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REPORT

Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy Measure Technical Report

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Statement of Subcontractor Relationship

Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE) subcontracted with Mathematica Policy Research (Mathematica) to produce the Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy Measure Technical Report.

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Project Team

Mathematica Policy Research

Christine Holland, MA, PMP	Measure Lead/Researcher
Fei Xing, PhD	Statistician
Angela Merrill, PhD	Project Director
Elizabeth Crane, BA	Project Manager/Research Assistant
Chris Rankin, MA	Programmer
Thomas Croghan, MD	Clinical Investigator

Center for Outcomes Research and Evaluation

Faseeha Altaf, MPH	Project Coordinator
Hayley Dykhoff, BA	Research Assistant
Lori Geary, MPH	Associate Director
Craig Parzynski, MS	Lead Analyst
Joseph Ross, MD, MHS	Clinical Investigator
Lori Schroeder, LLM, JD	Project Manager

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Peter B. Bach, MD, MAPP	Memorial Sloan-Kettering Cancer Center, Center for Health Policy and Outcomes (Director)
Stephen Edge, MD	Baptist Cancer Center (Cancer Center Director)
Andrew Glass, MD	Kaiser Permanente Northwest, Center for Health Research (Senior Investigator)
Mark Gorman	Consultant
Michael J. Hassett, MD, MPH	Dana-Farber Cancer Institute, Outpatient Clinic and Treatment Center (Staff Physician, Breast Oncology)
Karl Lorenz, MD, MSHS	UCLA, Department of Veterans Affairs (Associate Professor); Rand Health
Joan McClure, MS	National Comprehensive Cancer Network, Clinical Information and Publications (Senior Vice President)
Bruce Minsky, MD	MD Anderson Hospital, Department of Radiation Oncology (Professor and Director of Clinical Research)
Shirley Stagner, MSN, ONP, AOCNP	Lawrence Hospital Center, Cancer Survivorship Program (Nurse Practitioner)
Janet H. Van Cleave, PhD, MSN, AOCNP	New York University College of Nursing (Assistant Professor)
Sandra L. Wong, MD MS	University of Michigan Health System, Division of Surgical Oncology (Physician)

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J. Robert Beck, MD	American Oncologic Hospital (Fox Chase) (Senior Vice President and Chief Academic Officer)
Joe Jacobson, MD	Dana Farber Cancer Institute (Chief Quality Officer)
Barbara Jagels, MHA, RN, OCN	Seattle Cancer Care Alliance (Fred Hutchinson Cancer Research Center) (Director of Nursing and Clinical Excellence)
Dana Jenkins	Roswell Park Memorial Institute (Vice President of Organizational Improvement)
Tricia Kassab, RN, MS, CPHQ, HACP	City of Hope National Medical Center (Vice President of Quality and Patient Safety)
Jeremy Miransky, PhD	Memorial Hospital for Cancer and Allied Disease (MSKCC) (Quality Analytics Manager)
Shyroll Morris, MBA, MPH	University of Miami Hospital and Clinics
Thomas Ross, MS	H. Lee Moffitt Cancer and Research Institute Hospital, Inc. (Director of Quality and Safety)
Anthony Senagore, MD	University of Southern California Kenneth Norris Jr. Cancer Hospital (Chief of Colorectal Surgery)
Ron Walters, MD, MHA, MBA	The University of Texas MD Anderson Cancer Center (Associate Vice President of Medical Operations and Informatics)
Saul Weingart, MD, PhD	Dana Farber Cancer Institute (Vice President for Quality Improvement and Patient Safety)

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Peter B. Bach, MD, MAPP	Memorial Sloan-Kettering Cancer Center, Center for Health Policy and Outcomes (Director)
Stephen Edge, MD	Baptist Cancer Center (Cancer Center Director)
Michael J. Hassett, MD, MPH	Dana-Farber Cancer Institute, Outpatient Clinic and Treatment Center (Staff Physician, Breast Oncology)
Karl Lorenz, MD, MSHS	UCLA, Department of Veterans Affairs (Associate Professor); Rand Health
Allison Snyderman, PhD	Memorial Sloan-Kettering Cancer Center, Center for Health Policy and Outcomes (Researcher)
Tracy Spinks, CPH	MD Anderson Hospital, Cancer Care Delivery (Program Director)

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1. Executive Summary

This report presents the development process, testing results, and final specifications of the Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy measure, an outcome measure that calculates two separate risk-standardized rates for admissions and emergency department (ED) visits for 10 specific diagnoses following chemotherapy treatment in a hospital outpatient department (HOPD). By implementing this measure, the Centers for Medicare & Medicaid Services (CMS) intends to reduce the number of potentially avoidable inpatient admissions and ED visits for several conditions that are treatable in the ambulatory care setting among cancer patients receiving chemotherapy in an HOPD. Mathematica and its partner, the National Committee for Quality Assurance (NCQA), originally developed the measure for CMS. Mathematica continues to oversee measure reevaluation and maintenance in conjunction with CORE under contract to CMS for a project supporting the development and implementation of outpatient outcome and efficiency measures across CMS programs. This risk-standardized quality measure will help assess the care provided to cancer patients and inform quality improvement efforts to reduce potentially preventable admissions and ED visits.

1.1. Rationale for Assessing Admissions and Emergency Department Visits Following Hospital Outpatient Chemotherapy

This measure focuses on cancer patients receiving chemotherapy treatment in a hospital outpatient setting. Each year, approximately 22 percent of patients with cancer receive chemotherapy, increasingly in HOPDs [1, 2]. Outpatient hospital-based chemotherapy rose from 17 to 30 percent of all chemotherapy provided to Medicare patients from 2008 to 2012, and this trend is likely to continue [1]. Chemotherapy treatment can have severe, predictable side effects, which, if inappropriately managed, can reduce patients' quality of life and increase healthcare utilization and costs. On average, cancer patients receiving chemotherapy have one hospital admission and two ED visits per year; approximately 40 percent of these admissions and 50 percent of these ED visits stem from complications of chemotherapy [2]. This risk-standardized measure seeks to increase transparency in the quality of care patients receive and to provide information to help physicians and hospitals mitigate patients' need for acute care, which can be a burden on patients, and increase patients' quality of life.

1.2. Measure Development

Mathematica and NCQA originally developed the measure in accordance with CMS's measure development guidance [3] and with the support of multidisciplinary clinical and research experts. Mathematica and CORE now manage ongoing measure reevaluation and maintenance

activities. We convened a Technical Expert Panel (TEP) of physicians, nurses, patient advocates, and experts in quality improvement to provide input on key methodological decisions during measure development, and continue to meet with the Expert Working Group to support ongoing measure refinement and maintenance. In addition, we consulted with the Cancer Hospital Workgroup consisting of representatives from each of the 11 PPS-exempt cancer hospitals (PCHs) to understand their internal quality measurement and improvement activities and to gain their perspective on the importance and usefulness of clinical quality measures for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. Finally, we held a 45-day public comment period to solicit comments from a broader range of stakeholders. This guidance helped inform the process of developing, testing, and revising the measure specifications, including the measure cohort, outcome, and risk-adjustment model, through multiple rounds of quantitative testing. This report presents the final measure specifications, methodology, and testing results.

1.3. Measure Specifications

The measure estimates hospital-level, risk-standardized rates of inpatient admissions or ED visits for cancer patients (excluding leukemia patients) ages 18 years or older for at least one of the following diagnoses - anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis - within 30 days of outpatient chemotherapy treatment at a short-stay, acute care hospital. The measure calculates and reports the two mutually exclusive outcome rates (inpatient admissions and ED visits) separately. A patient can qualify for only one outcome; the measure assesses the ED visit outcome only for patients who do not qualify for the inpatient admission outcome. The measure counts patients who experience both an inpatient admission and an ED visit during the performance period toward the inpatient admission outcome. As a result, the two rates provide a comprehensive performance estimate of quality of care following hospital-based outpatient chemotherapy treatment.

The measure uses a two-level hierarchical logistic regression model to estimate risk-standardized outcome rates. This approach accounts for the clustering of patients within hospitals and variation in sample size. The measure calculates the hospital-specific risk-adjusted rate as the ratio of a hospital's "predicted" number of outcomes to "expected" number of outcomes multiplied by the national observed outcome rate. It uses separate models for the inpatient admission and ED visit outcomes. The models adjust for clinical comorbidities and the number of outpatient chemotherapy administrations during the performance period (exposure) to account for differences among patients that may influence the outcome in ways that do not relate to the quality of outpatient chemotherapy care.

1.4. Measure Testing and Results

We tested the measure using the National Quality Forum (NQF) criteria for scientific soundness and importance, including testing the risk-adjustment model, assessing sociodemographic status (SDS) risk factors, and evaluating the measure score variation in development and validation split samples. The measure testing aligns with national guidelines for publicly reported outcomes measures and with the technical approach to outcomes measurement set forth in NQF guidance for outcomes measures [4], CMS Measure Management System (MMS) guidance [3], and the guidance in the American Heart Association scientific statement, "Standards for Statistical Models Used for Public Reporting of Health Outcomes." [5] The model showed good fit and discrimination across risk groups and the two hospital types (PCH and non-PCH). For summarizing the results from testing, we calculate each risk-adjustment model (for hospital visits and ED visits) among all hospitals, and present overall and stratified results by hospital type (PCH and non-PCH). Across all hospital types, the risk-standardized inpatient admission rate (RSAR) ranged from 6.0 to 24.9 percent. The risk-standardized ED visit rate (RSEDR) ranged from 2.1 to 7.5 percent.

1.5. Summary

Mathematica, NCQA, and CORE developed a measure for CMS to assess cancer patients' outpatient chemotherapy care and inform quality improvement efforts to reduce potentially preventable admissions and ED visits. This measure incorporates input received from stakeholders and experts during all stages of measure development, is scientifically sound, and reveals important variation in the quality of chemotherapy-related care in HOPDs.

2. Introduction

Cancer care is a priority area for outcomes measurement because cancer is an increasingly prevalent condition associated with considerable morbidity, mortality, and healthcare spending. In 2015, there were more than 1.6 million new cases of cancer in the United States [6]. Each year, approximately 22 percent of patients with cancer receive chemotherapy [2]. Unscheduled ED visits and hospital admissions are significant sources of utilization and cost among this population; on average, cancer patients receiving chemotherapy have one hospital admission and two ED visits per year. Approximately 40 percent of those admissions and 50 percent of those ED visits stem from complications of chemotherapy [2].

Recent studies of cancer outpatients show that the most commonly cited symptoms and reasons for hospital visits are pain, anemia, fatigue, nausea and/or vomiting, fever and/or febrile neutropenia, shortness of breath, dehydration, diarrhea, and anxiety/depression [7]. These predictable complications affect patients' quality of life and pose a heavy financial burden; using commercial claims data, Fitch and Pyenson reported that the national average cost of a chemotherapy-related admission was $22,000, and the average cost of a chemotherapy-related ED visit was $800 [8]. In addition, Medicare payments for cancer treatment totaled $34.4 billion in 2011, representing almost 10 percent of Medicare fee-for-service (FFS) spending [9].

