CMS Special Innovation Project
Maintenance and Development of Medication Measures

(Contract Number: HHSM-500-2011-FL10C; SIP-FL-01)

Public Comment Summary Report

Measure #701a – Adverse Drug Events: Hyperglycemia
Measure #701b – Adverse Drug Events: Hypoglycemia

Date of Public Comment Summary Report – November 13, 2013

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PUBLIC COMMENT SUMMARY REPORT

Introduction

The Centers for Medicare & Medicaid Services (CMS) has contracted with FMQAI under the CMS Medication Measures Special Innovation Project to use electronic health record (EHR) data to develop new quality measures that can be used to identify and prevent adverse drug events and adverse events of medical care in the hospital inpatient setting. In following the measure development process outlined in the Blueprint for the CMS Measures Management System (Version 9.2), FMQAI released a Call for Public Comment on two proposed adverse drug event (ADE) measures:

- Measure #701a Adverse Drug Events: Hyperglycemia
- Measure #701b Adverse Drug Events: Hypoglycemia

The Call for Public Comment allowed stakeholder organizations and interested parties to provide input and critical suggestions that might not have been previously considered by the measure developer or the technical expert panel (TEP).

The methodology and results of the public comment period are summarized in this report. Results include the number of participants, the perspectives of commenters, and a summary of comments for each measure by category: Importance/Relevance, Scientific Acceptability, Feasibility, and General Comments. Preliminary recommendations for TEP consideration are also discussed. Verbatim comments for each measure, along with recommendations, actions taken, and CMS' responses related to the comments, are included in the Appendices.

Methodology

The public comment period was open from August 22, 2013, to September 6, 2013. FMQAI invited all interested healthcare professionals, stakeholder organizations, and individuals to provide comments on the two proposed ADE quality measures.

FMQAI notified 52 organizations/groups about the opening of the public comment via e-mail, requested TEP members and federal guests of the Medication Measures Special Innovation Project to forward the e-mail invitation to their expert contacts, and distributed the announcement to all Medicare Quality Improvement Organizations (QIOs) via the CMS Improving Individual Patient Care National Coordinating Center. (Please see Appendix A for the list of stakeholders.) FMQAI also worked with the Measures Manager, Health Services Advisory Group, Inc. (HSAG), to publish the announcement of the public comment period on the CMS website [https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html].

For each measure, commenters were given access to the Measure Information Form and the Measure Justification Form, which contained details on the measure specifications, rationale, literature supporting the importance of the measure, and results from the field testing. In addition, the measure has been specified using the Measure Authoring Tool (MAT). The XML file, the value sets, and the human-readable HTML file generated by MAT with a list of data elements were available for the commenters' review.

To provide comments on the proposed measures, commenters used a web-based data collection tool (SurveyMonkey®). FMQAI reviewed the comments to identify the source of the comment (individual or organization); summarized the comments by measure; addressed each of the comments; and made preliminary recommendations for TEP consideration.

Results

Number of Participants

Nineteen participants provided comments on the glycemic control measures. Of these, 14 used the web-based data collection tool, 2 submitted comments via e-mail, and 3 shared comments by letter. An additional 9 participants provided some information about themselves (e.g., contact name, organization, and/or perspective of the commenter) via the web-based data collection tool but did not provide comments.

Perspective of Commenters

Of the 19 commenters, 11 (57.9%) represented an individual's perspective, and 8 (42.1%) reflected an organization's perspective. "Individual" or "organizational" perspective was assigned, based on the commenter's selection during submission of comments. Table 1 shows the affiliations of the 19 commenters.

Table 1. Perspective of Commenters

Commenter Perspective	Number	Percent (N=19)
Individual	11	57.9%
Organizational	8	42.1%
Type of Organization		
Accrediting Organization	0	0.0%
Consumer Group	1	5.3%
Health Plan/Payer Organization	0	0.0%
Health Professional Organization	4	21.1%
Industry/Supplier	0	0.0%
Medicare Quality Improvement Organization (QIO)	1	5.3%
Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	7	36.8%
Public/Community Health Agency	2	10.5%
Research	1	5.3%
Other (please specify)	2	10.5%
[No response]	1	5.3%

Summary of Measure-Specific Comments

For each measure, the commenters were instructed to provide their feedback on 4 categories: Importance/Relevance, Scientific Acceptability, Feasibility, and General Comments. The comments were summarized by FMQAI and are presented here by measure and category.

Measure #701a – Adverse Drug Events: Hyperglycemia

1. Importance/Relevance (14 comments received)
    a. Ten comments indicated that the proposed measure was important and the measure was valuable for the assessment of medication-related harm.
    b. Three comments suggested that the causality between hyperglycemic and outcome was ambiguous and that the proposed measure was not a true measure of quality with regard to the management of hyperglycemia.
    c. One comment inquired about the availability of benchmark data by CMS.

2. Scientific Acceptability (12 comments received)
    a. Four comments favorably supported the measure and found the technical specifications to be acceptable as proposed.
    b. Four comments raised concerns regarding the scientific basis of the blood glucose threshold for hyperglycemia and determining the occurrence of some hyperglycemic events based on one glucose value.
    c. One comment questioned how the measure, as defined, would be actionable by providers and requested clarification as to why the measure did not include all patients and why the measure was defined as a percentage in lieu of hospital days.
    d. One comment inquired about the availability of benchmark data by CMS.
    e. One comment suggested an alternate measure concept that correlates hyperglycemia with the length of stay, and another comment suggested measuring the number of hyperglycemic patient-days.

3. Feasibility (12 comments received)
    a. Four comments favorably supported the feasibility of the measure and indicated that the data are readily available.
    b. Another four comments raised concerns over the availability and integration of EHR data with laboratory and billing to calculate accurately an automated measure rate. In addition, there were concerns about the potential undue burden on the hospitals to report these data.
    c. Three comments were related to the measure definition and suggested the exclusion of neonatal, pediatric, and diabetic ketoacidosis (DKA) patients and patients with only one blood glucose result.
    d. One comment inquired about the availability of a data repository to report the measure rate if the measure were to be implemented.

4. General Comments (11 comments received)
    a. Five comments expressed favorable support for the measure and indicated that the measure would have positive impact on the quality of patient care.
    b. The other six comments reiterated the concerns raised in the previous categories, suggesting that the hyperglycemic thresholds be reevaluated as well as timing of

repeat blood glucose measurements in relation to meals; persistent hyperglycemia should be trended versus a single point in time; and hyperglycemia is generally not considered an adverse drug event in the absence of drugs that contribute to elevated glucose levels.

Measure 701b – Adverse Drug Events: Hypoglycemia

1. Importance/Relevance (14 comments received)
    a. Eight comments expressed support for the measure and found the proposed measure to be an important and valuable step toward improving patient safety. In addition, one of the comments suggested further endeavors are needed to identify the causes of hypoglycemia in diabetes self-care.
    b. Two comments expressed that the measure, as currently defined, is not reflective of the clinical practice for hypoglycemia management, and one comment indicated that hypoglycemia was not a common problem.
    c. One comment suggested that the measure, as currently defined, would under-report hypoglycemic rates due to the low blood glucose threshold used in the measure.
    d. One comment inquired about the availability of benchmark data by CMS, and another comment inquired about linking the measure with historical data.

2. Scientific Acceptability (11 comments received)
    a. Six comments favorably supported the measure and found the technical specifications to be acceptable as proposed.
    b. Three comments recommended establishing an alternative blood glucose threshold of <70 mg/dL for identifying hypoglycemic events.
    c. One comment expressed that the measure numerator is not reflective of the clinical practice for hypoglycemia management.
    d. One comment suggested modifying the measure to a day-weighted measure as the number of blood glucose checks typically increase for patients with hypoglycemic events, thereby artificially increasing the rate of hypoglycemia.

3. Feasibility (13 comments received)
    a. Four comments agreed that the data were readily available or that hospitals were already tracking some form of the data needed for this measure.
    c. Four comments raised concerns over the availability and integration of EHR data with laboratory and billing to calculate accurately an automated measure rate. In addition, there were concerns about the potential undue burden on the hospitals to report these data.
    b. Three comments suggested that the measure definition was complex and that a standard data collection protocol needs to be established.
    c. Two comments stated that the measure, as currently defined, would not be feasible.

4. General Comments (9 comments received)
    a. Six comments expressed favorable support for the measure, and one of the comments suggested a further investigation of hospital admissions that resulted from hypoglycemia.
    b. Two comments reiterated the concerns raised in the previous categories, such as the issue with measure feasibility and the need to establish an alternative blood glucose threshold.
    c. One comment suggested specifying the numerator and denominator for the hyper- and hypoglycemia measures in a similar way and incorporating the emergency department admissions that resulted in inpatient admissions.

Verbatim Comments

Verbatim comments, listed in the order in which they were received by date for each measure, are included in Appendices B and C. Comments appear as they were received and have not been edited for spelling, punctuation, grammar, etc.

Preliminary Recommendations for TEP Consideration

After review and evaluation of the public comments received on the proposed glycemic control measures, the project team does not recommend any specific modifications to the measures at this time. However, the team proposes that CMS and the TEP consider and discuss the following topics related to the measures:

Measure 701a – Adverse Drug Events: Hyperglycemia

1. Discuss re-naming the measure to avoid any concern with classification of ADEs.
2. Discuss the feasibility concerns regarding the availability of EHR data and EHR-integrated point-of-care (POC) glucose testing.

