caused by an ADE. Individuals aged 65 years and older are more likely than any other population group to require treatment in the emergency department for ADEs. (AMA, 2007).
A Systematic Review on "Prevalence of Adverse Drug Events in Ambulatory Care" finds that "In the ambulatory care setting, adverse drug events (ADEs) have been reported to occur at a rate of 25%. Approximately 39% of these ADEs were preventable. Since many ADEs are associated with medication errors, and thus potentially preventable, understanding the nature of medication errors in ambulatory care settings can direct attention toward improvement of medication safety in ambulatory care." Data extracted and synthesized across studies indicated the median preventable ADE rates in ambulatory care-based studies were 16.5%. (Tache et al., 2011).

The Agency for Healthcare Research and Quality's (AHRQ) National's Healthcare Disparities Report (2011) identified the rate of adverse drug events (ADE) among Medicare beneficiaries in ambulatory settings 50 per 1,000 person-years. In 2005, AHRQ reported data on adults age 65 and over who received potentially inappropriate prescription medicines in the calendar year, by race, ethnicity, income, education, insurance status, and sex. The disparities were identified as follows: older Asians were more likely than older Whites to have inappropriate drug use (20.3% compared with 17.3%); Older Hispanics were less likely than older non-Hispanic Whites to have inappropriate drug use (13.5% compared with 17.6%); Older women were more likely than older men to have inappropriate drug use (20.2% compared with 14.3%); there were no statistically significant differences by income or education.

Weeks et al. (2010) noted fragmented medication records across the health care continuum, inaccurate reporting of medication regimens by patients, and provider failure to acquire all of the necessary elements of medication information from the patient or record, present significant obstacles to obtaining an accurate medication list in the ambulatory care setting. Because these obstacles require solutions demonstrating improvements in access to information and communication, the Institute of Medicine and others have encouraged the incorporation of IT solutions in the medication reconciliation process. In a survey administered to office-based physicians with high rates of EMR use, Weeks et al. found there is an opportunity for universal medication lists utilizing health IT.

**CLINICAL RECOMMENDATION STATEMENTS:**
The Joint Commission's 2015 Ambulatory Care National Patient Safety Goals guide provides to maintain and communicate accurate patient medication information. Specifically, the section "Use Medicines Safely NPSG.03.06.01" states the following: "Maintain and communicate accurate patient medication information. The types of information that clinicians use to reconcile medications include (among others) medication name, dose, frequency, route, and purpose. Organizations should identify the information that needs to be collected to reconcile current and newly ordered medications and to safely prescribe medications in the future." (Joint Commission, 2015, retrieved at: Joint Commission's 2015 Ambulatory Care National Patient Safety Goals guide).

The National Quality Forum's 2010 update of the Safe Practices for Better Healthcare, states healthcare organizations must develop, reconcile, and communicate an accurate patient medication list throughout the continuum of care. Improving the safety of healthcare delivery saves lives, helps avoid unnecessary complications, and increases the confidence that receiving medical care actually makes patients better, not worse. Every healthcare stakeholder group should insist that provider organizations demonstrate their commitment to reducing healthcare error and improving safety by putting into place evidence-based safe practices.

The AMA's published report, The Physician's Role in Medication Reconciliation, identified the best practice medication reconciliation team as one that is multidisciplinary and—in all settings of care—will include physicians, pharmacists, nurses, ancillary health care professionals and clerical staff. The team’s variable requisite knowledge, skills, experiences, and perspectives are needed to make medication reconciliation work as safely and smoothly as possible. Team members may have access to vital information or data needed to optimize medication safety. Because physicians are ultimately responsible for the medication reconciliation process and subsequently accountable for medication management, physician leadership and involvement in all phases of developing and initiating a medication reconciliation process or model is important to its success.
**MEASURE #226 – PREVENTIVE CARE AND SCREENING: TOBACCO USE: SCREENING AND CESSION INTERVENTION**

**RATIONALE:**
This measure is intended to promote adult tobacco screening and tobacco cessation interventions for those who use tobacco products. There is good evidence that tobacco screening and brief cessation intervention (including counseling and/or pharmacotherapy) is successful in helping tobacco users quit. Tobacco users who are able to stop smoking lower their risk for heart disease, lung disease, and stroke.