This measure aims to reduce the number of potentially avoidable inpatient admissions and ED visits among cancer patients receiving chemotherapy in the HOPD for several conditions that are treatable in ambulatory cancer care. Admissions and ED visits for the conditions this measure captures—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—may result from unmet needs and gaps in care among outpatient chemotherapy patients, which, if addressed, could reduce admissions and ED visits and increase patients' quality of life [7, 10, 11]. Professional societies, including the American Society of Clinical Oncology, National Comprehensive Cancer Network, Oncology Nursing Society, and Infectious Diseases Society of America recommend evidence-based interventions to prevent and treat the common, predictable side effects and complications of chemotherapy that comprise the outcome diagnoses for this measure. In addition, measure testing revealed that approximately 95 percent of patients received outpatient chemotherapy treatment from the same hospital throughout the year, indicating that measuring chemotherapy administration is a reliable method for determining hospital accountability in providing high quality care and managing any associated outcomes. This measure assesses these potentially preventable admissions and ED visits to provide meaningful, actionable quality information to hospitals.

Providing meaningful information on these quality differences will incentivize providers to (1) administer appropriate chemotherapy treatment, (2) educate patients on all aspects of their

treatment plans, and (3) manage predictable side effects and complications of chemotherapy. By publicly reporting rates of hospital admissions and ED visits for Medicare patients receiving outpatient chemotherapy, CMS aims to raise awareness of the need for improved care for these patients and address the information gap between treating physicians and hospitals managing negative patient outcomes. As a result, this measure should help reduce avoidable hospital admissions and ED visits, improve the quality of care in HOPDs, and increase cancer patients' quality of life.

3. Methods

3.1. Measure Development Process

Mathematica and NCQA originally developed the measure under CMS's guidance and with the support of multidisciplinary clinical and research experts under a CMS project supporting the development of quality measures for use in the PCHQR program. Mathematica and CORE now manage ongoing measure reevaluation and maintenance activities under contract to CMS for a project supporting the development and implementation of outpatient outcome and efficiency measures across CMS programs. Both the development and reevaluation teams include multidisciplinary experts in health services research, statistics, and quality measure development. During measure development, we convened a 12-member TEP of physicians, nurses, patient advocates, and experts in quality improvement to provide input on key methodological decisions. The TEP reviewed and commented on evidence provided in an environmental scan, reviewed measure specifications, and reviewed guidance relating to public comment and testing of the measure. In addition, we consulted the Cancer Hospital Workgroup, which contained representatives from each of the 11 PCHs, to understand their internal quality measurement and improvement activities and to gain their perspective on the importance and usefulness of clinical quality measures for the PCHQR program. We also met with the Expert Working Group, which contains a subset of members of the original TEP and Cancer Hospital Workgroup, in the later stages of development. Furthermore, we held a 45-day public comment period to solicit stakeholder input on the measure specifications through the CMS Measures Management System Call for Public Comment webpage [12]. This guidance and stakeholder input helped inform the process of developing, testing, and revising the measure specifications, including the measure cohort, outcome, and risk-adjustment model, through the initial and final rounds of quantitative testing. This report presents the final measure specifications, methodology, and testing results.

3.2. Data Sources

Consistent with scientific consensus standards for publicly reported outcome measures [5], we used Medicare administrative claims and enrollment data to correctly identify patients for inclusion in the measure, adjust for clinical variables, and accurately attribute outcomes to the hospitals providing care.

To develop and test the measure, we used Medicare 100 percent FFS data with a period of performance from July 1, 2012 through June 30, 2013. We derived the 2012–2013 Development and Validation Split Samples used for testing by selecting two random samples without replacement from the Medicare July 2012 to June 2013 Full Sample. The measure

includes data for all non-federal acute care hospitals. We used several types of files to define the cohort, define the outcomes, and collect data for risk-adjustment:

- **Cohort**: We used Medicare hospital outpatient and inpatient Standard Analytic Files (SAFs) to capture chemotherapy treatment administered in HOPDs; we used Medicare hospital inpatient SAFs to capture chemotherapy treatment administered in an HOPD that may be bundled on an inpatient claim due to the CMS 3-day payment window policy. We used Medicare hospital outpatient and inpatient SAFs and Carrier (Part B Physician) claims SAFs to identify cancer diagnoses. Finally, we used enrollment database and denominator files to determine enrollment and demographic information.
- **Outcomes**: We used Medicare hospital outpatient and inpatient SAFs to define the two outcomes of qualifying hospital admissions (from inpatient SAFs) and qualifying ED visits (from outpatient SAFs).
- **Comorbidities**: We used Medicare hospital outpatient and inpatient SAFs and Carrier (Part B Physician) claims SAFs to identify cancer diagnoses and comorbidities for risk-adjustment.

In addition to these quantitative data sets, our testing drew from other qualitative sources, including our TEP, the Cancer Hospital Workgroup, and a public comment period.

3.3. Study Cohort

The target population for this measure is Medicare FFS patients receiving chemotherapy treatment in a hospital outpatient setting. Section 3.3.1 details the measure inclusion and exclusion criteria for the patients in the cohort.

3.3.1. Inclusion Criteria

- This measure includes all adult Medicare FFS patients with a diagnosis of cancer aged 18 years or older at the start of the performance period (Appendix Table A.1, Sheet "Denominator Details: Cancer Diagnosis").

Rationale: The measure includes patients aged 18 years or older because all adult cancer patients with a treatment plan allowing for chemotherapy treatment in a hospital outpatient setting should receive proper care management to reduce the need for acute care for the specific conditions the measure addresses. In addition, the measure includes all adult patients, rather than only those aged 65 or older, to assess a broader population and more comprehensively evaluate the quality of care provided by HOPDs.

We explored the potential bias of including patients aged 18 to 64 years (in addition to patients aged 65 or older) in the cohort by (1) reviewing patient characteristics separately for these two subsets, (2) reviewing the observed performance rates for these two subsets, and (3) fitting the risk-adjustment model separately for these two subsets. We found that patients aged 18 to 64 years represent 13 percent of the final measure cohort, and although the younger population has higher observed outcome rates, the risk-adjustment models behave similarly on both subsets of patients. Based on these findings, we determined there was not a strong statistical or clinical reason to exclude the younger patients. We therefore include all adult patients 18 years and older in the measure cohort.

- The measure includes chemotherapy treatment at HOPDs identified using Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) procedure and medication procedure codes, ICD-9-CM chemotherapy encounter diagnosis codes, or revenue center codes for chemotherapy administration. In addition, it uses specific ICD-9-CM procedure codes on inpatient claims to identify chemotherapy services subject to the CMS 3-day billing rule (as described in Section 3.3.3 below). The measure does not include oral chemotherapy because it is challenging to identify oral chemotherapy administrations without using pharmacy claims data; furthermore, most oral chemotherapies have fewer adverse reactions that result in admissions. We used ICD-9-CM codes during development and testing; however, the final measure specifications will include ICD-10-CM and ICD-10-PCS codes for future implementation. Please see the Denominator Details tabs for Chemotherapy Procedures, Encounters, and Medications in Appendix Table A.1 for a full listing of codes and a coding crosswalk between ICD-9 and ICD-10 codes.

Rationale: Using claims data allows for consistent identification of chemotherapy administration in HOPDs and aligns with the NQF criteria (4) and CMS standards for claims-based models for publicly reported measures (3).

3.3.2. Exclusion Criteria

To make the measure as inclusive as possible, we excluded only those patient groups for which hospital visits do not typically indicate quality or for which risk-adjustment would not be adequate. These exclusions prevent unfair distortion of performance results, and after applying them, the measure captured 75.0 percent of all qualifying patients (Figure 1). The exclusions are very narrowly targeted and are necessary to ensure that the cohort is clinically coherent and has complete data available to calculate risk-adjustment and capture outcomes. The three measure exclusions are as follows:

- Patients with a diagnosis of leukemia at any time during the performance period (ICD-9 and ICD-10 code sets are available in Appendix Table A.1, Sheet "Denominator Exclusion Details: Leukemia").

Rationale: The measure excludes patients with leukemia because, given the high toxicity of treatment and recurrence of disease, admissions among this population do not reflect poorly managed outpatient care. Patients with leukemia have an expected admission rate due to frequent relapse, which is not the type of admission the measure intends to capture.

- Patients who were not enrolled in Medicare FFS Parts A and B in the year before their first outpatient chemotherapy treatment during the performance period.

Rationale: The measure excludes these patients to ensure that complete patient diagnosis data will be available for the risk-adjustment model, which uses the year before the first chemotherapy treatment during the period to identify comorbidities.

- Patients who do not have at least one outpatient chemotherapy treatment followed by continuous enrollment in Medicare FFS Parts A and B in the 30 days after the procedure.

Rationale: The measure excludes these patients to ensure that full data will be available for outcome assessment.

3.3.3. Identification of Chemotherapy Treatments Affected by the Medicare 3-Day Payment Window Policy

The measure depends on identifying chemotherapy treatments performed in HOPDs. The Medicare 3-day payment window policy affects our ability to identify some outpatient chemotherapy treatments performed at HOPDs. The policy states that outpatient services (including some non-diagnostic services such as chemotherapy) provided by a hospital or any Part B entity wholly owned or wholly operated by a hospital (such as an HOPD) in the three calendar days before a patient's inpatient admission are considered related to the admission [13]. For outpatient chemotherapy treatments subject to the 3-day payment policy, the outpatient chemotherapy service should be bundled and billed with the inpatient claim.

To ensure inclusion of all patients and HOPD chemotherapies, the measure first identifies all chemotherapy treatments during the performance period within the hospital outpatient claims file and then supplements this cohort by identifying chemotherapy treatments included on inpatient claims with a date of service *prior to or equal to* the date of admission on the claim. The measure includes as outpatient services chemotherapy procedures on inpatient claims with the same date of service as the admission date because, clinically, patients would receive an outpatient chemotherapy treatment and then have a qualifying inpatient admission. That is, we

do not expect non-leukemia patients with a qualifying admission for the 10 potentially preventable conditions the measure captures to receive chemotherapy on that same day, as generally they would not receive chemotherapy if they required acute care for these diagnoses. We will continue to assess this approach to identifying chemotherapy treatments subject to CMS 3-day payment window billing during annual measure maintenance and prior to implementation.

3.4. Outcome

The measure assesses two outcomes for each patient in the cohort. The first outcome is one or more inpatient admissions within 30 days of any chemotherapy treatment in an HOPD during the performance period with either: (1) a primary discharge diagnosis of anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis; or (2) a primary discharge diagnosis of cancer and a secondary diagnosis of one of those 10 diagnoses on the same claim. Appendix Table A.1 shows the ICD-9 and ICD-10 diagnosis codes for each of these conditions on the Numerator Details sheets (Sheets 1-10).

The second outcome is any ED visit over the same time period with the same qualifying diagnoses listed above. The measure assesses the ED visit outcome only for patients who did not experience a qualifying inpatient admission. In addition, a patient can experience only one qualifying outcome event. If the patient experiences a qualifying inpatient admission following the first treatment and a qualifying ED visit following the second treatment, the patient qualifies only for the inpatient admission outcome. As a result, the rates provide a comprehensive performance estimate of patients' quality of care following hospital-based outpatient chemotherapy treatment.

The measure calculates the two rates separately because the severity and cost of an inpatient admission differ from those of an ED visit, but both adverse events are important signals of quality and represent outcomes of care that are important to patients. Below are three possible scenarios that illustrate the measure algorithm.