Measure 701b – Adverse Drug Events: Hypoglycemia

1. Discuss the feasibility concerns regarding the availability of EHR data and EHR-integrated POC glucose testing.
2. Discuss the public comment recommendation to add an alternate numerator for mild hypoglycemic episode using <70 mg/dL as the threshold for blood glucose level, and discuss a suggested concept of measuring hypoglycemic events that lead to admissions or emergency department visits.

Comments have been reviewed by CMS and the TEP for potential modification of the measures, and recommendations, actions taken, and CMS' responses related to the comments are included in Appendices B and C.

Appendix

Appendix A: Stakeholders Invited to Participate in Public Comment

	Stakeholder Organization Name
1.	Academy of Managed Care Pharmacy
2.	Agency for Healthcare Research and Quality (AHRQ)
3.	American Academy of Family Physicians (AAFP)
4.	American Academy of Orthopedic Surgeons (AAOS)
5.	American Association of Clinical Endocrinologists (AACE)
6.	American Association of Colleges of Pharmacy (AACP)
7.	American Association of Endocrine Surgeons (AAES)
8.	American Association of Hip and Knee Surgeons (AAHKS)
9.	American Association of Retired Persons (AARP)
10.	American College of Cardiology (ACC)
11.	American College of Chest Physicians (ACCP)
12.	American College of Emergency Physicians (ACEP) – Quality Improvement and Patient Safety Section
13.	American College of Surgeons (ACS)
14.	American College of Surgeons (ACS) – National Surgical Quality Improvement Program (NSQIP)
15.	American Diabetes Association (ADA)
16.	American Health Information Management Association (AHIMA)
17.	American Hospital Association (AHA)
18.	American Medical Association (AMA)
19.	American Medical Informatics Association (AMIA)
20.	American Nurses Association (ANA)
21.	American Pharmacists Association (APhA)
22.	American Society of Health System Pharmacists (ASHP)
23.	American Society of Nephrology (ASN)
24.	American Thoracic Society (ATS)
25.	America’s Essential Hospitals (previously National Association of Public Hospitals & Health Systems)
26.	America's Health Insurance Plans (AHIP)
27.	Association for Professionals in Infection Control and Epidemiology (APIC)

	Stakeholder Organization Name
28.	Centers for Disease Control and Prevention (CDC)
29.	Centers for Medicare & Medicaid Services (CMS)
30.	Endocrine Society
31.	Federal Interagency ADE Workgroup – Diabetes Agents
32.	Hart Health Strategies
33.	Health Services Advisory Group (HSAG)
34.	Healthcare Leadership Council
35.	Hospital Inpatient Quality Reporting (IQR) Program – National Coordinating Center
36.	Hospital Outpatient Quality Reporting (OQR) Program
37.	Hospital Quality Alliance (HQA)/Discern Consulting
38.	Infectious Diseases Society of America (IDSA)
39.	Institute for Healthcare Improvement (IHI)
40.	Institute for Safe Medication Practices (ISMP)
41.	Johns Hopkins Hospital
42.	The Joint Commission
43.	Lantana Consulting Group
44.	National Committee for Quality Assurance (NCQA)
45.	Office of the National Coordinator for Health Information Technology (ONC)
46.	Pharmacy Quality Alliance, Inc. (PQA)
47.	Premier
48.	Society of Critical Care Medicine (SCCM)
49.	Society of General Internal Medicine
50.	Office of the Assistant Secretary, U.S. Department of Health & Human Services
51.	University Hospital Consortium
52.	University of California San Diego

Appendix B: Verbatim Public Comments for Measure 701a – ADE: Hyperglycemia

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
1.	08/26/2013 (via e-mail)	Charlene Avery, MD; Director; Office of Clinical & Preventive Services; Health and Human Services; Indian Health Service	Health Plan/Payer Organization	Organizational	Importance/Relevance: Hello, thank you for the opportunity to comment. The detailed information was very helpful. The importance and relevance of minimizing the potential for adverse consequences related to poor glucose control whether hyper- or hypoglycemia cannot be overemphasized. Scientific Acceptability: The references and identification of quality of evidence were helpful to support the scientific acceptability of the proposed measures. Feasibility: The feasibility seems well examined (very tedious but do-able). General: For general comments, I concur. Thank you again for the opportunity to comment.	Importance/Relevance: CMS agrees. No change is required. Scientific Acceptability: CMS appreciates the comment. No change is required. Feasibility: CMS appreciates the comment. No change is required. General: No change is required.
2.	08/27/2013	Michael Higgins	Research	Individual	Importance/Relevance: While important, how well can this data be bridged to historical data? Scientific Acceptability: No comment Feasibility: No comment General: No comment	Importance/Relevance: The link to historical data would be institution specific prior to measure implementation. No change is required. Scientific Acceptability: No change is required. Feasibility: No change is required. General: No change is required.
3.	08/27/2013	Therese Staublin, PharmD; Medication Safety Coordinator; Personal	Provider Organization (e.g., hospital, nursing home, home	Individual	Importance/Relevance: No comment Scientific Acceptability:	Importance/Relevance: No change is required. Scientific Acceptability:

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
			health agency, ambulatory care center)		No comment Feasibility: hyperglycemia should be defined in order to standardize rather than allow institutions to define for themselves. Standards should be different for neonates and perhaps for pediatrics. Or these groups should be excluded. General: No comment	No change is required. Feasibility: Hyperglycemia is defined in the measure specifications. The measure only includes adult patients age 18 years and older. No change is required. General: No change is required.
4.	08/27/2013	Therese Franco, MD; Hospitalist; Virginia Mason Medical Center	Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Individual	Importance/Relevance: There is most certainly value in the outcome oriented metrics (i.e. blood glucose values). While it is some "bottom line" reflection of the care, hyper and hypoglycemia can also occur for physiologic reasons, so there is a certain appeal to a more process oriented metric and one with more longevity. Hyperglycemia in the hospital is a marker of poor health, certainly acutely, but also, presumably, chronically. Consider previous examples of clinical associations with poor outcomes where outcomes did not improve with treatment of those indices. Specifically, recall that patients who found to be anemic on presentation for myocardial infarction did not have better outcomes with transfusions. Another example that comes to mind is treatment of hyperhomocysteinemia with supplemental folate, which did not improve vascular disease outcomes. While there is strong evidence for association between hyperglycemia and poor outcomes, the causality remains less clear. Scientific Acceptability: The technical details of exactly how these rates are measured warrant close scrutiny. Consider the hyperglycemic patient. For example, a patient with DKA typically has blood glucose values checked hourly while on an infusion. This may artificially increase the rate of hyperglycemia. It seems that day weighted measures (example: number of hyperglycemic patient-days), are potentially more clinically appropriate than true rates. Feasibility:	Importance/Relevance: No change is required. Scientific Acceptability: Please note that patients with DKA are excluded from measurement. The measure is calculating hyperglycemia as the sum of the percentage of hospital days in hyperglycemia for each admission in the denominator. No change is required. Feasibility:

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
					Blood glucose is a readily available measure that is known to be associated with poor outcomes, while the latter two measures I mentioned (process and longer term) are significantly more complex and difficult to obtain. General: We need provider (all disciplines MD, PA, RN, RD) engagement so that providers will pursue appropriate evidence based therapies because they believe it is the right thing to do, not because they are trying to meet a specific glycemic cut point. This is an exciting time to be a part of medicine, and these early metrics will be a formative experience for clinicians as we move forward in the era of value-based purchasing. We want the experience to be a positive one, one in which providers and patients can achieve the metrics and experience continuous improvement firsthand.	CMS agrees with the commenter. No change is required. General: No change is required.
5.	08/27/2013	Melissa A. Marshall, PharmD, BCPS; Clinical Coordinator Diabetes Care; University of Miami Hospital	Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Individual	Importance/Relevance: Will CMS be providing Benchmarks for these Glucometrics? Do you recommend any specific programs for tracking these #'s? Scientific Acceptability: How will the #'s be rated as acceptable or unacceptable. We need national benchmarks. Feasibility: In order to derive this data, typically requires a website to upload de-identified patient glucose data. I found a free university-based site that offers this service called Glucometrics. Is this acceptable? General: No comment	Importance/Relevance: CMS has not determined the actual benchmarks at this point in the measure development process. CMS plans to examine the state and national rates and will propose benchmarks in the future. No change is required. Scientific Acceptability: Please see above. No change is required. Feasibility: Should CMS select the measure for a reporting program, the specific protocol for transmitting data will be specified at that time. No change is required. General: No change is required.
6.	08/28/2013	Tara Higgins, RPh; Program Coordinator; Healthcentric Advisors	Medicare Quality Improvement Organization	Organizational	Importance/Relevance: The importance is greatest for those patients that are critically ill. It is also clinically important for patients with wounds and for	Importance/Relevance: No change is required.