**CLINICAL RECOMMENDATION STATEMENTS:**
The following evidence statements are quoted verbatim from the referenced clinical guidelines:

- All patients should be asked if they use tobacco and should have their tobacco use status documented on a regular basis. Evidence has shown that clinic screening systems, such as expanding the vital signs to include tobacco use status or the use of other reminder systems such as chart stickers or computer prompts, significantly increase rates of clinician intervention. (Strength of Evidence = A) (U.S. Department of Health and Human Services. Public Health Service, 2008)

- All physicians should strongly advise every patient who smokes to quit because evidence shows that physician advice to quit smoking increases abstinence rates. (Strength of Evidence = A) (U.S. Department of Health and Human Services. Public Health Service, 2008)

- Minimal interventions lasting less than 3 minutes increase overall tobacco abstinence rates. Every tobacco user should be offered at least a minimal intervention, whether or not he or she is referred to an intensive intervention. (Strength of Evidence = A) (U.S. Department of Health and Human Services. Public Health Service, 2008)

- The combination of counseling and medication is more effective for smoking cessation than either medication or counseling alone. Therefore, whenever feasible and appropriate, both counseling and medication should be provided to patients trying to quit smoking. (Strength of Evidence = A) (U.S. Department of Health and Human Services. Public Health Service, 2008)

- Clinicians should encourage all patients attempting to quit to use effective medications for tobacco dependence treatment, except where contraindicated or for specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers, and adolescents). (Strength of Evidence = A) (U.S. Department of Health and Human Services. Public Health Service, 2008)

- The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products. (A Recommendation) (U.S. Preventive Services Task Force, 2009)

**MEASURE #350 – TOTAL KNEE REPLACEMENT: SHARED DECISION MAKING: TRIAL OF CONSERVATIVE (NON-SURGICAL) THERAPY**

**RATIONALE:**
A trial of non-surgical therapy should be used prior to surgery, when possible. Non-surgical therapy may include the use of NSAIDs, other analgesics, exercise, or injections. For patients with severe disability, the patient and surgeon may decide after a thorough review of conservative options that the optimal treatment is to proceed with the operative intervention.

This measure is designed for use by physicians and eligible health care professionals managing ongoing care for all patients undergoing a total knee replacement. This measure addresses the preoperative period.

**CLINICAL RECOMMENDATION STATEMENTS:**
AAOS 2008 Treatment Guideline of Osteoarthritis of the Knee (AAOS, 2008)
AAOS suggests that patients with symptomatic OA of the knee be encouraged to participate in self-management educational programs. (Level of Evidence II Grade B.)

AAOS recommends that patients with symptomatic OA of the knee who are overweight (BMI >25) should be encouraged to lose weight (a minimum of 5% of body weight) and maintain their weight at a lower level with an appropriate program for dietary modification and exercise. (Level of Evidence I Grade A.)

AAOS recommends that patients with symptomatic OA of the knee be encouraged to participate in low-impact aerobic fitness exercises. (Level of Evidence I Grade A.)

AAOS suggests that patients with symptomatic OA of the knee use patellar taping for short-term relief of pain and improvement in function. (Level of Evidence II Grade B.)

AAOS suggests that patients with symptomatic OA of the knee use patellar taping for short-term relief of pain and improvement in function. (Level of Evidence II Grade B.)

AAOS suggests that intra-articular corticosteroids be used for short-term pain relief for patients with symptomatic OA of the knee. (Level of Evidence II Grade B.)


Patients with knee OA who are not obtaining adequate pain relief and functional improvement from a combination of non-pharmacological and pharmacological treatment should be considered for joint replacement therapy.