- Scenario 1: A patient receives one outpatient chemotherapy treatment during the performance period. Within 30 days of the treatment, the patient experiences a qualifying inpatient admission for nausea. The measure counts the patient toward the inpatient admission outcome.
- Scenario 2: A patient receives six outpatient chemotherapy treatments at the same hospital during the performance period. Within 30 days of the sixth treatment, the patient experiences a qualifying inpatient admission for pain. The measure counts the patient toward the inpatient admission outcome. This scenario is very similar to Scenario 1 in that both patients experienced a single qualifying event, but the patient

in Scenario 2 had an increased risk of experiencing a qualifying outcome since he or she underwent more treatments during the performance period. The risk-adjustment model adjusts for the patient-specific number of chemotherapy treatments during the period to control for this varied exposure (see Section 3.5.2).

- Scenario 3: A patient receives six outpatient chemotherapy treatments at the same hospital during the performance period. Within 30 days of the first treatment, the patient experiences a qualifying inpatient admission for dehydration. Within 30 days of the sixth treatment, the patient experiences a qualifying ED visit for nausea. Although this single patient experienced two qualifying outcomes, one admission and one ED visit, the measure counts the patient toward the inpatient admission outcome only because it is the more severe and costly outcome with the greatest impact on the patient's life.

The 10 conditions that the measure captures are commonly cited reasons for hospital visits among cancer outpatients, and are potentially preventable through appropriately managed outpatient care and increased communication with the patient [7]. During measure development, our TEP recommended expanding the outcomes to include both neutropenia and fever to avoid missing any diagnoses of neutropenic fever; since diagnosis of neutropenia requires lab results and a single ICD-9 code for neutropenic fever does not exist, we agreed that it was reasonable to expand the outcomes to include fever and capture all potentially qualifying diagnoses.

Below is additional evidence about managing these conditions on an outpatient basis:

- **Anemia**: There are many therapeutic agents available to treat anemia as well as clinical guidelines on how to prevent and manage anemia in patients receiving chemotherapy treatment [14] [15].

- **Dehydration**: Dehydration can be prevented by educating patients on the importance of fluid intake and monitoring patients that have reduced oral intake or appetite loss. Health care professionals should also closely monitor patients at risk for chemotherapy-induced diarrhea and vomiting for signs of dehydration [16].

- **Diarrhea**: Providers can often treat chemotherapy-induced diarrhea on an outpatient basis, and effective treatment of diarrhea can prevent dehydration [16]. Existing evidence supports management of diarrhea, although evidence about prevention continues to evolve [17].

- **Emesis and nausea**: Chemotherapy-induced nausea and vomiting can be prevented and effectively managed in the outpatient setting [18]. Studies and reviews have shown the effectiveness of specific drugs for prevention and management of nausea

and vomiting resulting from particular chemotherapy regimens and their effects on quality of life [19] [20] [21] [22].

- **Neutropenia and fever**: A systematic review and meta-analysis of randomized controlled trials concluded that prophylactic granulocyte colony-stimulating factors significantly reduce neutropenic fever [23].
- **Pain**: A number of pharmacological treatments for pain exist, including opioids. However, many patients receive inadequate analgesia [24] [25]. Optimal pain control can be achieved through combining pharmacological and non-pharmacological approaches, in addition to assessing and reassessing patients' pain [26].
- **Pneumonia and sepsis**: The relationship between neutrophil count and the risk of infection is well established and studies have shown that providers can identify risk factors and implement appropriate prophylactic measures, such as colony-stimulating factor, to prevent neutropenia and associated complications [27]. Because of this relationship and the need for lab results to confirm neutropenia, claims often capture neutropenia as the related infection, such as pneumonia and sepsis. The measure includes pneumonia and sepsis as outcomes to capture the same population [27] [23].

3.4.1. Outcome Time Frame

The measure limits the outcome time frame to the 30 days (including the day of treatment) following the date of each chemotherapy treatment in an outpatient setting for four reasons. First, existing literature suggests that the vast majority of adverse events occur within 30 days after treatment [11, 28, 29], indicating that a 30-day period is a reasonable time frame to observe the side effects of treatment. Second, we observed in our own data that the highest rates of hospital visits occur within 30 days after chemotherapy treatment. Third, restricting the time frame links patients' experiences more closely to the hospitals that provided their recent treatment while accounting for variations in duration between outpatient treatments. Fourth, relating the time frame to a specific chemotherapy administration supports the idea that the admission stems from the management of side effects of treatment and ongoing care, rather than progression of the disease or other unrelated events.

3.4.2. Outcome Attribution

The measure attributes the outcome to the hospital(s) where the patient received chemotherapy treatment during the 30 days before the qualifying outcome event. If a patient received outpatient chemotherapy treatment from more than one hospital in the 30 days before a qualifying outcome event, the measure will attribute the outcome to both hospitals, which results in differences between the number of unique patients and the number of unique

patient-provider combinations. For example, if a patient received an outpatient chemotherapy treatment at Hospital A on January 1 and a second treatment at Hospital B on January 10, and then experienced a qualifying admission on January 15, the measure would count this outcome for both Hospital A and Hospital B because both hospitals provided outpatient chemotherapy treatment to the patient within the 30-day window. However, if a patient received an outpatient chemotherapy treatment from Hospital A on January 1 and a second treatment from Hospital B on March 1, and then experienced a qualifying outcome on March 3, the measure would attribute this outcome only to Hospital B. Measure testing revealed that only about 5 percent of patients received outpatient chemotherapy treatment from more than one hospital during the year, indicating that measuring chemotherapy administration is a reliable method for determining hospital accountability in providing high-quality care and managing any associated outcomes.

3.5. Model Development

3.5.1. Overview

We use a two-level hierarchical logistic regression model to estimate risk-standardized outcome rates (Appendix B.2). This approach accounts for the clustering of patients within hospitals and variation in sample size. We use separate models for each outcome (inpatient admissions and ED visits).

The models adjust for clinical comorbidities and chemotherapy exposure to account for differences among patients that may influence the outcome in ways that do not relate to the quality of outpatient chemotherapy care. This approach aligns with available standards for publicly reported outcome measures [4].

3.5.2. Candidate Variables for Patient-Level Risk-Adjustment

The measure development team used the same variable selection process for both models. Candidate risk-adjustment variables were patient-level clinical and demographic factors that were likely to predict the outcomes based on prior literature, clinical judgment, and empirical analysis. We limited our initial selection of candidate variables for the preliminary risk-adjustment model to variables with a strong clinical rationale for inclusion as identified in the literature and through clinical expert input (Appendix Table B.1). We describe these variables below.

Demographic variables: In alignment with the specifications of other NQF-endorsed claims-based outcome measures, as well as the NQF guidelines at the time of development, we included age and sex as candidate covariates. As part of our SDS analyses (Section 3.5.7), we

also assessed race, Medicaid-dual eligible status, and Agency for Healthcare Research and Quality (AHRQ) Socioeconomic Status (SES) Index score. The AHRQ SES Index score represents a zip code-level socioeconomic status proxy indicator variable [30].

Comorbidities: The model adjusts for case-mix differences based on the comorbidities of the patient at the time of the first outpatient chemotherapy treatment during the performance period. We define comorbidities using Condition Categories (CCs) from Version 12 (V12) of the CMS-HCC risk-adjustment model, which are clinically meaningful groupings of more than 15,000 ICD-9-CM diagnosis codes. We used FY 2008–2012 CC Version 12. With a subset of our TEP, we reviewed all 189 CCs to determine whether they were clinically appropriate and mathematically necessary (that is, we assessed their prevalence within the cohort) for potential inclusion in the model.

For each potential CC group, we considered the prevalence of the condition in our cohort, whether the condition would be likely to affect admission for one of the 10 numerator qualifying diagnoses, and whether including the condition in the model would incentivize providers to deliver appropriate treatment, even when that variable is theoretically unrelated to admission for one of the identified reasons. For example, patients with diabetes may have gastric paresis, a condition that slows emptying of the stomach and increases the likelihood of nausea. Adjusting for diabetes might reduce incentives to provide chemotherapy drugs that would be less likely to cause nausea in patients with diabetes and gastric paresis. The CCs selected for inclusion were bundled with other clinically related CCs for empirical assessment of significance within the model. We initially selected for both models nine bundled CCs (for ICD-9-CM): diabetes (CCs 15–20), metabolic disorders (CCs 21–24), gastrointestinal disorders (CCs 25–36), psychiatric disorders (CCs 48–66), neurological conditions (CCs 67–76), cardiovascular disease (CCs 77–106), respiratory disorders (CCs 107–110), renal disease (CCs 128–131), and other injuries (CC 162).

Indicators of disease severity: We explored cancer type as an indicator of disease severity available in claims data by assessing the distribution of patients across a granular level of cancer diagnoses. In conjunction with a subset of our TEP, we aggregated these granular cancer types into nine clinically related and decently sized groupings: (1) breast cancer, (2) digestive cancer, (3) genitourinary cancer, (4) respiratory cancer, (5) lymphoma, (6) prostate cancer, (7) secondary cancer of the lymph nodes, (8) secondary cancer of solid tumor, and (9) other cancers. The CCs that define each of these comorbidities and the ICD-9-CM codes that define the cancer categories are included in Appendix Table A.1 (Sheet "Risk Model Specs.")

Exposure: We also assessed the number of outpatient chemotherapy treatments during the performance period (that is, exposure). The exposure variable is necessary because the measure estimates the risk-adjustment models at the patient level and the number of

outpatient chemotherapy treatments varies by patient. Patients with more treatments during the period have an increased probability of experiencing an outcome because the algorithm looks for an outcome after each treatment. The exposure variable is the count of outpatient chemotherapy administrations the patient experienced at the attributed hospital during the performance period.

Interactions: Through discussion with our Expert Working Group, we determined that the age variable and the different cancer types are likely to generate the most clinically relevant interactions. Based on this input, we tested age-cancer type interaction terms as candidate covariates.

The resulting set of candidate risk-adjustment variables included 21 variables that were the initial starting point for both models (Appendix Table B.1).

3.5.3. Final Variable Selection

To select the final variables to include in the risk-adjustment models, we fit a logistic regression model to predict each outcome with the candidate variable set. To develop a parsimonious model, we then removed non-significant variables from the initial model using a stepwise purposeful selection method described by Hosmer and Lemeshow [31, 32]. Our goal was to minimize the number of variables in the model while preserving model performance (as measured by the c-statistic). During this process, for each of the two models, we removed the least significant variable in the model one at a time until only statistically significant variables remained in the model ($p<0.05$, assessed using a likelihood ratio test). We tested interaction terms between age and cancer type and retained them in the model only if they were significant at a level of $p<0.01$. We applied the more stringent threshold for statistical significance of interaction terms to ensure that the model included only interactions that have a higher likelihood of being true interactions. For the inpatient admission outcome model, only the interaction of age x digestive cancer was significant (p-value for interaction <0.001). However, due to the minimal improvement in model fit (AIC 76245 without interaction term and 76238 with interaction term) and model discrimination (c-statistic 0.725 without interaction term and 0.725 with interaction term) and our desire to create the most parsimonious model, we did not include any interaction terms in our final model. No interaction terms met this criterion for the ED visit outcome model. Tables 1 and 2 show the final risk-adjustment model variables. The hospital admission model includes 20 variables and the ED visit model includes 15 variables, described in more detail in Section 4.2.1.