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
			(QIO)		healing of wounds. Scientific Acceptability: The measure needs to include what the definition is of hyperglycemia which based on the literature support should be greater than 180 dL/mg however, the data is strongest in critically ill patients. The measure could be restricted to ICU patients only to focus on the strongest evidence. Feasibility: Consider excluding patients with only one blood glucose result. Include only patients with more than one blood glucose result. General: Hyperglycemia is not commonly an adverse drug event except in the presence of use of steroids, oral or IV, and is more commonly due to the patient's self-care of their diabetes or due to the stress of the hospitalization. Hypoglycemia is more commonly a ADE.	Scientific Acceptability: The measure specifications include the definition of hyperglycemia, which is >200 mg/dL, since that was the highest threshold recommended by the literature and clinical practice guidelines. The measure is stratified by ICU versus non-ICU patients. No change is required. Feasibility: Patients with only one blood glucose result that is considered hyperglycemic are included for measurement, because the expectation is that patients with markedly elevated blood glucose values should be monitored until levels are normoglycemic or when the patient is discharged. No change is required. General: CMS is planning to rename the measures Glycemic Control: Hyperglycemia and Glycemic Control: Hypoglycemia to avoid any concern with classification of ADEs.
7.	08/31/2013	Manny Hernandez, M.Eng.; President; Diabetes Hands Foundation	Other (please specify)	Individual	Importance/Relevance: It is VERY important to measure this. People with diabetes should not run elevated blood sugars unnecessarily. It has been well established through the Diabetes Control and Complications Trial (DCCT) that "keeping blood glucose levels as close to normal as possible slows the onset and progression of the eye, kidney, and nerve damage caused by diabetes." Scientific Acceptability: I am not a scientist. I cannot contribute to this question. Feasibility: It seems to me that this should be doable as a measure of	Importance/Relevance: CMS agrees and appreciates the comments from the patient perspective. No change is required. Scientific Acceptability: Not applicable. Feasibility: No change is required.

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
					quality of care during hospital stays for people with diabetes. General: It has been the experience of large numbers of patients with diabetes in an inpatient setting, that they experience hyperglycemic events during their stay directly in connection with the way in which their insulin (specially fast acting insulins) is dosed while in the hospital, i.e. as part of hospital personnel rounds, instead of directly tied to the patient's meals. As a consequence, patients tend to run blood sugars well over 200 mg/dL for hours because they tend to receive their insulin shots in a fashion that meets the hospital's rounds format and not the timing required by the diabetic patient's body to ensure tighter glycemic control. To this point, while I am thankful for CMS taking steps to measure hyperglycemic events in an inpatient setting, causal elements should be incorporated into the thinking behind the measure to help avoid unnecessary high blood sugars during hospital stays.	General: No change is required.
8.	09/01/2013	Diana Mercurio, RPh; Clinical Pharmacist/Diabetes Educator; St Joseph Health Care of RI	Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Individual	Importance/Relevance: Hyperglycemia is generally NOT an adverse drug event. Patients often enter the hospital with A1c greater than 8 What correlation between anti diabetic drugs administered and hyperglycemia are you trying to draw? I would hope that ALL patients with elevated blood sugars would be on an anti diabetic medication Scientific Acceptability: Meaningless data How does hyperglycemia correlate with length of stay may be a better measure Feasibility: See above General: See above	Importance/Relevance: CMS is planning to rename the measures Glycemic Control: Hyperglycemia and Glycemic Control: Hypoglycemia to avoid any concern with classification of ADEs. Scientific Acceptability: CMS disagrees. Hospitals will be able to compare their performance to national benchmarks and by improving overall glycemic control will reduce associated outcomes, such as length of stay. No change is required. Feasibility: See above. General: See above.
9.	09/01/2013	Megan Moraska;	Other (please	Organizational	Importance/Relevance:	Importance/Relevance:

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
		Encore Health Resources; Houston, TX	specify)		Measuring hyperglycemia in hospitalized patients is an important measure as described by the references in the Measure Information Form of the study by Furnary et al that found that hyperglycemia in the inpatient setting has been associated with increased hospital mortality and a predictor of complications and serious infections. Scientific Acceptability: Measuring average percentage of hyperglycemic hospital days for the patient population does not feel actionable. A patient with a 2 day length of stay who has a single elevated glucose on admission will have a 50% rate, which will be interpreted as a high rate, but represents only one result. Also the definition is limiting the population to those with a diabetes diagnosis, those receiving antidiabetic medications, or those with at least one elevated glucose; we question why the population is not all inpatients? We would like to understand the rationale to measure this as a percentage vs. measuring hospital days in general? Also, we question having just one elevated glucose qualify a patient? In the study by Umpierrez et al (2002, J Clin Endorcrinol Metab Mar;87;(3):978-82), hyperglycemia was defined as: "admission or in-hospital fasting glucose level of 126 mg/dl or more or a random blood glucose level of 200 mg/dl or more on 2 or more determinations". It is our opinion that to truly measure if a patient had "real" hyperglycemia during this admission, the measure may need to incorporate a comparison to HbA1C levels prior to admission.	CMS agrees. No change is required. Scientific Acceptability: Inclusion of all admissions in the denominator, many of whom are not at risk of developing hyperglycemia, would result in imprecise measure rates and compromise between-hospital comparisons, if the proportion of these admissions varied across institutions. For example, if hospital 1 has 80% admissions who will never develop hyperglycemia, but hospital 2 has 40%, hospital 1 would have better measure rates regardless of hospital 1's ability to appropriately control blood glucose. The definitions of the at-risk population are aimed at capturing every admission at risk for developing hyperglycemia. In order to accurately define the population at risk for developing hyperglycemia, the measure takes a three-pronged approach, including a diagnosis of diabetes mellitus, receipt of anti-hyperglycemic medication, or a single blood glucose >200 mg/dL. All three definitions include an inherent risk for sustained hyperglycemia. The single BG level criterion is included because non-diabetic patients who develop hyperglycemia during admission (e.g., post-surgery or after exposure to large doses of steroids) and whose glucose needs are not addressed would not be captured in the denominator (and thus, numerator). In other words, the measure would incentivize providers to ignore acutely evolving blood glucose management needs. The measure quantifies the percentage of hyperglycemic days, but averages the percentage across patients who are at risk of developing hyperglycemia. The purpose is to express the measure rate on the level of patients and show the proportion of

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
						the hospital days for which a patient may experience prolonged hyperglycemia. Feasibility: The measure has been tested across four EHR systems in nine different hospitals nationally, and testing indicated that the hospitals could electronically extract the variables required for measurement. CMS agrees that specifications will need to be explicit regarding prescription drug nomenclature prior to widespread adoption of RxNorm as a standard. The time related to the lab order is defined as the time that the specimen was collected. CMS recognizes that hospitals that have not yet integrated POC testing will be at risk for inaccurate measure calculation. CMS will clarify the intent with regard to POC testing in the specifications and consider this issue in the design of a validation protocol if the measure is selected for implementation. POC data are required for valid calculation of measure rates. The requirement for procedure start and end times is to harmonize the measure with the existing SCIP Inf-4 measure in the Hospital Inpatient Quality Reporting Program. CMS does not agree that determining glycemic control prior to admission through HbA1c would improve the validity of the measure. If a patient is hyperglycemic during an admission, it is incumbent upon the hospital to manage the hyperglycemia, regardless of whether the patient was hyperglycemic upon admission.
					Feasibility: Measuring directly out of the EHR should avoid the need for manual chart review, however there is a need for manual documentation of a patient's diagnosis for the patients with diabetes to qualify for this measure. Including that as a constraint for inclusion may result in missed patients if facilities are not yet documenting 100% of patient information in the patient record. The data element form allows the definition to be ICD9 or ICD10 as well as SNOMED, which may require an interface to a billing system that includes the final billing codes as well as DRG information. This creates additional complexity to the measure. The definition will need to clearly delineate the specific medications included as "antidiabetic agents" so that it can be translated across all EHRs. In addition, although all EHRs are to use RxNorm, RxNorm includes a number of pharmaceutical terminologies under its umbrella (e.g., NDDF, MultumDrug, etc.), and the definition will need to apply to all pharmaceutical terminologies. Other concerns of feasibility is identification of the specific test result and timing of it, for example is the date/time related to the lab order, collection time, or result time? The EHRs must also include results any point-of-care (POC) glucose tests done at the bedside so that all glucose results are included. For facilities that have EHRs that do not interface this information, the calculation will be dependent upon manual data entry of the POC results into the system, which creates another risk for inaccurate calculation if data was not entered correctly be the end user. It is also unclear why procedure information is part of the data element definition as procedures are not part of the measure, as well as why med admin date/time is needed? As noted in the prior comment, it is our opinion that to truly measure if hyperglycemia is "real" during the current admission, a comparison to HbA1C prior to admission would be required, which introduces a large degree of complexity to obtain outpatient information related to an inpatient stay. In summary, there is complexity to this measure related to dependencies of end user data entry for diagnoses and test results, integration of billing data, suggested integration of outpatient data, as well as the need for specific definitions of	