**MEASURE #351 – TOTAL KNEE REPLACEMENT: VENOUS THROMBOEMBOLIC AND CARDIOVASCULAR RISK EVALUATION**

**RATIONALE:**
Prior to a total knee replacement the patient's venous thromboembolic and cardiovascular risk should be evaluated. A population-based study of all Olmstead County, Minnesota, patients undergoing a total hip or knee arthroplasty from 1994 - 2008, reported that patients undergoing a total knee arthroplasty with a previous history of a cardiac event or a thromboembolic event were associated with an increased risk of a 90-day cardiac or thromboembolic event following surgery. (Singh JA, Jensen MR, Harmsen WS, Gabriel SE, Lewallen DG, 2011)

A study using the Danish national resident registries compared all patients undergoing a primary THR and TKR from 1998 – 2007 to control groups not undergoing one of the procedures and found that the AMI rate 2 weeks after TKR was increased 31-fold compared to the control group. (Lalmohamed A, Vestergaard P, Klop C, Grove EL, 2012)

Any preoperative disease state should be identified and managed prior to surgery to minimize the risk of the surgical procedure.

This measure is designed for use by physicians and eligible health care professionals managing ongoing care for all patients undergoing a total knee replacement. This measure addresses the preoperative period.

**CLINICAL RECOMMENDATION STATEMENT:**

In patients with known coronary artery disease (CAD) or the new onset of signs or symptoms suggestive of CAD, baseline cardiac assessment should be performed. In the asymptomatic patient, a more extensive assessment of history and physical is warranted in those individuals 50 years of age or older, because the evidence related to the determination of cardiac risk factors and derivation of a Revised Cardiac Risk Index occurred in this population. Preoperative cardiac evaluation must therefore be carefully tailored to the circumstances that have prompted the evaluation and to the nature of the surgical illness.

**MEASURE #352 – TOTAL KNEE REPLACEMENT: PREOPERATIVE ANTIBiotic INFUSION WITH PROXIMAL TOURNIQUET**

**RATIONALE:**
The Surgical Care Improvement Project (SCIP) evaluates the timing and appropriateness of the prophylactic antibiotic. This measure evaluates that the prophylactic antibiotic is completely infused prior to the inflation of the tourniquet.

This measure is designed for use by physicians and eligible health care professionals managing ongoing care for all patients undergoing a total knee replacement. This measure addresses the intraoperative period.

**CLINICAL RECOMMENDATION STATEMENT:**
National Surgical Infection Prevention Project Advisory Statement 2004 (Bratzler DW, Houck PM, 2005)

If a proximal tourniquet is used, the antimicrobial should be completely infused before inflation.

**MEASURE #353 – TOTAL KNEE REPLACEMENT: IDENTIFICATION OF IMPLANTED PROSTHESIS IN OPERATIVE REPORT**

**RATIONALE:**
It is important to capture the type of prosthesis used. The rates of prosthesis failure which will require a revision increases from 10 percent at 10 years to approximately 20 percent at 20 years following surgery. (National Institutes of Health, 2003) The FDA requires appropriate tracking of the device but this information may not be readily available to the surgeon performing the revision. The surgeon performing a future revision needs to be able to identify the prosthesis and size of the prosthesis that were used in the initial surgery, to determine if a complete revision is required or if a partial revision could be performed. The initial operative report should contain the necessary information which will ultimately help the future treating physician who performs the revision surgery.

This measure is designed for use by physicians and eligible health care professionals managing ongoing care for all patients undergoing a total knee replacement. This measure addresses the immediate postoperative period.

**CLINICAL RECOMMENDATION STATEMENT:**
Medical Device Tracking Requirements 2008 (Federal Register, 2008)

Effective tracking of devices from the manufacturing facility, through the distributor network (including distributors, retailers, rental firms and other commercial enterprises, device user facilities, and licensed practitioners) and ultimately, to the patient is necessary for the effectiveness of remedies prescribed by the act, such as patient notification (section 518 (a) of the act) or device recall (section 518 (e) of the act). 21 CFR 821.1 (b)

Effective tracking of devices from the manufacturing facility, through the distributor network (including distributors, retailers, rental firms and other commercial enterprises, device user facilities, and licensed practitioners) and ultimately, to the patient is necessary for the effectiveness of remedies prescribed by the act, such as patient notification (section 518 (a) of the act) or device recall (section 518 (e) of the act). 21 CFR 821.1 (b)