3.5.4. Model Performance

We derived the 2012–2013 Development and Validation Split Samples by selecting two random samples, without replacement, from the July 2012 to June 2013 Full Sample. Each patient-provider combination had equal probability of selection into either the Development or the Validation Split Sample. To assess performance of the patient-level risk-adjustment models, we tested both the models' discrimination (or predictive) ability using c-statistics and their calibration capability via outputs such as (1) risk decile plots between observed and predicted inpatient admissions or ED visits and (2) the overfitting indices. A c-statistic of 1.0 indicates perfect prediction, implying that patients' outcomes can be predicted completely by their risk factors. Discrimination in predictive ability measures the ability to distinguish high-risk from low-risk subjects. Good model discrimination is indicated by a wide range between the lowest and highest deciles.

We assess model calibration by (1) analyzing the risk decile plots and (2) calculating over-fitting indices. The risk decile plots measure the distance between predicted values and observed values to determine the reasonability of the model fit. Over-fitting refers to the phenomenon in which a model describes the relationship between predictive variables and outcome well in one group of patients, but fails to provide valid predictions in another distinct group of patients. Over-fitting indices ($\gamma 0$, $\gamma 1$) provide evidence of over-fitting and require several steps to calculate. The mathematical process is described here: Let b denote the estimated vector of regression coefficients. Predicted Probabilities (p) = 1/(1+exp{-Xb}), and Z = Xb (e.g., the linear predictor that is a scalar value for everyone). A new logistic regression model that includes only an intercept and a slope by regressing the logits on Z is fitted in the Validation Split Sample, e.g., Logit(P(Y=1|Z)) = $\gamma 0 + \gamma 1 Z$. Estimated values of $\gamma 0$ far from 0 and estimated values of $\gamma 1$ far from 1 provide evidence of over-fitting.

3.5.5. Model Validation

We assessed adequacy of the patient-level risk-adjustment models by comparing each model's performance in the Development Split Sample with its performance in the Validation Split Sample. As described above, we computed three diagnosis statistics for assessing the risk-adjustment model performance: model discrimination using c-statistic, model calibration via risk decile plots, and over-fitting indices. We evaluated the model performance first in the Development Split Sample. We then re-tested the model performance using the Validation Split Sample. We did this separately for the inpatient admission outcome model and the ED visit outcome model.

3.5.6. Calculation of Hospital-Level Measure Score

We assessed hospital-level variation in performance score using the Medicare Full Sample. Specifically, we estimated the measure score for hospitals using Medicare FFS claims with a performance period of July 1, 2012, to June 30, 2013, and calculated results for all hospitals, PCHs, and non-PCHs. In addition, we estimated the minimum hospital case count to reach a signal-to-noise reliability (intraclass correlation coefficient [ICC]) threshold of 0.4. However, the measure calculation and results presented in this report include all cases and do not take minimum case count into account.

The measure's two-level hierarchical logistic regression model accounts for the clustering of patients within hospitals and variation in sample size. The measure calculates the hospital-specific risk-adjusted rate as the ratio of a hospital's "predicted" number of outcomes to "expected" number of outcomes multiplied by the national observed outcome rate. It estimates the expected number of outcomes for each hospital using the hospital's patient mix and the average hospital-specific intercept (that is, the average intercept among all hospitals in the sample). The measure estimates the predicted number of outcomes for each hospital using the same patient mix, but an estimated hospital-specific intercept. Operationally, the measure obtains the expected number of outcomes for each hospital by summing the expected probabilities of outcomes for all patients treated at the hospital. It calculates the expected probability of outcomes for each patient via the hierarchical model, which applies the estimated regression coefficients to the observed patient characteristics and adds the average of the hospital-specific intercept. It calculates the predicted number of outcomes for each hospital by summing the predicted probabilities for all patients in the hospital. The measure calculates the predicted probability for each patient through the hierarchical model, which applies the estimated regression coefficients to the observed patient characteristics and adds the hospital-specific intercept. If a hospital's ratio of predicted to expected outcomes is less than 1, it indicates that the hospital is performing better than expected given its case mix. If a hospital's ratio of predicted to expected outcomes is greater than 1, it indicates that the hospital is performing worse than expected given its case mix. For ease of interpretation, we transform this ratio to a rate by multiplying by the national observed rate for that outcome.

3.5.7. Sociodemographic Status Testing

We assessed the relationship between the measure outcomes and SDS factors in accordance with NQF measure development guidelines. We used three variables for analysis: race, Medicaid dual-eligible status, and the AHRQ SES Index score. We identified race and Medicaid dual-eligible status using Medicare enrollment data. The AHRQ SES Index score represents a zip-code level socioeconomic status proxy indicator variable [30]. We used these variables as

proxies for SDS based on our findings from the measure development and literature review process and in accordance with NQF guidance for risk-adjustment for SES and SDS factors [33]. In addition, these variables are available within or link directly to Medicare administrative claims data.

We sought to: (1) examine the magnitude and direction of bivariate relationship between available SDS variables and the outcome, (2) assess whether hospitals with high proportions of low-SDS patients are more likely to have worse performance, (3) analyze how risk-adjustment for the SDS variables changes model diagnostics and hospital rankings, and (4) differentiate between the hospital and patient contribution to any association between the SDS variables and the outcome of interest. This approach to assessing SDS factors included analyzing patient-level sociodemographic variables, interpreting and comparing performance scores with and without SDS factors in the risk-adjustment model, and determining the SDS factors (if any) for inclusion in the final risk-adjustment model.

3.5.8. Statistical Software

We used SAS version 9.4 (SAS Institute Inc., Cary, NC) to perform statistical analyses. We estimated the hierarchical logistic regression model using the GLIMMIX procedure in SAS.

4. Results

4.1. Development and Validation Split Samples

As described in Section 3.2, we used a cohort created from Medicare FFS data to develop and test aspects of this measure. We applied the measure specifications to each data set to develop the testing cohort. The information below represents the final cohort after applying measure exclusions.

After applying all inclusion and exclusion criteria, the Medicare Full Sample included 240,446 unique patients treated at 3,765 hospitals between July 1, 2012 – June 30, 2013. This includes a total of 252,408 patient-provider combinations because 5 percent of patients received an outpatient chemotherapy treatment at more than one hospital. Analysis of the Medicare Full Sample showed that patients who received outpatient chemotherapy treatment were fairly evenly divided by sex (50.2 percent male) and had an average age of 72.2 years. The top three cancer types (including secondary cancer types) were Secondary Cancer–Solid Tumor (40.2 percent), Other Cancers (39.8 percent), and Digestive Cancer (24.2 percent). The top three primary cancer types were Digestive Cancer (24.2 percent), Respiratory Cancer (21.8 percent), and Genitourinary Cancer (19.8 percent). The Full Sample included many patients with more than one type of cancer. Table 1 shows the patient characteristics for the Full Sample and by hospital type for each risk-adjustment variable.

As described above, we derived the 2012–2013 Development and Validation Split Samples by selecting two random samples without replacement from the Medicare Full Sample. Each patient-provider combination had equal probability of selection into either the Development or the Validation Split Sample. The Development Split Sample included 123,149 unique patients at 3,483 hospitals, including a total of 126,204 patient-provider combinations. The Validation Split Sample included 123,115 unique patients at 3,469 hospitals, including a total of 123,115 patient-provider combinations. The mean age of patients and frequency of cancer type risk-adjustment variables were similar in the Development and Validation Split Samples, with mean ages of 72.2 years and 72.1 years, respectively. The top three cancer types of Secondary Cancer–Solid Tumor, Other Cancers, and Digestive Cancer were also the same in both samples (Table 2).

4.2. Patient-Level Risk-Adjustment Model

4.2.1. Candidate and Final Variables

The candidate variables for both models included age, sex, exposure, cancer type, and certain clinical comorbidities (Appendix Table B.1).

The inpatient admission and ED visit models included different sets of final covariates. The risk-adjustment model for inpatient admissions has 20 patient-level variables (age, sex, exposure, 9 comorbidity variables, and 8 cancer categories) (Table 3). The risk-adjustment model for ED visits has 15 patient-level variables (age, sex, exposure, 6 comorbidity variables, and 6 cancer categories) (Table 4). The ED visit model does not include the variables for renal disease, diabetes, metabolic disorder, lymphoma, or prostate cancer that the inpatient admission model includes because we did not find them predictive for this outcome using our selection criteria described in Section 3.5.3.

4.2.2. Model Performance

Using the Development Split Sample, both models showed strong discrimination (or predictive ability), fit, and predictive calibration. The c-statistics of 0.73 (inpatient) and 0.63 (ED visit) indicated good model discrimination. The models had a wide range of predictive ability between the lowest decile and highest decile, indicating that they could distinguish high-risk subjects from low-risk subjects (Table 5). In addition, the risk decile plots showed that the models fit similarly in each of the risk deciles across a broad range of risk (Figures 2 and 3).The overfitting indices values of close to 0 for γ0 and close to 1 for γ1 further indicated good calibration of the models (Table 5).

4.2.3. Model Validation

The inpatient and ED visit models had similar performance in the Development and Validation Split Samples data sets, with strong model discrimination and fit. Predictive ability was also similar across data sets (Table 5). Specifically, the c-statistics were 0.73 in the Development Split Sample and 0.72 in the Validation Split Sample for both inpatient admission models. The c-statistics were 0.63 for the Development Split Sample and 0.64 for the Validation Split Sample for the ED visits models. In addition, the models exhibited a similar wide range in predictive ability between the lowest decile and highest decile across the Development and Validation Split Samples. The regression coefficients of the models were stable in the Development and Validation Split Samples for both the inpatient and ED visit models (Tables 6 and 7). Although the point estimates for the sex variable in the inpatient admission model, cardiovascular disease in the ED visit model, and breast cancer variables in the ED visit model were statistically significant in the Development Split Sample and associated with a risk of admission in the Validation Split Samples, the confidence intervals across the two samples overlapped.

4.3. Hospital-Level Measure Score

We produced overall results for the full sample of all hospitals and stratified the results for PCHs and non-PCHs (Table 8). The total number of hospitals with at least one attributed patient

was 3,765; all 11 PCHs had attributed patients. The observed inpatient admission outcome rate had an average of 8.3 percent and ranged from 0 to 100 percent for all hospital types (Table 8). The risk-standardized inpatient admission rate (RSAR) had an average of 10.4 percent among all three groups and ranged from 6.0 to 24.9 percent, with a similar distribution for each hospital type (Figure 4, Table 9).

The observed ED visit rate had an average of 4.3 percent and ranged from 0 to 100 for all hospital types (Table 5). The rate of risk-standardized ED visits (RSEDR) had an average of 4.2 percent and ranged from 2.1 to 7.5 percent, also with similar distribution by hospital type (Figure 5, Table 9).

The measure is calculated among all hospitals with at least one attributed patient. However, we explored the minimum case size required to meet moderate reliability. To achieve a moderate level of reliability (ICC of at least 0.4), we found a minimum case size of 25 patients. This threshold may be applied in future public reporting.

4.4. Sociodemographic Status Testing

SDS testing included analysis of patient- and hospital-level findings. At the *patient-level*, the results demonstrated that "low SDS" patients as characterized by three individual indicators (Medicaid dual eligibility, race as black, and a low AHRQ SES Index Score) are more likely to have an inpatient admission and ED visit than "higher SDS" patients (Table 10). At the *hospital-level*, no between-hospital effects were observed for hospital case-mix by Medicaid dual-eligibility, race, or the AHRQ SES Index score (Table 11). Specifically, there was no clear relationship between the median risk-standardized rates and hospitals' case mix by these three SDS factors. In addition, the distributions of risk-standardized rates overlapped significantly across hospitals grouping by these three SDS factors, suggesting that hospitals caring for a greater percentage of low SDS patients have similar rates of inpatient admission and ED visits within 30 days of hospital-based outpatient chemotherapy.