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
					medications and lab tests, and specific definition of test result timing. General: It is the opinion of this reviewing group that hyperglycemic days is an important quality measure as it can contribute to poor outcomes. However, this group questions the value of measuring percent of patient days for a subset of the inpatient population, as that metric does not seem to be comprehensive. We recommend a definition of hyperglycemia that has been clinically validated in studies vs. a patient having to have only one elevated glucose. We also have concerns about the measure definition and feel the measure is at risk to not reflect what is expected due to the dependencies that will be present with some facilities for manually entered diagnoses and POC glucose results. Lastly, we question the definition of "hyperglycemia" as an adverse drug event, as it can happen de novo to inpatients unrelated medications received.	General: CMS appreciates the detailed comments. Please see comments above and planned actions.
10.	09/03/2013	Bennet Dunlap, MSHC; Diabetes Advocacy; Diabetes Advocates	Consumer Group	Organizational	Importance/Relevance: The Diabetes Advocates, a group of over 100 leading social media advocates for people with diabetes, applauds CMS for developing tools to quantify the burden of hyperglycemia and hypoglycemia in older Americans. We live with and appreciate the struggle of blood sugar variations. Understanding hyperglycemia and hypoglycemia is critical to effective diabetes care. Over twenty five million American have been diagnosed with diabetes. Significantly more are undiagnosed or have pre diabetes. High and low blood sugars are important not only in the clinical setting of the hospital but as reasons for admission, particularly through costly emergency care processes. It has been the experience of our advocates, as patients with diabetes in an inpatient setting, that hyperglycemic events during a hospital stay are often directly connected with the way in which insulin (specially fast acting insulins) is dosed while in the hospital, i.e. as part of hospital personnel rounds, instead of directly tied to the patient's meals and correction bolus needs. As a consequence, patients tend to run blood sugars well over 200 mg/dL for hours because they receive their insulin shots in a fashion that meets the hospital's rounds format and not the timing required by the diabetic patient's body to ensure tighter glycemic control. Budnitz et al in the New England Journal of	Importance/Relevance: CMS appreciates the comment regarding the measure importance. We are aware that another measure developer is currently working on a measure concept related to emergency department visits and hospital admissions for hypoglycemia. No change is required.

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
					Medicine Nov 2011, show that ADRs for hypoglycemia related to outpatient use of insulin as part of a diabetes regime is a significant cause for emergency room admissions for older Americans. This suggests that in addition to quantifying hypoglycemia in the hospital setting, CMS should identify more clearly hypoglycemia as a cause of preventable, costly hospital admission. Schnell at all in the Journal of Diabetes Science and Technology July 2013 conclude that, "Potential cost savings and clinical effects due to higher accuracy of BG meters should provide an impetus to implementation of tighter accuracy standards and development of glucose meters that provide highest possible accuracy." According to the U.S. Department of Health and Human Services' Medical Expenditure Panel Survey (MEPS), in 2012, the average/mean cost for an Emergency Room (ER) visit was $1,318 and in 2009, and the median cost was $615. In other words, we may have saved a little bit on the cost of blood glucose testing supplies up-front, but a few ER visits due to mistaken medication dosages are likely to erase those savings very quickly Amiel et all in Diabetic Medicine write, "The primary cause of hypoglycaemia in Type 2 diabetes is diabetes medication." they go on to observe that "Hypoglycaemia and fear of hypoglycaemia limit the ability of current diabetes medications to achieve and maintain optimal levels of glycaemic control." Medications and devices that lessen the risk of hypoglycemia will reduce costs and increase adherence to care plans to optimize glycemic control. CMS and the Technical Expert Panel should create measures that not only quantify the percentage of hypoglycemic inpatient events experienced by people with type 2 diabetes, but also facilitate the identification of causes of hypoglycemia in diabetes self care. Diabetes is primarily self managed by patients based on instructions from their health team in the outpatient environment. CMS should seek means to quantify hypoglycemia as a source of preventable hospitalization. Daniel S. Budnitz, M.D., M.P.H., Maribeth C. Lovegrove, M.P.H., Nadine Shehab, Pharm.D., M.P.H., and Chesley L. Richards, M.D., M.P.H. Emergency Hospitalizations for Adverse Drug Events in Older Americans N Engl J Med 2011; 365:2002-2012 November 24, 2011 DOI: 10.1056/NEJMsa1103053 Schnell O, Erbach M, Wintergerst E. Higher accuracy of self-monitoring of blood glucose in insulin-treated patients in Germany: clinical and	

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
					economical aspects. J Diabetes Sci Technol. 2013 Jul 1;7(4):904-12. S A Amiel, T Dixon, R Mann, and K Jameson Hypoglycaemia in Type 2 diabetes Diabet Med. 2008 March 1; 25(3): 245–254. doi: 10.1111/j.1464-5491.2007.02341. Scientific Acceptability: No comment. Feasibility: No comment. General: No comment.	Scientific Acceptability: No change is required. Feasibility: No change is required. General: No change is required.
11.	09/03/2013			Individual	Importance/Relevance: Important Scientific Acceptability: Acceptable Feasibility: Technically, the numerator and denominator statements are complex. Are we confident that this data can be pulled from EHRs with a minimum of manual processing on the part of hospitals?	Importance/Relevance: CMS appreciates the comment and agrees that the measure is important. No change is required. Scientific Acceptability: CMS appreciates the comment. No change is required. Feasibility: CMS recognizes that the numerator and denominator are complex. However, we are confident from the results of our field testing that hospitals will be able to fully automate the calculation of the measures. In addition, the measure, as specified, attempts to achieve a reasonable balance between validity and feasibility.

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
					General: No comment	General: No change is required.
12.	09/06/2013	Cynthia Reeves; PI Director; Platte Valley Medical Center	Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Individual	Importance/Relevance: It is a reasonable measure for non-critical care patients. Scientific Acceptability: There isn't a scientifically based standard for the upper limit of glucose levels which makes this problematic. "Seems like a good idea" is not strong evidence in which to penalize hospitals through value based purchasing or other financial incentives or penalties. Feasibility: Electronic abstraction will be needed and would be challenging for hospitals not meeting Meaningful Use Stage II, or if they do not have point of care devices integrated. General: It is an important patient population to positively impact.	Importance/Relevance: CMS agrees. No change is required. Scientific Acceptability: A threshold of >200 mg/dL is the highest threshold recommended by the literature and clinical practice guidelines. No change is required. Feasibility: We are confident from the results of our field testing that hospitals will be able to fully automate the calculation of the measures, if they have an electronic health record system. All required variables were found in discrete variable fields from our field testing hospitals. In addition, the measure, as specified, attempts to achieve a reasonable balance between validity and feasibility. No change is required. General: CMS agrees. No change is required.
13.	09/06/2013	Shekhar Mehta, PharmD Director; Clinical Guidelines and Quality Improvement; American Society of Health-System Pharmacists	Health Professional Organization	Organizational	Importance/Relevance: Very important and valuable in terms of assessing the status of medication related harm. Scientific Acceptability: Will help elucidate the root cause of potential systemic errors that can have a great impact on safety in the health-system, Provided data is supportive that use of this measure will enhance patient safety and ensure appropriate medication use	Importance/Relevance: CMS agrees. No change is required. Scientific Acceptability: CMS agrees. No change is required.

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
					and glycemic control in health-systems Feasibility: The required data may be difficult to obtain depending on level and use of certified EHR technology and necessity of hand abstraction from paper charts General: Key issue is the selection of a specific threshold value for hyperglycemia, that may omit capture of symptomatic patients. Also the timing of blood glucose measurements in relation to meals is important and additional details in the measure specifications should be included to make the abstraction of data very clear.	Feasibility: We are confident from the results of our field testing that hospitals will be able to fully automate the calculation of the measures, if they have an electronic health record system. All required variables were found in discrete variable fields from our field testing hospitals. In addition, the measure, as specified, attempts to achieve a reasonable balance between validity and feasibility. No change is required. General: The clinical significance of hyperglycemia (in the inpatient and outpatient environment) is not measured by symptoms, but rather by its association with morbidity and mortality. Evidence suggests that blood glucose >200 mg/dL is associated with increased morbidity and mortality, and guidelines agree that such values should be avoided. Furthermore, evidence suggests that lower blood glucose values are feasible without compromising safety. To our knowledge, no study that has evaluated the relationship between hyperglycemia and morbidity or mortality has considered meals in identifying patients.
14.	09/06/2013 (Comment Letter)	Shekhar Mehta, PharmD, MS; Director; Clinical Guidelines and Quality Improvement and Joshua J. Neumiller, PharmD, CDE, FASCP; Assistant Professor Department of Pharmacotherapy; College of Pharmacy;	Health Professional Organization	Organizational	Re: Comments on proposed glycemic adverse drug event quality measures Thank you on behalf of the American Society of Health-System Pharmacists (ASHP) for the opportunity to review draft quality measures in development by FMQAI. ASHP is the national professional organization whose nearly 40,000 members include pharmacists, pharmacy technicians, and pharmacy students who provide patient care services in hospitals, health systems, and ambulatory clinics. For 70 years, the Society has been on the forefront of efforts to improve medication use and enhance patient safety.	CMS appreciates the comments from ASHP. Please see the responses above.

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
		Washington State University; Spokane, WA Mary Sue McAslan, PharmD; Formulary Manager; Veterans Administration-Eastern Colorado Health Care System; Denver, CO Daniel Kent, B.S. Pharm, CDE; Clinical Specialist Diabetes/HIV; Center for Health Studies; Group Health Cooperative; Seattle, WA			ASHP can offer unique and vital assistance in efforts to improve the quality of patient care. The Society strongly believes that aligning efforts of stakeholders involved in healthcare delivery and focusing on high-leverage areas will vastly accelerate improvements in the healthcare quality. According to the Agency of Healthcare Research and Quality (AHRQ) fifty percent of patients aged 65 years and older take more than 5 medications with an ambulatory adverse drug event rate of 50.1 per 1,000 patient-years. Each event can add $1300.00 to healthcare expenditures.[1] In general, the Society supports the concept of using measures to assess the extent of medication related harm. However, ASHP believes the number and severity of adverse drug reactions at an institution is not predictable and is highly dependent on the size and type of the institution, patient case mix, and drugs used. ASHP believes that understanding the root cause of adverse events that may have resulted from a systemic process can have a great impact on improving safety in health-systems. The Society advocates for statutory protection in medication error reporting by health-care professionals (Policy 011), and also advocates for a just culture in medication error reporting (Policy 1021). The Society provides recommendations for the role of the medication safety leader, which includes use of process improvement methodology such as Kaizen and Failure Mode and Effects Analysis (FMEA). The organization also provides recommendations to maximize the role of the medication safety leader, as well as, guidelines on adverse drug reaction monitoring and reporting. [2,3] The Society also believes that the required data may be difficult to obtain depending on the level of implementation of certified electronic health record (EHR) system technology or whether the data had to be manually abstracted from paper charts. Availability of real-time actionable information is preferred so that medical harm can be prevented. The Society advocates for systems with efficient and rapid bidirectional flow of communication among patients and various providers. The Society would like to offer the following specific comments	

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
					and recommendations on the measures listed below: 1. CMS #701a – Adverse Drug Events: Hyperglycemia Description: Average percentage of hyperglycemic hospital days for individuals with a diagnosis of diabetes mellitus, anti-diabetic drugs (except metformin) administered, or at least one elevated glucose level during the hospital stay Comments: An important and key issue for the documentation of glycemic events during hospitalization is the specific thresholds chosen to define hyperglycemia and hypoglycemia. The timing of blood glucose measurements in relation to meals is also very important if postprandial glucose levels are to be included. Postprandial measurements should be taken at least 2 hours after finishing a meal. Additional clarity is needed in the description of CMS # to prevent liberal interpretation in documenting appropriate data. 2. CMS #701b – Adverse Drug Events: Hypoglycemia Description: The rate of hypoglycemic events following the administration of an anti-diabetic agent Comments: Again, it would be important to understand the specific threshold being used for this measure. Many clinical studies often define hypoglycemic events variably. A threshold of less than 70mg/dL should be used. The Society cautions against the use of a very low threshold such as 40mg/dL because such a low threshold could artificially lower capture rates and omit symptomatic patients. The choice of threshold may impact an institutions decision of monitoring blood glucose levels. Further, is the definition of hypoglycemia limited to biochemically confirmed hypoglycemic events or would these events be inclusive of symptomatic, nonconfirmed hypoglycemia? The Society would like to thank the following individuals for their contributions to these comments: • Joshua J. Neumiller, Pharm.D.CDE,FASCP, Assistant Professor Department of Pharmacotherapy	

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
					College of Pharmacy Washington State University Spokane, WA • Mary Sue McAslan, Pharm.D. Formulary Manager Veterans Administration-Eastern Colorado Health Care System Denver, CO • Daniel Kent, B.S. Pharm, CDE Clinical Specialist Diabetes/HIV Center for Health Studies Group Health Cooperative Seattle, WA ASHP is pleased to be part of transformational change in healthcare delivery and we look forward to ongoing participation in activities that support the goals of the National Quality Strategy and CMS. If you have any questions concerning the Society's comments, please contact Shekhar Mehta by phone at (301) 664-8815 or via e-mail at smehta@ashp.org. Regards Shekhar Mehta, Pharm.D., M.S. Director, Clinical Guidelines and Quality Improvement [1] Masica A, Touchette D. Evaluation of a Medication Therapy Management Program in Medicare Beneficiaries at High Risk of Adverse Drug Events: Study Methods. Pharmaceutical Outcomes Research Program: AHRQ. [2] American Society of Health-System Pharmacists. ASHP guidelines on adverse drug reaction monitoring and reporting. Am J Health-Syst Pharm.1995; 52:417–9 [3] American Society of Health-System Pharmacists. ASHP statement on the role of the medication safety leader. Best Practices of Hospitals and Health-System Pharmacies, 2012-2013. In press.  ASHP glycemic ADE measure comments C	

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
15.	09/06/2013	Stephanie Heckman, MSN, RN, ACNS-BC, CMSRN; Clinical Nurse Specialist; Franciscan St. Francis Health	Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Individual	Importance/Relevance: Although I find the proposed measure relevant the numerator and denominator are not true measures of a facilities practice related to managment of hyperglycemia. Scientific Acceptability: Looking at one episode of hyperglycemia is not reflective of good glycemic management practices, as many situations can impact blood glucose levels (i.e. steroid use, initiation of oral, enteral or parental nutrition, stopping or decreasing medication therapy prior to a procedure, etc...) therefore hyperglycemia should be trended over a period of time versus one event. Feasibility: Again looking at one hyperglycemic event any time during the hospital stay is not reflective of appropriate glycemic management. For instance patients that present with DKA and/ or HHS will have blood glucose levels above 200 mg/dL for a period of time until the DKA is resolved. This does not indicate poor management, rather the 'normal' resolution of DKA. General: Persistant hyperglycemia should be trended versus one point in time.	Importance/Relevance: CMS agrees that the measure is important, but we disagree that the measure would not reflect the management of hyperglycemia at an institution. Scientific Acceptability: The measure, as specified, will not quantify hyperglycemia based on one event. Hyperglycemia is measured over the course of the first 10 days of hospital admission and is averaged across all patients. No change is required. Feasibility: Please see above. In addition, patients with DKA and HHS are excluded. No change is required. General: Please see above. No change is required

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
16.	09/08/2013		Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Individual	Importance/Relevance: It is timely- and much needed. Most providers and nurses lack the knowledge of best practice related to diabetes management. I have been working with a couple of other colleagues who are experts in diabetes management- and we see daily- and I stress DAILY- the lack of knowledge of ordering providers, nurses and pharmacists to provide safe care related to anti-hyperglycemic agents in the hospital setting. It is an organizational problem that needs better management, and although the hypoglycemic rates at our organization are lower than many others, the hyperglycemic rates are too high- often because of fear of a hypoglycemic event- but often because of inappropriate dosing and adjustments, inappropriate medication ordered, and sometimes this results in a patient experiencing DKA because of this. When it happens to even one patient due to the lack of knowledge and best practice management- it is happening too often. Definitely support this as extremely important and it is long overdue, Scientific Acceptability: No concerns- accept as proposed. Feasibility: What healthcare consumers are currently spending due to errors and mismanagement of anti-hyperglycemic agents in the hospital setting, feasibility should not be an issue. Most healthcare organizations would recognize cost savings through reduced resource utilization that occurs with the current mismanagement. The longer lengths of stays and complications, the resources expended to correct a hyperglycemic event (or DKA) or an overcorrection resulting in a hypoglycemic event, and the value of a human life should far exceed what the costs will be to the organizations- it is one more core measure that can and should be supported! General: Long overdue- implement and be prepared to accept comments, criticisms and adjustments over time. To me and to my colleagues looking at these adverse drug events over the past two years in just one organization- this is exactly what is needed to protect our patients. Healthcare is incapable of making the	Importance/Relevance: CMS agrees that this is an important measure. No change is required. Scientific Acceptability: No change is required. Feasibility: CMS agrees. No change is required. General: CMS agrees. No change is required.

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
					corrections needed in the time needed. Support this fully and completely.	
17.	09/25/2013	Kevin Larsen, MD, FACP; Medical Director Meaningful Use; Office of the National Coordinator for Health Information Technology; U.S. Department of Health & Human Services	Public/Community Health Agency	Individual	General: I support both the inpatient hyperglycemia and inpatient hypoglycemia measures.	General: CMS appreciates the comment. No change is required.

*Comments appear verbatim and have not been edited for spelling, punctuation, grammar, etc.