SDS testing also included the assessment of hospital measure results before and after accounting for the SDS variables. We observed very high agreement of hospital rankings between risk-adjustment models that incorporated SDS variables and those that did not (Spearman rank correlation = 0.988 for the inpatient admission model and 0.984 for the ED visit model), suggesting that accounting for the SDS factors will not have a major impact on hospital rankings.

Additionally, model diagnostics exhibited similar performance with and without including SDS variables in the risk-adjustment. Specifically, model discrimination between risk-adjustment using final risk factors (Section 4.2.1) and using final risk factors plus SDS variables appeared to be similar (Tables 12 and 13). For example, for the Validation Split Sample, the inpatient

admission measure c-statistics were both 0.725 with and without adjusting for SDS variables. For the ED visit measure, the c-statistics were 0.636 without adjusting for SDS variables and 0.644 when adjusting for SDS variables. The model calibration results were very similar between risk-adjustment using the original risk factors and using original risk factors plus SDS variables. The results of overfitting indices remained similar with and without adding SDS variables in the risk-adjustment model (Tables 12 and 13).

Based on these findings, we did not include these SDS factors in the final measure specifications.

5. Summary

This outcome measure aims to assess the care provided to cancer patients and to inform quality improvement efforts to reduce potentially preventable hospital admissions and ED visits. The measure addresses the National Quality Strategy priority of promoting the most effective prevention and treatment practices for one of the leading causes of mortality. Poor performance on the measure reflects high resource use and significant negative consequences for patients and society that could potentially be avoided through higher quality care; admissions and ED visits are costly to payers and reduce patients' quality of life. The overall observed rates show that an average of 12 percent of patients in the cohort experience a potentially preventable qualifying outcome, and variation in performance among hospitals suggests actionable differences in quality of care. The measure risk-adjustment model aligns with the consensus standard for publicly reported outcome measures and relies on available administrative claims data. The study sample includes Medicare FFS patients receiving hospital outpatient chemotherapy and allows for valid comparisons of quality among hospitals. Clinical and subject-matter experts provided input throughout all stages of development, supporting our efforts to create a robust clinical quality measure that is consistent with CMS standards and suitable for public reporting.

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7. Tables and Figures

Table 1. Characteristics of the denominator population by hospital type

Characteristics	All Hospitals		Non-PCH Hospitals		PCH Hospitals	
	Number (#)	Percentage (%)	Number (#)	Percentage (%)	Number (#)	Percentage (%)
Number of unique patients	240,446	100.0	223,719	100.0	18,400	100.0
Demographics	--	--	--	--	--	--
Male	120,592	50.15	111,378	49.78	10,053	54.64
Female	119,854	49.85	112,341	50.22	8,347	45.36
Age, years (min – max)	19 - 104	n.a.	19 - 104	n.a.	20 - 99	n.a.
Age, years (mean)	72.2	n.a.	72.23	n.a.	71.64	n.a.
Age, years (25th percentile)	67	n.a.	67	n.a.	67	n.a.
Age, years (50th percentile)	72	n.a.	72	n.a.	72	n.a.
Age, years (75th percentile)	78	n.a.	78	n.a.	77	n.a.
Exposure	--	--	--	--	--	--
HOPD chemo treatments, number (min – max)	1 - 167	n.a.	1 - 167	n.a.	1 - 78	n.a.
HOPD chemo treatments, number (mean)	5.37	n.a.	5.24	n.a.	6.37	n.a.
HOPD chemo treatments, number (25th percentile)	2	n.a.	1	n.a.	2	n.a.
HOPD chemo treatments, number (50th percentile)	3	n.a.	3	n.a.	4	n.a.
HOPD chemo treatments, number (75th percentile)	7	n.a.	7	n.a.	8	n.a.
Cancer Type*	--	--	--	--	--	--
Breast Cancer	43,875	18.25	41,311	18.47	2,850	15.49
Digestive Cancer	58,069	24.15	53,456	23.89	5,111	27.78
Genitourinary Cancer	47,501	19.76	44,246	19.78	3,722	20.23
Respiratory Cancer	52,405	21.79	48,781	21.80	3,980	21.63
Lymphoma	43,367	18.04	40,676	18.18	3,051	16.58
Prostate Cancer	44,582	18.54	40,443	18.08	4,420	24.02
Other Cancer	95,671	39.79	88,157	39.41	8,367	45.47
Secondary Cancer of the Lymph Nodes	45,799	19.05	39,446	17.63	6,988	37.98
Secondary Cancer of Solid Tumors	101,435	42.19	91,423	40.87	11,111	60.39

Characteristics	All Hospitals		Non-PCH Hospitals		PCH Hospitals	
	Number (#)	Percentage (%)	Number (#)	Percentage (%)	Number (#)	Percentage (%)
Comorbidities*	--	--	--	--	--	--
Cardiovascular Disease	216,215	89.92	200,978	89.84	16,755	91.06
Diabetes	79,225	32.95	73,541	32.87	6,223	33.82
Gastrointestinal Disorders	179,746	74.76	166,314	74.34	14,828	80.59
Metabolic Disorders	15,129	6.29	14,184	6.34	1,051	5.71
Neurological Conditions	69,897	29.07	64,094	28.65	6,370	34.62
Other Injury	67,857	28.22	63,015	28.17	5,349	29.07
Psychiatric Disorders	110,547	45.98	102,692	45.90	8,646	46.99
Renal Disease	50,405	20.96	47,328	21.16	3,409	18.53
Respiratory Disorders	86,184	35.84	80,801	36.12	5,907	32.10

*A single patient may have Medicare claims indicating more than one cancer type and/or more than one comorbidity. As a result, the percentages presented above do not sum to 100.

Note: 1,673 patients were treated at both a PCH and a non-PCH. These patients are included in both the PCH and non-PCH columns, and as a result, the total patient counts presented above do not sum to the total number of unique patients in the full sample across all hospitals.

Source: Full Sample for July 1, 2012, through June 30, 2013.

Table 2. Characteristics of the denominator population by sample group

Characteristics	After Exclusions					
	All Hospitals		Development Split Sample		Validation Split Sample	
	Number (#)	Percentage (%)	Number (#)	Percentage (%)	Number (#)	Percentage (%)
Number of unique patients	240,446	100.00	123,149	51.22	123,115	51.20
Demographics	--	--	--	--	--	--
Male	120,592	50.15	61,690	50.09	61,525	49.97
Female	119,854	49.85	61,459	49.91	61,590	50.03
Age, years (min – max)	19 - 104	n.a.	21 - 104	n.a.	19 - 104	n.a
Age, years (mean)	72.2	n.a.	72.19	n.a.	72	n.a
Age, years (25th percentile)	67	n.a.	67	n.a.	67	n.a
Age, years (50th percentile)	72	n.a.	72	n.a.	72	n.a
Age, years (75th percentile)	78	n.a.	78	n.a.	78	n.a
Exposure	--	--	--	--	--	--
HOPD chemo treatments, number (min – max)	1 - 167	n.a.	1 - 167	n.a.	1 - 159	n.a
HOPD chemo treatments, number (mean)	5.37	n.a.	5.24	n.a.	5	n.a
HOPD chemo treatments, number (25th percentile)	2	n.a.	1	n.a.	1	n.a
HOPD chemo treatments, number (50th percentile)	3	n.a.	3	n.a.	3	n.a
HOPD chemo treatments, number (75th percentile)	7	n.a.	7	n.a.	7	n.a
Cancer Type*	--	--	--	--	--	--
Breast Cancer	43,875	18.25	22,561	18.32	22,401	18.20
Digestive Cancer	58,069	24.15	29,960	24.33	29,726	24.14
Genitourinary Cancer	47,501	19.76	24,281	19.72	24,564	19.95
Respiratory Cancer	52,405	21.79	26,897	21.84	26,767	21.74
Lymphoma	43,367	18.04	22,469	18.25	22,320	18.13
Prostate Cancer	44,582	18.54	22,740	18.47	22,605	18.36
Other Cancer	95,671	39.79	34,759	28.23	34,814	28.28
Secondary Cancer of the Lymph Nodes	45,799	19.05	23,671	19.22	23,562	19.14
Secondary Cancer of Solid Tumors	101,435	42.19	52,161	42.36	52,319	42.50

Characteristics	After Exclusions					
	All Hospitals		Development Split Sample		Validation Split Sample	
	Number (#)	Percentage (%)	Number (#)	Percentage (%)	Number (#)	Percentage (%)
Comorbidities*	--	--	--	--	--	--
Cardiovascular Disease	216,215	89.92	110,759	89.94	110,718	89.93
Diabetes	79,225	32.95	40,401	32.81	40,576	32.96
Gastrointestinal Disorders	179,746	74.76	92,203	74.87	92,251	74.93
Metabolic Disorders	15,129	6.29	7,812	6.34	7,697	6.25
Neurological Conditions	69,897	29.07	35,821	29.09	35,918	29.17
Other Injury	67,857	28.22	34,759	28.23	34,814	28.28
Psychiatric Disorders	110,547	45.98	56,492	45.87	56,791	46.13
Renal Disease	50,405	20.96	25,605	20.79	25,974	21.10
Respiratory Disorders	86,184	35.84	44,007	35.73	44,197	35.90

*A single patient may have Medicare claims indicating more than one cancer type and/or more than one comorbidity. As a result, the percentages presented above do not sum to 100.

Note: A single patient may be attributed to more than one hospital if the patient received outpatient chemotherapy treatments from more than one hospital during the performance period. The Development Split Sample and the Validation Split Sample were constructed at the patient-provider level in alignment with the measure calculation approach; however, this table displays patient characteristics for the two samples at the individual patient level. As a result, the number of unique patients in the Development and Validation Split Samples does not sum to the total number of patients in the full sample across all hospitals.

Source: Development and Validation Split Samples for July 1, 2012 through June 30, 2013.

Table 3. Hierarchical logistic regression model variable coefficients, odds ratios (ORs), and 95% confidence intervals (CIs) for the inpatient admission outcome

Variable	Coefficient Estimate	OR	CI
Intercept	-3.339		
Age (years above 18, continuous)	-0.011	0.989	(0.987, 0.990)
Gender (male)	-0.043	0.958	(0.930, 0.987)
Number of HOPD chemotherapy treatments during period	0.032	1.032	(1.03, 1.034)
Respiratory disorders (CC 107–110)	0.228	1.256	(1.221, 1.291)
Renal disease (CC 128–131)	0.266	1.304	(1.265, 1.344)
Diabetes (CC 15–20)	0.086	1.090	(1.061, 1.121)
Other injuries (CC 162)	0.065	1.067	(1.037, 1.097)
Metabolic disorder (CC 21–24)	0.286	1.331	(1.275, 1.391)
Gastrointestinal disorder (CC 25–36)	0.336	1.399	(1.348, 1.451)
Psychiatric disorder (CC 48–66)	0.202	1.223	(1.190, 1.257)
Neurological conditions (CC 67–76)	0.105	1.111	(1.080, 1.142)
Cardiovascular disease (CC 77–106)	0.254	1.290	(1.224, 1.359)
Breast cancer (ICD codes 174.0–175.9)	-0.110	0.896	(0.861, 0.932)
Digestive cancer (ICD codes 150.0–159.9)	0.325	1.384	(1.342, 1.427)
Respiratory cancer (ICD codes 160.0–165.9)	0.467	1.595	(1.546, 1.646)
Lymphoma (ICD codes 200.00–203.82)	0.736	2.087	(2.016, 2.161)
Other cancer (ICD codes 140.0–149.9, 170.0–173.99, 176.0–176.9, 179, 182.0–182.8, 190.0–199.2, 209.00–209.36)	0.366	1.442	(1.404, 1.481)
Prostate cancer (ICD code 185)	-0.293	0.746	(0.712, 0.782)
Secondary–lymph (ICD codes 196.0–196.9)	0.253	1.288	(1.249, 1.328)
Secondary–solid (ICD codes 197.0–198.82, 209.70–209.79)	0.733	2.081	(2.020, 2.144)

Source: Full Sample for July 1, 2012 through June 30, 2013.
ICD and CC definitions are based on ICD-9-CM and Version 12 CCs, respectively.