Appendix C: Verbatim Public Comments for Measure 701b – ADE: Hypoglycemia

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
1.	08/26/2013 (via e-mail)	Charlene Avery, MD; Director; Office of Clinical & Preventive Services; Health and Human Services; Indian Health Service	Health Plan/Payer Organization	Organizational	Importance/Relevance: Hello, thank you for the opportunity to comment. The detailed information was very helpful. The importance and relevance of minimizing the potential for adverse consequences related to poor glucose control whether hyper- or hypoglycemia cannot be overemphasized. Scientific Acceptability The references and identification of quality of evidence were helpful to support the scientific acceptability of the proposed measures Feasibility: The feasibility seems well examined (very tedious but do-able). General: For general comments, I concur. Thank you again for the opportunity to comment.	Importance/Relevance: CMS agrees. No change is required. Scientific Acceptability: CMS appreciates the comment. No change is required. Feasibility: CMS appreciates the comment. No change is required. General: No change is required.
2.	08/27/2013	Michael Higgins	Research	Individual	Importance/Relevance: Same question as for the hyper, which is how well can this data be bridged to historical data? Scientific Acceptability: No comment Feasibility: No comment General: No comment	Importance/Relevance: The link to historical data would be institution specific prior to measure implementation. No change is required. Scientific Acceptability: No change is required. Feasibility: No change is required. General: No change is required

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
3.	08/27/2013	Therese Staublin, PharmD; Medication Safety Coordinator; Personal	Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Individual	Importance/Relevance: No comment Scientific Acceptability: No comment Feasibility: hypoglycemia should be defined in order to standardize rather than allow institutions to define for themselves. Standards should be different for neonates and perhaps for pediatrics. Or these groups should be excluded. General: No comment	Importance/Relevance: No change is required. Scientific Acceptability: No change is required. Feasibility: Per the measure specifications, hypoglycemia is defined as blood glucose <40 mg/dL. The measure only includes adult patients age 18 years and older. No change is required. General: No change is required.
4.	08/27/2013	Therese Franco, MD; Hospitalist; Virginia Mason Medical Center	Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Individual	Importance/Relevance: Hypoglycemia is immediately threatening to life and health, therefore critically important to track. It will be come even more important to track once providers start to pursue more aggressive care of hyperglycemic patients in the hospital. Scientific Acceptability: The technical details of exactly how these rates are measured warrant close scrutiny. In particular, consider the rate of hypoglycemia metric. Is this a rate of blood glucose values throughout the hospital on any given day/week/month? Most institutions have a hypoglycemia protocol that requires repeating the blood glucose checks on a hypoglycemic patient until the value has normalized. This increased number of blood glucose checks at low values would artificially increase the rate of hypoglycemia. A day weighted measure (example: number of patient days with hypoglycemia) will increase the complexity of the measure, but is potentially a more accurate reflection of the quality of care. Feasibility: Blood glucose values are a readily available measure that	Importance/Relevance: CMS agrees. No change is required. Scientific Acceptability: The measure only considers hypoglycemic events that occur 20 hours apart to avoid repeated detection of the same event. In addition, the measure uses hospital days in its denominator to account for varying times at risk. Feasibility: CMS proposes that the intent of the measures as defined is

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
					is important to track. It would be most informative to track the rates or patient days with hypoglyemic events relative to the rates or patient days with hyperglycemia so that we can ensure providers are not improving hyperglycemia with the expense of hypoglycemia. General: We need provider (all disciplines MD, PA, RN, RD) engagement so that providers will pursue appropriate evidence based therapies because they believe it is the right thing to do, not because they are trying to meet a specific glycemic cut point. This is an exciting time to be a part of medicine, and these early metrics will be a formative experience for clinicians as we move forward in the era of value-based purchasing. We want the experience to be a positive one, one in which providers and patients can achieve the metrics and experience continuous improvement firsthand.	to balance any unintended consequences. The hyperglycemia measure has essentially the same denominator as the hypoglycemia measure under the assumption that the risk for hyperglycemia is independent from the number of days that are included in the measure. The hyperglycemia measure is summarized on the level of individual admissions (and then averaged) for ease of interpretation. Because the incidence of hypoglycemia is so rare, the same patient-level summary is not appropriate for the hypoglycemia measure. It should also be noted that rates are very different and would be difficult to compare either way. General: CMS appreciates the comment.
5.	08/27/2013	Melissa A. Marshall, PharmD, BCPS; Clinical Coordinator; Diabetes Care; University of Miami Hospital	Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Individual	Importance/Relevance: I think it is relevant to provide national benchmarks and to decrease hypoglycemic events to the least possible in order to reduce morbidity, mortalility and length of stay.	Importance/Relevance: No change is required.

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
					Scientific Acceptability: I think you should have 2 cut-offs. Less than 70 mg/dL (mild) and also less than 40 mg/dL which is considered severe hypoglycemia. Either way between 70 and 40mg/dL there is a large gap and adrenergic and neuroglycopenic are already taking place by that point. It is important to track the more mild events too because really at blood glucose of 100 mg/dL, insulin doses should be decreased to avoid the big drops. Feasibility: You should create a tutorial for how to derive glucometrics per patient days and give benchmarks. General: No comment	Scientific Acceptability: CMS appreciates the comment. CMS suggests that currently there is limited evidence that mild hypoglycemia (blood glucose <70 mg/dL) is preventable. However, clinical experts agree that the majority of hypoglycemic events with blood glucose <40 mg/dL are preventable. Therefore, the publicly reported measure will be limited to the most severe events with blood glucose <40 mg/dL. However, for internal quality improvement, we will include an alternative numerator for reporting mild hypoglycemic events (BG 41-69 mg/dL). Feasibility: Prior to any implementation of the measures, explicit specifications will be provided. No change is required. General: No change is required.
6.	08/28/2013	Tara Higgins, RPh; Program Coordinator; Healthcentric Advisors	Medicare Quality Improvement Organization (QIO)	Organizational	Importance/Relevance: The measure will under report hypoglycemic rates as currently defined due to the extreme low blood sugar reading and that if the patient responses to correction of the hypoglycemia, the patient is not counted in the measure. Scientific Acceptability: Less than 40 mg/dL seems very low for the definition of hypoglycemia. In clinical practice less than 70 mg/dL is commonly used. Also, the measure excludes patients with a second value greater than or equal to 80 mg/dL in 5 minutes. The fact that there was a hypoglycemic ADE event and it was treated and the patient responded does not address the need for prevention of the hypoglycemic event.	Importance/Relevance: CMS appreciates the comment. CMS suggests that currently there is limited evidence that mild hypoglycemia (blood glucose <70 mg/dL) is preventable. However, clinical experts agree that the majority of hypoglycemic events with blood glucose <40 mg/dL are preventable. Therefore, the publicly reported measure will be limited to the most severe events with blood glucose <40 mg/dL. However, for internal quality improvement, we will include an alternative numerator for reporting mild hypoglycemic events (BG 41-69 mg/dL). Scientific Acceptability: Please see the response above.

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
					Feasibility: Easier to calculate and report when based on the single hypoglycemic value versus looking for a second value and what the number is to consider if the patient is included in the measure or excluded. General: Why is the hypoglycemia and hyperglycemia rates calculated differently? Seems that the description, numerator and denominator should be the same for both measures. May want to consider including emergency department admissions that result in inpatient admissions in this measure. The goal being to keep patients from having hypoglycemic adverse drug events that result in admissions. Opportunity in the hospital to adjust treatments and education patient to reduce future admissions.	Feasibility: Repeat measurement is used to exclude false positives and was empirically derived. General: CMS proposes the intent of the measures, as defined, is to balance any unintended consequences. The measures differ in specification to allow for the most valid approach of measuring two very different types of events. CMS agrees that inpatient admissions via the emergency department are important to measure. We are aware that another measure developer is currently working on a measure concept related to emergency department visits and hospital admissions for hypoglycemia.
7.	08/30/2013	Christine S Spencer, RN; Surgical Clinical Reviewer; Lawrence + Memorial Hospital	Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Organizational	Importance/Relevance: will review and advise Scientific Acceptability: will review and advise Feasibility: will review and advise General: will review and advise	Importance/Relevance: No change is required. Scientific Acceptability: No change is required. Feasibility: No change is required. General: No change is required.

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
8.	08/31/2013	Manny Hernandez, M.Eng.; President; Diabetes Hands Foundation	Other (please specify)	Individual	Importance/Relevance: It is VERY important to measure this. People with diabetes should not run elevated blood sugars unnecessarily. It has been well established through the Diabetes Control and Complications Trial (DCCT) that "keeping blood glucose levels as close to normal as possible slows the onset and progression of the eye, kidney, and nerve damage caused by diabetes." Additionally, hypoglycemic episodes can lead to dangerous states in the short term that can result more costly to the system as a whole, putting the person at terrible risks. Scientific Acceptability: I am not a scientist. I cannot contribute to this question. Feasibility: It seems to me that this should be doable as a measure of quality of care during hospital stays for people with diabetes. General: As a patient advocate and a person with diabetes myself, I applaud CMS for developing tools to quantify the burden of hypoglycemia as an adverse drug events on older Americans. Budnitz et al in the New England Journal of Medicine Nov 2011, show that ADRs for hypoglycemia related to outpatient use of insulin as part of a diabetes regime is a significant cause for emergency room admissions for older Americans. This suggests that in addition to quantifying hypoglycemia in the hospital setting, CMS should identify more clearly hypoglycemia as a cause of preventable, costly hospital admission. Schnell at all in the Journal of Diabetes Science and Technology July 2013 conclude that, "Potential cost savings and clinical effects due to higher accuracy of BG meters should provide an impetus to implementation of tighter accuracy standards and development of glucose meters that provide highest possible accuracy." Amiel et all in Diabetic Medicine write, "The primary cause of hypoglycaemia in Type 2 diabetes is diabetes medication." they go on to observe that	Importance/Relevance: CMS appreciates the comment. No change is required. Scientific Acceptability: No change is required. Feasibility: No change is required. General: CMS agrees and appreciates the comments from the patient's perspective. No change is required.

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
					"Hypoglycaemia and fear of hypoglycaemia limit the ability of current diabetes medications to achieve and maintain optimal levels of glycaemic control." Medications and devices that lessen the risk of hypoglycemia will reduce costs and increase adherence to care plans to optimize glycemic control. CMS and the Technical Expert Panel should create measures that not only quantify the percentage of hypoglycemic inpatient events experienced by people with type 2 diabetes, but also facilitate the identification of causes of hypoglycemia in diabetes self care. Diabetes is primarily self managed by patients based on instructions from their health team in the outpatient environment. CMS should seek means to quantify hypoglycemia as a source of preventable hospitalization.	
9.	09/01/2013	Diana Mercurio, RPh; Clinical Pharmacist/ Diabetes Educator; St Joseph Health Care of RI	Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Individual	Importance/Relevance: Rapid acting insulin lasts only 6 hours Blood glucose doesn't go from 40 to 80 in 5 min Minimum retest time is 15 min (JC requires retest within 30 min) I do not see this as providing any usable data Scientific Acceptability: No comment Feasibility: Not a feasible study based on comments in number 13 General: No comment	Importance/Relevance: The intent of the measure specification regarding the re-measurement of glucose in 5 minutes is to reduce the incidence of false positive hypoglycemic events. No change is required. Scientific Acceptability: No change is required. Feasibility: No change is required. General: No change is required.
10.	09/01/2013	Megan Moraska; Encore Health Resources; Houston, TX	Other (please specify)	Organizational	Importance/Relevance: We believe there is great value in the measurement of hypoglycemia as an adverse drug event. Hypoglycemia following insulin administration is mentioned in Rozich's article about the IHI trigger tool (Rozich et al, 2003, Qual Saf Health Care 2003;12:194-2000). Also, as the measure information form states, it is the third most frequently occurring adverse drug event and has been associated with negative outcomes.	Importance/Relevance: CMS agrees. No change is required.

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					Scientific Acceptability: The numerator and denominator statements are very clear as to the parameters of the measure with specific result values, and timing constraints of the result to the administration of the drug. We appreciate the check-and-balance that an event will only qualify as hypoglycemia if the hypoglycemia glucose result is not followed by another glucose value greater than 80 mg/dL within 5 minutes, and was at least 20 hours after the last hypoglycemia event. However, the metric definition seems to have two measures in one: Hypoglycemia after short-acting insulin (where the hypoglycemic event occurs within 12 hours of insulin administration) and hypoglycemia after non-insulin antidiabetic agents (where the hypoglycemic event occurs within 24 hours of the administration of the anti-diabetic agent). Feasibility: The definition will need to clearly delineate the specific medications included as "antidiabetic agents" so that it can be translated across all EHRs. In addition, although all EHRs are to use RxNorm, RxNorm includes a number of pharmaceutical terminologies under its umbrella (e.g., NDDF, MultumDrug, etc.), and the definition will need to apply to all pharmaceutical terminologies. Other concerns of feasibility is identification of the specific test result and timing of it, for example is the date/time related to the lab order, collection time, or result time? The EHRs must also include results any point-of-care glucose tests done at the bedside so that all glucose results are included. For facilities that have EHRs that do not interface this information, the calculation will be dependent upon manual data entry of the POC results into the system, which creates a risk for inaccurate calculation if data was not entered correctly by the end user. We feel that combining the different timings of hypoglycemia for insulin (event is within 12 hours of administration) and non-insulin anti-diabetic agents (event is within 24 hours) introduces unnecessary complexity, and that NQF should consider separating these metrics into two separate measures and re-evaluate combining them once results are available.	Scientific Acceptability: CMS appreciates the comment. It will be clarified in the specifications that the 24-hour follow-up includes all anti-diabetic agents, except short-acting/rapid-acting insulin, for which 12 hours is used. CMS will review stratified data with the TEP for insulin versus oral anti-diabetics; however, CMS does not anticipate any changes to the current specification. Feasibility: CMS agrees regarding the specification of anti-diabetic agents, which will be provided in the technical specifications in addition to the Rx Norm specifications. See comment above regarding 12-hour versus 24-hour time frame.

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					General: We feel there is great value in creating an eMeasure for hypoglycemia following insulin and following anti-diabetic agents. The EHR has information available for medication administration and test results, and with specific requirements clarified, we believe this metric would provide value to hospitals that now rely on self-reporting or randomly sampled chart reviews to track these events. There is risk to missing data from manually collected point-of-care glucose tests, which could result in some events not being counted, but we feel that the value of the metric outweighs this risk. All measures will require a period of validation against charted data to ensure calculations are measuring what is expected.	General: CMS agrees and appreciates the comment. No change is required.
11.	09/03/2013	Bennet Dunlap, MSHC; Diabetes Advocacy; Diabetes Advocates	Consumer Group	Organizational	Importance/Relevance: The Diabetes Advocates, a group of over 100 leading social media advocates for people with diabetes, applauds CMS for developing tools to quantify the burden of hyperglycemia and hypoglycemia in older Americans. We live with and appreciate the struggle of blood sugar variations. Understanding hyperglycemia and hypoglycemia is critical to effective diabetes care. Over twenty five million American have been diagnosed with diabetes. Significantly more are undiagnosed or have pre diabetes. High and low blood sugars are important not only in the clinical setting of the hospital but as reasons for admission, particularly through costly emergency care processes. It has been the experience of our advocates, as patients with diabetes in an inpatient setting, that hyperglycemic events during a hospital stay are often directly connected with the way in which insulin (specially fast acting insulins) is dosed while in the hospital, i.e. as part of hospital personnel rounds, instead of directly tied to the patient's meals and correction bolus needs. As a consequence, patients tend to run blood sugars well over 200 mg/dL for hours because they receive their insulin shots in a fashion that meets the hospital's rounds format and not the timing required by the diabetic patient's body to ensure tighter glycemic control. Budnitz et al in the New England Journal of Medicine Nov 2011, show that ADRs for hypoglycemia related to outpatient use of	Importance/Relevance: CMS appreciates the comment regarding measure importance. We will review with the TEP the suggestion to consider developing a measure related to hypoglycemia as a cause of hospital admission. No change is required.

No.	Date Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments*	Recommendations/ Actions Taken/ CMS' Response
					insulin as part of a diabetes regime is a significant cause for emergency room admissions for older Americans. This suggests that in addition to quantifying hypoglycemia in the hospital setting, CMS should identify more clearly hypoglycemia as a cause of preventable, costly hospital admission. Schnell at all in the Journal of Diabetes Science and Technology July 2013 conclude that, "Potential cost savings and clinical effects due to higher accuracy of BG meters should provide an impetus to implementation of tighter accuracy standards and development of glucose meters that provide highest possible accuracy." According to the U.S. Department of Health and Human Services' Medical Expenditure Panel Survey (MEPS), in 2012, the average/mean cost for an Emergency Room (ER) visit was $1,318 and in 2009, and the median cost was $615. In other words, we may have saved a little bit on the cost of blood glucose testing supplies up-front, but a few ER visits due to mistaken medication dosages are likely to erase those savings very quickly. Amiel et all in Diabetic Medicine write, "The primary cause of hypoglycaemia in Type 2 diabetes is diabetes medication." they go on to observe that "Hypoglycaemia and fear of hypoglycaemia limit the ability of current diabetes medications to achieve and maintain optimal levels of glycaemic control." Medications and devices that lessen the risk of hypoglycemia will reduce costs and increase adherence to care plans to optimize glycemic control. CMS and the Technical Expert Panel should create measures that not only quantify the percentage of hypoglycemic inpatient events experienced by people with type 2 diabetes, but also facilitate the identification of causes of hypoglycemia in diabetes self care. Diabetes is primarily self managed by patients based on instructions from their health team in the outpatient environment. CMS should seek means to quantify hypoglycemia as a source of preventable hospitalization. Daniel S. Budnitz, M.D., M.P.H., Maribeth C. Lovegrove, M.P.H., Nadine Shehab, Pharm.D., M.P.H., and Chesley L. Richards, M.D., M.P.H. Emergency Hospitalizations for Adverse Drug Events in Older Americans N Engl J Med 2011; 365:2002-2012 November 24, 2011 DOI: 10.1056/NEJMsa1103053 Schnell O, Erbach M,	

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					Wintergerst E. Higher accuracy of self-monitoring of blood glucose in insulin-treated patients in Germany: clinical and economical aspects. J Diabetes Sci Technol. 2013 Jul 1;7(4):904-12. S A Amiel, T Dixon, R Mann, and K Jameson Hypoglycaemia in Type 2 diabetes Diabet Med. 2008 March 1; 25(3): 245–254. doi: 10.1111/j.1464-5491.2007.02341. Scientific Acceptability: No comment Feasibility: No comment General: No comment	 Scientific Acceptability: No change is required. Feasibility: No change is required. General: No change is required.
12.	09/03/2013			Individual	Importance/Relevance: Important Scientific Acceptability: Acceptable Feasibility: Technically complex measure. Will need to be tested across multiple EHRs to be sure it can be derived with a minimum of manual processing on the part of hospitals. General: No comment	Importance/Relevance: CMS agrees. No change is required. Scientific Acceptability: CMS appreciates the comment. No change is required. Feasibility: The measure has been tested across four EHR systems in nine different hospitals nationally, and testing indicated the measure was feasible. No change is required. General: No change is required.