Table 4. Hierarchical logistic regression model variable coefficients, odds ratios (ORs), and 95% confidence intervals (CIs) for the ED visit outcome

Variable	Coefficient Estimate	OR	CI
Intercept	-2.948		
Age (years above 18, continuous)	-0.015	0.985	(0.983, 0.987)
Gender (male)	-0.161	0.851	(0.815, 0.888)
Number of HOPD chemotherapy treatments during period	0.036	1.036	(1.034, 1.039)
Respiratory disorders (CC 107–110)	0.105	1.111	(1.065, 1.159)
Other injuries (CC 162)	0.155	1.167	(1.120, 1.217)
Gastrointestinal disorder (CC 25–36)	0.295	1.344	(1.275, 1.416)
Psychiatric disorder (CC 48–66)	0.146	1.157	(1.111, 1.206)
Neurological conditions (CC 67–76)	0.093	1.098	(1.053, 1.144)
Cardiovascular disease (CC 77–106)	0.110	1.116	(1.042, 1.196)
Breast cancer (ICD codes 174.0–175.9)	0.070	1.073	(1.016, 1.133)
Digestive cancer (ICD codes 150.0–159.9)	0.191	1.210	(1.157, 1.266)
Respiratory cancer (ICD codes 160.0–165.9)	0.102	1.108	(1.055, 1.163)
Other cancer (ICD codes 140.0–149.9, 170.0–173.99, 176.0–176.9, 179, 182.0–182.8, 190.0–199.2, 209.00–209.36)	0.094	1.099	(1.055, 1.144)
Secondary–lymph (ICD codes 196.0–196.9)	0.080	1.084	(1.034, 1.136)
Secondary–solid (ICD codes 197.0–198.82, 209.70–209.79)	0.174	1.190	(1.140, 1.241)

Source: Full Sample for July 1, 2012 through June 30, 2013.

Table 5. Risk-adjustment model performance in the Medicare development and validation split samples

	2012–2013 Development Split Sample	2012–2013 Validation Split Sample
Inpatient Admission Model	--	--
Time Period	July 1, 2012–June 30, 2013	July 1, 2012–June 30, 2013
Number of unique patients	123,149	123,115
Number of patients with at least one qualifying admission	12,808	12,965
Calibration (γ0,γ1)	(0, 1)	(0.01, 1.00)
c-statistic	0.73	0.72
Predictive Ability (Lowest-Highest Risk Decile)	2.09%–27.70%	2.16%–27.98%
ED Visit Model	--	--
Time Period	July 1, 2012–June 30, 2013	July 1, 2012–June 30, 2013
Number of unique patients	123,149	123,115
Number of patients with at least one qualifying ED visit	5,251	5,169
Calibration (γ0,γ1)	(0, 1)	(-0.04, 0.99)
c-statistic	0.63	0.64
Predictive Ability (Lowest-Highest Risk Decile)	1.91%–8.33%	1.93–8.22%

Source: Development and Validation Split Samples for July 1, 2012 through June 30, 2013.

Table 6. Model variable coefficients, odds ratios (ORs), and 95% confidence intervals (CIs) in the development and validation split samples for the inpatient admission outcome

Explanation	Development Split Sample			Validation Split Sample		
	Coefficient Estimate	OR	CI	Coefficient Estimate	OR	CI
Intercept	-3.325	--	--	-3.197	--	--
Age	-0.011	0.989	(0.987, 0.991)	-0.013	0.987	(0.985, 0.989)
Sex	-0.049	0.952	(0.911, 0.994)	-0.040	0.961	(0.92, 1.004)
Number of HOPD chemotherapy treatments during period	0.030	1.03	(1.028, 1.033)	0.029	1.029	(1.027, 1.032)
Respiratory disorders	0.187	1.206	(1.157, 1.256)	0.274	1.315	(1.263, 1.37)
Renal disease	0.295	1.342	(1.284, 1.404)	0.237	1.267	(1.212, 1.325)
Diabetes	0.110	1.116	(1.072, 1.162)	0.070	1.072	(1.03, 1.116)
Other injuries	0.062	1.063	(1.02, 1.108)	0.061	1.063	(1.02, 1.108)
Metabolic disorder	0.275	1.317	(1.235, 1.404)	0.311	1.365	(1.281, 1.454)
Gastrointestinal disorder	0.368	1.445	(1.368, 1.526)	0.303	1.354	(1.284, 1.429)
Psychiatric disorder	0.238	1.268	(1.218, 1.321)	0.163	1.178	(1.131, 1.226)
Neurological conditions	0.115	1.121	(1.077, 1.168)	0.089	1.094	(1.05, 1.139)
Cardiovascular disease	0.208	1.232	(1.142, 1.329)	0.315	1.37	(1.268, 1.481)
Breast cancer	-0.111	0.895	(0.845, 0.949)	-0.109	0.897	(0.847, 0.951)
Digestive cancer	0.304	1.355	(1.295, 1.417)	0.352	1.422	(1.359, 1.487)
Respiratory cancer	0.468	1.597	(1.526, 1.672)	0.479	1.615	(1.543, 1.69)
Lymphoma	0.739	2.094	(1.991, 2.203)	0.745	2.107	(2.002, 2.216)
Other cancer	0.364	1.439	(1.384, 1.497)	0.365	1.441	(1.385, 1.498)
Prostate cancer	-0.321	0.726	(0.677, 0.777)	-0.294	0.746	(0.697, 0.798)
Secondary – lymph	0.257	1.292	(1.236, 1.351)	0.229	1.257	(1.203, 1.314)
Secondary – solid	0.723	2.06	(1.973, 2.151)	0.740	2.095	(2.007, 2.188)

Source: Development and Validation Split Samples for July 1, 2012 through June 30, 2013.

Table 7. Model variable coefficients, odds ratios (ORs), and 95% confidence intervals (CIs) in the development and validation split samples for the ED visit outcome

Explanation	Development Split Sample			Validation Split Sample		
	Coefficient Estimate	OR	CI	Coefficient Estimate	OR	CI
Intercept	-2.928	--	--	-2.925	--	--
Age	-0.015	0.985	(0.982, 0.988)	-0.015	0.985	(0.982, 0.988)
Sex	-0.162	0.85	(0.799, 0.905)	-0.147	0.864	(0.811, 0.919)
Number of HOPD chemotherapy treatments during period	0.033	1.033	(1.030, 1.037)	0.035	1.035	(1.032, 1.039)
Respiratory disorders	0.113	1.119	(1.053, 1.189)	0.093	1.097	(1.032, 1.167)
Other injuries	0.173	1.189	(1.12, 1.262)	0.133	1.142	(1.074, 1.214)
Gastrointestinal disorder	0.296	1.345	(1.246, 1.451)	0.281	1.325	(1.227, 1.43)
Psychiatric disorder	0.137	1.147	(1.081, 1.217)	0.163	1.177	(1.109, 1.249)
Neurological conditions	0.095	1.1	(1.035, 1.168)	0.084	1.087	(1.023, 1.156)
Cardiovascular disease	0.111	1.118	(1.01, 1.236)	0.089	1.093	(0.988, 1.209)
Breast cancer	0.097	1.102	(1.019, 1.192)	0.038	1.038	(0.959, 1.125)
Digestive cancer	0.219	1.245	(1.167, 1.328)	0.160	1.174	(1.099, 1.254)
Respiratory cancer	0.105	1.111	(1.036, 1.192)	0.097	1.101	(1.026, 1.182)
Other cancer	0.100	1.105	(1.042, 1.171)	0.079	1.082	(1.02, 1.148)
Secondary – lymph	0.086	1.089	(1.018, 1.166)	0.088	1.092	(1.02, 1.169)
Secondary – solid	0.149	1.16	(1.091, 1.233)	0.195	1.215	(1.143, 1.293)

Source: Development and Validation Split Samples for July 1, 2012 through June 30, 2013.

Table 8. Observed outcome rates, among hospitals with any case size

Hospital type	Hospitals	Mean (%)	Standard Deviation	Min. (%)	25th Pctl.	Median (%)	75th Pctl.	Max. (%)
Observed Inpatient Admission Rate	--	--	--	--	--	--	--	--
All hospitals	3,765	8.3	0.11	0.0	0.0	6.5	12.1	100.0
Non-PCHs	3,754	8.2	0.11	0.0	0.0	6.4	12.1	100.0
Only PCHs	11	11.8	0.02	7.9	10.4	12.0	13.7	15.5
Observed ED Visits Rate	--	--	--	--	--	--	--	--
All hospitals	3,765	4.3	0.09	0.0	0.0	1.4	5.3	100.0
Non-PCHs	3,754	4.3	0.09	0.0	0.0	1.3	5.3	100.0
Only PCHs	11	4.0	0.02	1.4	2.8	4.2	5.5	6.0

Source: Full Sample for July 1, 2012, through June 30, 2013.

Table 9. Risk-adjusted outcome rates, among hospitals with any case size

	Hospitals	Mean (%)	Standard Deviation	Min. (%)	25th Pctl.	Median (%)	75th Pctl.	Max. (%)
RSAR	--	--	--	--	--	--	--	--
All hospitals	3,765	10.4	1.28	6.0	9.8	10.2	10.8	24.9
Non-PCHs	3,754	10.4	1.28	6.0	9.8	10.2	10.8	24.9
Only PCHs	11	10.4	1.82	7.9	9.4	9.7	11.1	13.8
RSEDR	--	--	--	--	--	--	--	--
All hospitals	3,765	4.2	0.53	2.1	4.0	4.1	4.4	7.5
Non-PCHs	3,754	4.2	0.52	2.3	4.0	4.1	4.4	7.5
Only PCHs	11	3.7	1.09	2.1	2.9	3.9	4.7	5.5

Source: Full Sample for July 1, 2012, through June 30, 2013.

Table 10. Patient-Level Association between SDS Variables and the Outcomes

SDS variable	SDS status	Had at least one inpatient admission within 30 days		Had at least one ED visit within 30 days	
		Number (#)	Percentage (%)	Number (#)	Percentage (%)
Medicaid Dual Eligibility	No	20,441	9.7	7,945	3.8
	Yes	5,636	13.7	2,550	6.2
	Total	**26,077**	--	**10,495**	--
Race	Non-black	22,748	10.0	9,074	4.0
	Black	3,329	12.9	1,421	5.5
	Total	**26,077**	--	**10,495**	--
AHRQ SES Index	1st quartile	6,987	11.5	2,918	4.8
	2nd quartile	6,427	10.5	2,624	4.3
	3rd quartile	6,206	10.1	2,421	3.9
	4th quartile	6,068	9.4	2,333	3.6
	Total	**25,688**	--	**10,296**	--

Source: Full Sample for July 1, 2012, through June 30, 2013.

Note: 4,088 patient-provider combinations were missing zip code information and were not linked with the AHRQ SES Composite Index. These missing zip codes explain the difference in total counts seen in the table above.

Table 11. Summary of patients who experienced qualifying outcomes within 30 days of hospital-based outpatient chemotherapy, by SDS variable type

Hospital-Specific Proportions	Quartile	Range	RSAR		RSEDR	
			Median	Interquartile range (IQR, 1st quartile – 3rd quartile)	Median	IQR
Dual Eligible Patients	--	--	--	--	--	--
	1	(0.000, 0.090)	10.241	10.015 – 10.449	4.127	4.046 – 4.148
	2	(0.090, 0.181)	10.148	9.501 – 10.954	4.076	3.864 – 4.494
	3	(0.182, 0.307)	10.163	9.653 – 10.950	4.100	3.916 – 4.430
	4	(0.307, 1.000)	10.210	9.922 – 10.781	4.121	4.023 – 4.389
Black Patients	--	--	--	--	--	--
	1	(0.000, 0.000)	10.207	9.966 – 10.487	4.125	4.056 – 4.292
	2	(0.000, 0.007)	10.608	9.043 – 11.909	4.430	3.858 – 5.290
	3	(0.007, 0.106)	10.135	9.410 – 11.150	4.049	3.816 – 4.476
	4	(0.106, 1.000)	10.229	9.769 – 11.100	4.095	3.857 – 4.329
Patients with low AHRQ SES Composite Score	--	--	--	--	--	--
	1	(0.000, 0.022)	10.230	9.995 – 10.609	4.122	4.031 – 4.205
	2	(0.022, 0.190)	10.098	9.518 – 10.960	4.072	3.881 – 4.437
	3	(0.190, 0.525)	10.219	9.742 – 11.104	4.102	3.886 – 4.398
	4	(0.526, 1.000)	10.203	9.902 – 10.533	4.130	4.047 – 4.382

Source: Full Sample for July 1, 2012, through June 30, 2013.

Table 12. Model discrimination and overfitting for risk-adjustment for the inpatient admission outcome

	Risk Factors	
	Original Risk Factors	Original Risk Factors and SDS Variables
Model Discrimination		
C-statistics: Development Split Sample	0.725	0.726
C-statistics: Validation Split Sample	0.725	0.725
Model Overfitting		
γ_0	0.006	0.002
γ_1	0.996	0.995

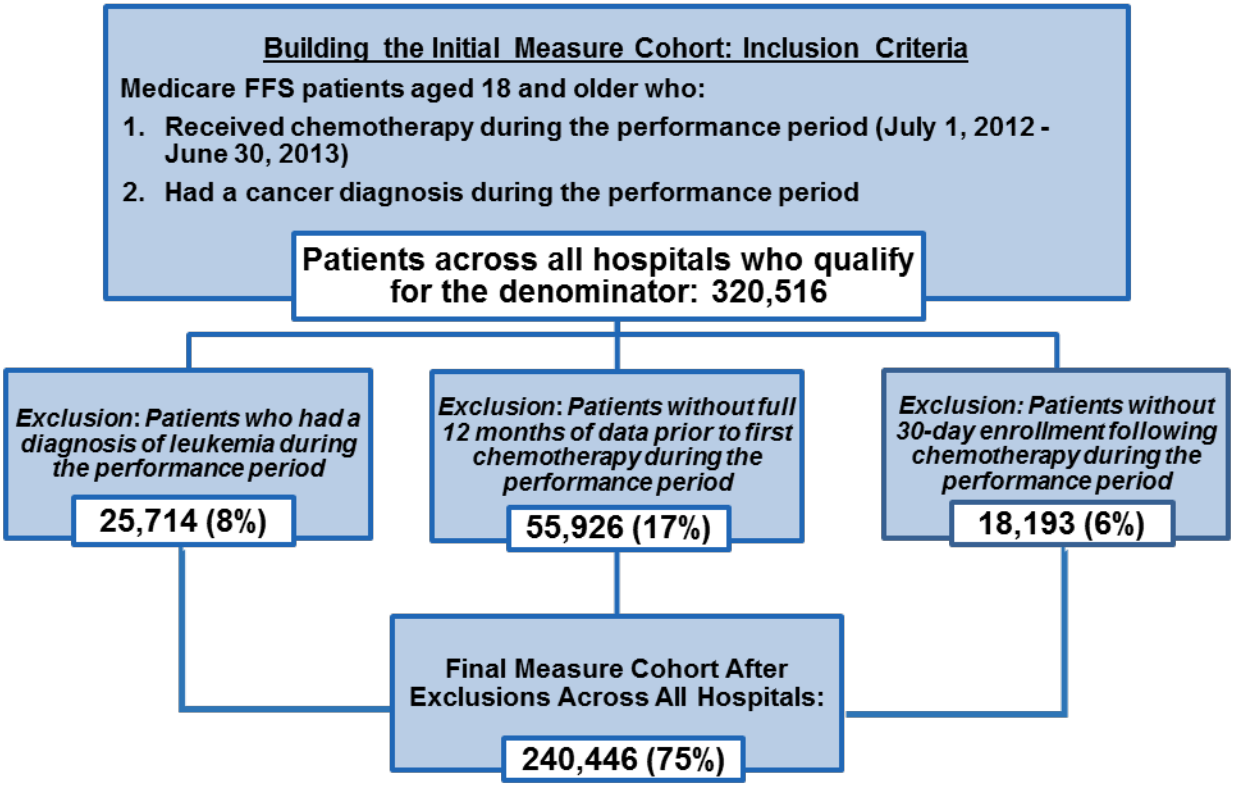
Source: Development and Validation Split Samples for July 1, 2012 through June 30, 2013.

Table 13. Model discrimination and overfitting for risk-adjustment for the ED visit outcome

	Risk Factors	
	Original Risk Factors	Original Risk Factors and SDS Variables
Model Discrimination		
C-statistics: Development Split Sample	0.635	0.636
C-statistics: Validation Split Sample	0.633	0.644
Model Overfitting		
γ_0	-0.039	-0.032
γ_1	0.993	0.995

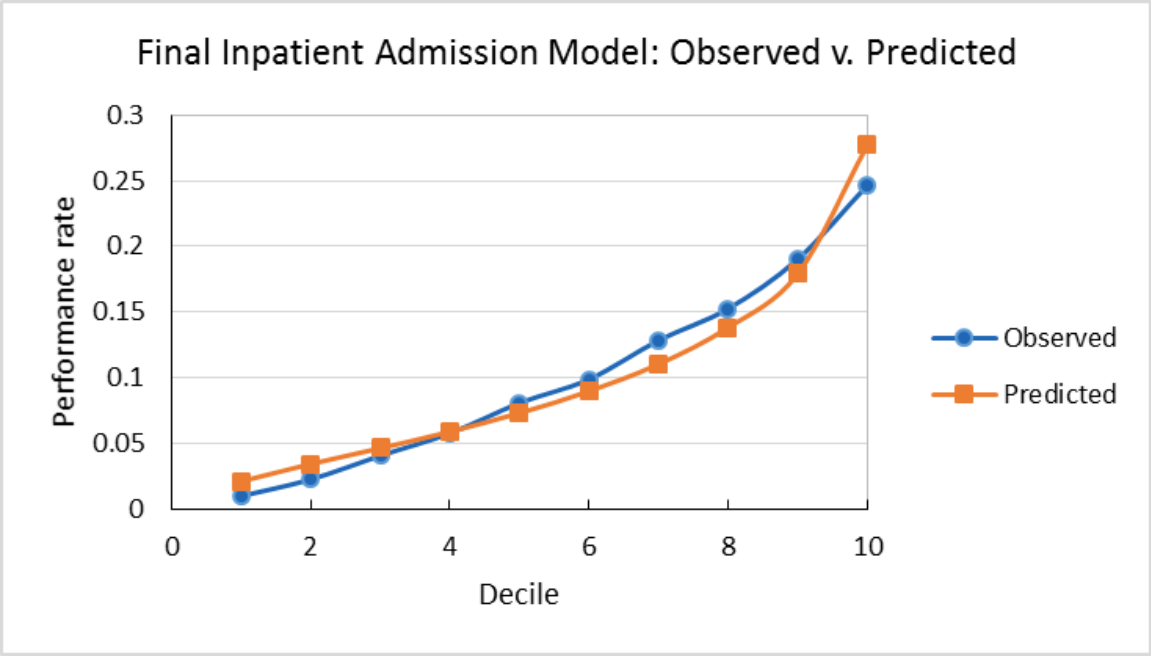
Source: Development and Validation Split Samples for July 1, 2012 through June 30, 2013.

Figure 1. Flow diagram of the cohort



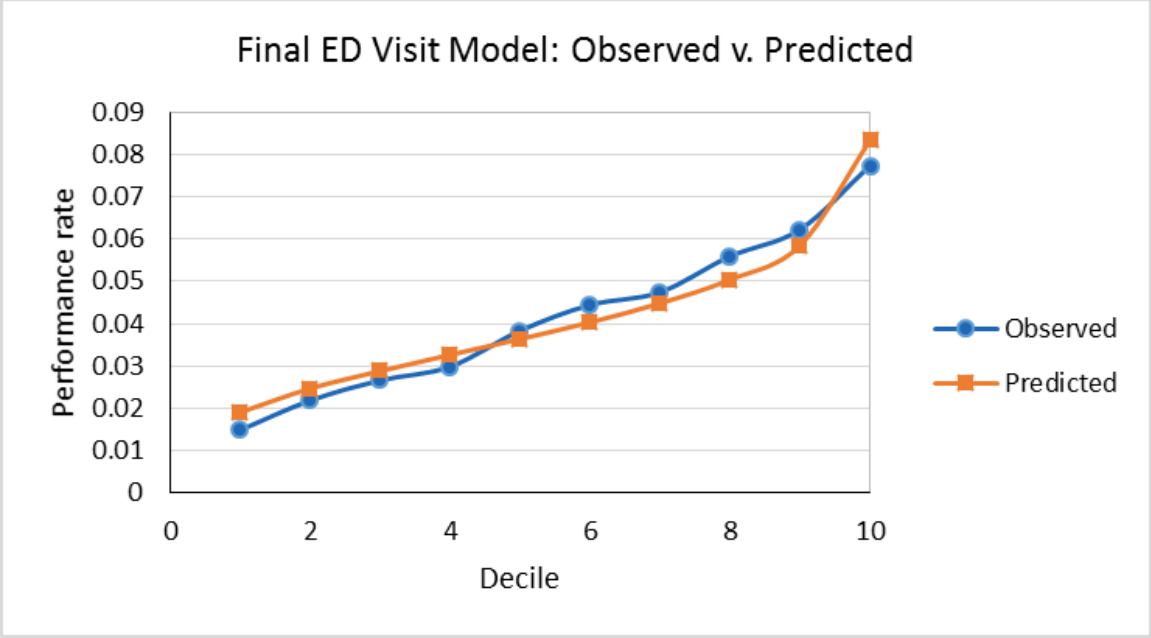
Source: Full Sample for July 1, 2012, through June 30, 2013.

Figure 2. Inpatient admission outcome model: Plot of observed vs. predicted values for risk deciles



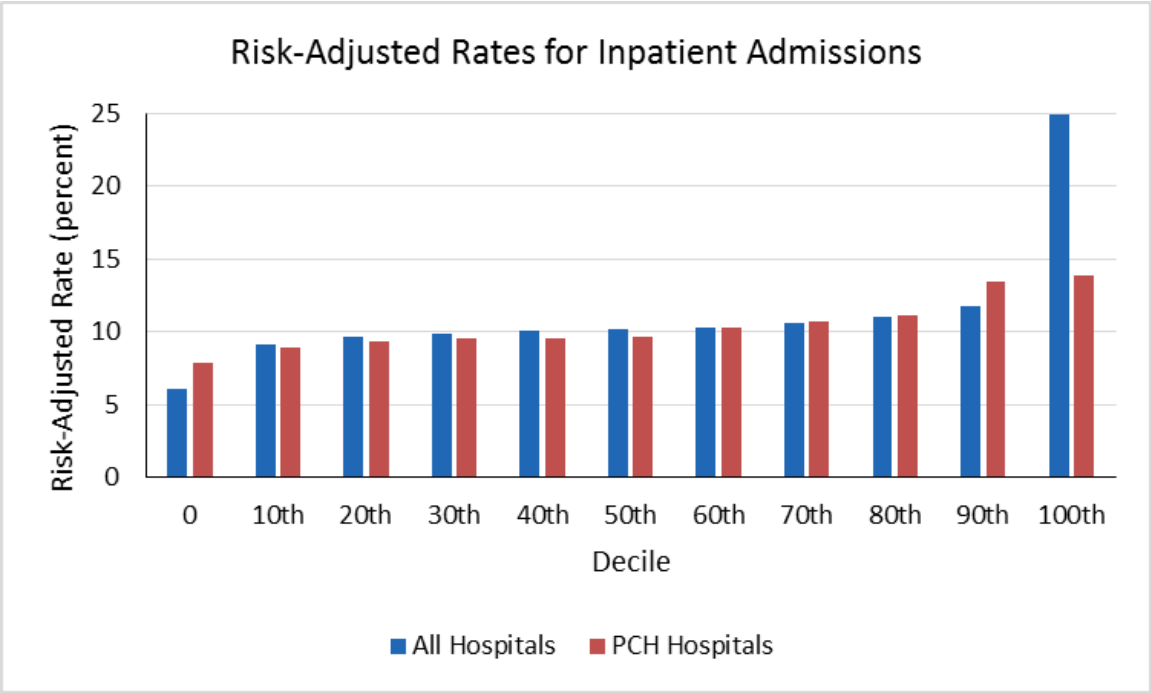
Source: Development Split Sample for July 1, 2012, through June 30, 2013.

Figure 3. ED visit outcome model: Plot of observed vs. predicted values for risk deciles



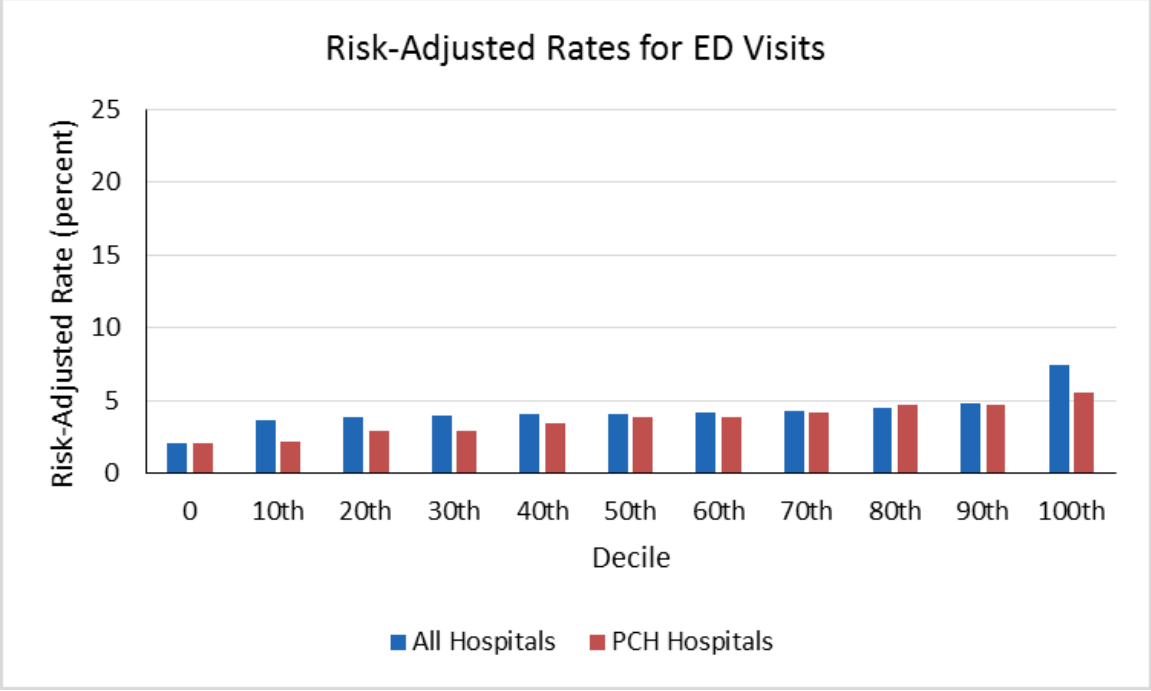
Source: Development Split Sample for July 1, 2012, through June 30, 2013.

Figure 4. Risk-adjusted rates for inpatient admissions



Source: Full Sample for July 1, 2012, through June 30, 2013.

Figure 5. Risk-adjusted rates for ED visits



Source: Full Sample for July 1, 2012, through June 30, 2013.

8. Appendices

Appendix A: Data Dictionary for Denominator/Cohort, Outcomes, and Risk-Adjustment Factors

Please see Appendix Table A.1: Data Dictionary for Denominator/Cohort, Outcomes, and Risk-Adjustment Factors, accompanying this report in a separate Microsoft Excel workbook within the same zip file, located https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

Appendix B: Risk-Adjustment Model Development

B.1. Candidate Variables Considered For Risk-Adjustment

Table B.1. shows the risk-adjustment candidate variables considered during measure development.

Table B.1. Candidate variables considered for risk-adjustment

Variables	Rationale
Age	Increasing risk of adverse events with increasing age
Male	Differing risks for adverse events for different genders; associated with cancer type
Exposure	Increasing risk of adverse events with increasing number of chemotherapy treatments
Respiratory Disorder	May increase the risk of adverse event; exogenous to defined outcome
Renal Disease	May increase the risk of adverse event; exogenous to defined outcome
Diabetes	May increase the risk of adverse event; exogenous to defined outcome
Other Injuries	May increase the risk of adverse event; exogenous to defined outcome
Metabolic Disorders	May increase the risk of adverse event; exogenous to defined outcome
Gastrointestinal Disorders	May increase the risk of adverse event; exogenous to defined outcome
Psychiatric Disorders	May increase the risk of adverse event; exogenous to defined outcome
Neurological Conditions	May increase the risk of adverse event; exogenous to defined outcome
Cardiovascular Disease	May increase the risk of adverse event; exogenous to defined outcome
Breast Cancer	Differing risks for adverse events by cancer type given differences in associated severity and treatment plans

Variables	Rationale
Digestive Cancer	Differing risks for adverse events by cancer type given differences in associated severity and treatment plans
Genitourinary Cancer	Differing risks for adverse events by cancer type given differences in associated severity and treatment plans
Respiratory Cancer	Differing risks for adverse events by cancer type given differences in associated severity and treatment plans
Lymphoma	Differing risks for adverse events by cancer type given differences in associated severity and treatment plans
Other Cancer	Differing risks for adverse events by cancer type given differences in associated severity and treatment plans
Prostate Cancer	Differing risks for adverse events by cancer type given differences in associated severity and treatment plans
Secondary Cancer of Lymph Nodes	Differing risks for adverse events by cancer type given differences in associated severity and treatment plans
Secondary Cancer of Solid Tumors	Differing risks for adverse events by cancer type given differences in associated severity and treatment plans

B.2. Risk-Standardized Measure Score Calculation Algorithm

We fitted a hierarchical generalized linear model (HGLM), which accounts for the clustering of observations within hospitals. We assume the outcome is a known exponential family distribution and relates linearly to the covariates via a known linked function, *h*. For our model, we assumed a binomial distribution and a logit link function. Further, we accounted for the clustering within hospital by estimating a hospital-specific effect, α_i, which we assume follows a normal distribution with mean μ and variance τ^2, the between-hospital variance component. The following equations define the HGLM:

(1) $h(Y_{ij}) = \alpha_i + \beta \boldsymbol{Z}_{ij}$

(2) $\alpha_i = \mu + \omega_i;\ \omega_i \sim N(0\tau^2)$
$i = 1...I; j = 1...n_i$

Where Y_{ij} denotes the outcome (equal to 1 if patient has one or more qualifying inpatient admissions or one or more qualifying ED visits (and no inpatient admissions for the ED visit measure) within 30 days of hospital outpatient chemotherapy treatment, 0 otherwise) for the *j-th* patient who had an outpatient chemotherapy at the *i-th* hospital; $\boldsymbol{Z}_{ij} = (Z_{1ij}, Z_{2ij}, \ldots Z_{pij})$ is a set of *p* patient-specific covariates derived from the data; and *I* denotes the total number of hospitals and n_i the number of outpatient chemotherapy treatments performed at hospital *i*. The hospital-specific intercept of the *i-th* hospital, α_i, defined above, comprises μ, the adjusted average intercept over all hospitals in the sample, and ω_i, the hospital-specific intercept deviation from μ. A point estimate of ω_i, greater or less than 0, determines whether hospital performance is worse or better compared to the adjusted average outcome.

We estimate the HGLM using the SAS software system (GLIMMIX procedure).

B.3. Provider Performance Reporting

Using the HGLM defined by Equations (1) - (2), we estimate the parameters $\hat{\mu}$, $\{\hat{\alpha}_1, \hat{\alpha}_2 \cdots \hat{\alpha}_I\}$, $\hat{\beta}$, and $\hat{\tau}^2$. We calculate a standardized outcome, s_i, for each hospital by computing the ratio of the number of predicted hospital visits to the number of expected hospital visits, multiplied by the unadjusted overall hospital visit rate, $\overline{y}$. Specifically, we calculate:

(3) Predicted value $\quad \hat{y}_{ij}(Z) = h^{-1}(\hat{\alpha}_i + \hat{\beta}\boldsymbol{Z}_{ij})$

(4) Expected value $\quad \hat{e}_{ij}(Z) = h^{-1}(\hat{\mu} + \hat{\beta}\boldsymbol{Z}_{ij})$

(5) $$s_i(Z) = \frac{\sum_{j=1}^{n_i} \hat{y}_{ij}(Z)}{\sum_{j=1}^{n_i} \hat{e}_{ij}(Z)} \times \overline{y}$$

If the "predicted" number of hospital visits is higher (lower) than the "expected" number of hospital visits, then that hospital's $\hat{s}_i$ will be higher (lower) than the unadjusted average.