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13.	09/06/2013	Cynthia Reeves; PI Director; Platte Valley Medical Center	Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Individual	Importance/Relevance: Though significant when it occurs, it is not a common problem, and it is responded to quickly. Scientific Acceptability: There is strong evidence of the critical nature of blood glucose below 40. Feasibility: The feasibility of capturing this data and sorting through it including time of administraiton of medications and glucose readings is limited. This would require a huge time investment for Information Technology departments to develop reporting for electronic systems and would not be possible for paper systems. General: It is not feasible.	Importance/Relevance: Hypoglycemia is one of the most frequently occurring adverse drug events in the inpatient hospital setting. In a recent study of Medicare patients published by the Office of the Inspector General (OIG), adverse drug events represented one-third of all adverse events in hospitals, and hypoglycemia represented the third most common adverse drug event. In addition, hypoglycemia is associated with increased length of stay and in-hospital mortality. [Office of the Inspector General. (2010). *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*. Retrieved December 14, 2011, from http://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf] No change is required. Scientific Acceptability: CMS agrees. No change is required. Feasibility: The measure has been tested across four EHR systems in nine different hospitals nationally, and testing indicated the measure was feasible. No change is required. General: Please see above. No change is required.
14.	09/06/2013	Shekhar Mehta, PharmD; Director; Clinical Guidelines and Quality Improvement; American Society of Health-System Pharmacists	Health Professional Organization	Organizational	Importance/Relevance: Very important and valuable in terms of assessing the status of medication related harm.	Importance/Relevance: CMS agrees. No change is required. .

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					Scientific Acceptability: Will help elucidate the root cause of potential systemic errors that can have a great impact on safety in the health-system. Provided data is supportive that use of this measure will enhance patient safety and ensure appropriate medication use and glycemic control in health-systems. Feasibility: The required data may be difficult to obtain depending on level and use of certified EHR technology and necessity of hand abstraction from paper charts. General: Again the very important issue is the selection of the specific threshold value for hypoglycemia, that may omit capture of symptomatic patients.	Scientific Acceptability: CMS agrees. No change is required. Feasibility: The measure has been tested across four EHR systems in nine different hospitals nationally, and testing indicated the measure was feasible. No change is required. General: CMS selected the most severe cases of hypoglycemia that may result in patient harm and were considered by clinical experts to be preventable to facilitate comparisons between hospitals. We anticipate that quality improvement interventions that result in reduced rates of severe events will also have the potential to reduce less severe hypoglycemic episodes in which the patient is symptomatic

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15.	09/06/2013 (Comment Letter)	Shekhar Mehta, PharmD, MS; Director; Clinical Guidelines and Quality Improvement	Health Professional Organization	Organizational	Re: Comments on proposed glycemic adverse drug event quality measures Thank you on behalf of the American Society of Health-System Pharmacists (ASHP) for the opportunity to review draft quality measures in development by FMQAI. ASHP is the national professional organization whose nearly 40,000 members include pharmacists, pharmacy technicians, and pharmacy students who provide patient care services in hospitals, health systems, and ambulatory clinics. For 70 years, the Society has been on the forefront of efforts to improve medication use and enhance patient safety. ASHP can offer unique and vital assistance in efforts to improve the quality of patient care. The Society strongly believes that aligning efforts of stakeholders involved in healthcare delivery and focusing on high-leverage areas will vastly accelerate improvements in the healthcare quality. According to the Agency of Healthcare Research and Quality (AHRQ) fifty percent of patients aged 65 years and older take more than 5 medications with an ambulatory adverse drug event rate of 50.1 per 1,000 patient-years. Each event can add $1300.00 to healthcare expenditures.[1] In general, the Society supports the concept of using measures to assess the extent of medication related harm. However, ASHP believes the number and severity of adverse drug reactions at an institution is not predictable and is highly dependent on the size and type of the institution, patient case mix, and drugs used. ASHP believes that understanding the root cause of adverse events that may have resulted from a systemic process can have a great impact on improving safety in health-systems. The Society advocates for statutory protection in medication error reporting by health-care professionals (Policy 011), and also advocates for a just culture in medication error reporting (Policy 1021). The Society provides recommendations for the role of the medication safety leader, which includes use of process improvement methodology such as Kaizen and Failure Mode and Effects Analysis (FMEA). The	CMS appreciates the comments from ASHP. Please see responses above.

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					organization also provides recommendations to maximize the role of the medication safety leader, as well as, guidelines on adverse drug reaction monitoring and reporting. [2,3] The Society also believes that the required data may be difficult to obtain depending on the level of implementation of certified electronic health record (EHR) system technology or whether the data had to be manually abstracted from paper charts. Availability of real-time actionable information is preferred so that medical harm can be prevented. The Society advocates for systems with efficient and rapid bidirectional flow of communication among patients and various providers. The Society would like to offer the following specific comments and recommendations on the measures listed below: 1. CMS #701a – Adverse Drug Events: Hyperglycemia Description: Average percentage of hyperglycemic hospital days for individuals with a diagnosis of diabetes mellitus, anti-diabetic drugs (except metformin) administered, or at least one elevated glucose level during the hospital stay Comments: An important and key issue for the documentation of glycemic events during hospitalization is the specific thresholds chosen to define hyperglycemia and hypoglycemia. The timing of blood glucose measurements in relation to meals is also very important if postprandial glucose levels are to be included. Postprandial measurements should be taken at least 2 hours after finishing a meal. Additional clarity is needed in the description of CMS # to prevent liberal interpretation in documenting appropriate data. 2. CMS #701b – Adverse Drug Events: Hypoglycemia Description: The rate of hypoglycemic events following the administration of an anti-diabetic agent Comments: Again, it would be important to understand the specific	

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					threshold being used for this measure. Many clinical studies often define hypoglycemic events variably. A threshold of less than 70mg/dL should be used. The Society cautions against the use of a very low threshold such as 40mg/dL because such a low threshold could artificially lower capture rates and omit symptomatic patients. The choice of threshold may impact an institutions decision of monitoring blood glucose levels. Further, is the definition of hypoglycemia limited to biochemically confirmed hypoglycemic events or would these events be inclusive of symptomatic, nonconfirmed hypoglycemia? The Society would like to thank the following individuals for their contributions to these comments: • Joshua J. Neumiller, Pharm.D.CDE,FASCP, Assistant Professor, Department of Pharmacotherapy, College of Pharmacy, Washington State University Spokane, WA • Mary Sue McAslan, Pharm.D. Formulary Manager, Veterans Administration-Eastern Colorado Health Care System Denver, CO • Daniel Kent, B.S. Pharm, CDE Clinical Specialist Diabetes/HIV, Center for Health Studies, Group Health Cooperative Seattle, WA ASHP is pleased to be part of transformational change in healthcare delivery and we look forward to ongoing participation in activities that support the goals of the National Quality Strategy and CMS. If you have any questions concerning the Society's comments, please contact Shekhar Mehta by phone at (301) 664-8815 or via e-mail at smehta@ashp.org. Regards Shekhar Mehta, Pharm.D., M.S. Director, Clinical Guidelines and Quality Improvement [1] Masica A, Touchette D. Evaluation of a Medication Therapy Management Program in Medicare Beneficiaries at	

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					High Risk of Adverse Drug Events: Study Methods. Pharmaceutical Outcomes Research Program: AHRQ. [2] American Society of Health-System Pharmacists. ASHP guidelines on adverse drug reaction monitoring and reporting. Am J Health-Syst Pharm.1995; 52:417–9 [3] American Society of Health-System Pharmacists. ASHP statement on the role of the medication safety leader. Best Practices of Hospitals and Health-System Pharmacies, 2012-2013. In press.  ASHP glycemic ADE measure comments C	

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16.	09/06/2013	Stephanie Heckman, MSN, RN, ACNS-BC, CMSRN; Clinical Nurse Specialist; Franciscan St. Francis Health	Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Individual	Importance/Relevance: This measure is relevant, however the numerator and denominator are not reflective of appropriate hypoglycemia treatment and/ or prevention. Scientific Acceptability: Looking for a blood glucose value greater than 80 mg/dL within 5 minutes of the preceding value is not reflective of evidence based standards. When treating hypoglycemia the rule of 15 is followed.....give 15 gm of carbohydrates and re-check the blood glucose level in 15 min. Checking in 5 min would not allow for an appropriate response. Additionally if the blood glucose level is < 40 mg/dL it often requires more than one treatment of 15 gms of carbohydrates. Feasibility: This measure is not feasible as written based upon the 5 min re-check alone. General: No comment	Importance/Relevance: Please see response under Scientific Acceptability. Scientific Acceptability: The intent of the measure specification regarding the re-measurement of glucose in 5 minutes is to reduce the incidence of false positive hypoglycemic events. CMS will clarify this intent in the technical specifications. Feasibility: Please see response under Scientific Acceptability. General: No change is required.
17.	09/08/2013		Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Individual	Importance/Relevance: Although somewhat complex for the measurement team- would support this as a step towards better patient safety. Scientific Acceptability: Acceptable. Feasibility: Again, one life is more than worth the cost of implementation. Most organizations are doing some tracking of this already- and most understand they are far from where they need to be. Organizational culture is slow to change in healthcare without a regulatory push. My hat is off to organizations that do this well- but most do not or we would not be talking about these proposals.	Importance/Relevance: CMS appreciates the comment. No change is required. Scientific Acceptability: No change is required. Feasibility: No change is required.

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					General: Long overdue and needed!	General: No change is required.
18.	09/25/2013	Kevin Larsen, MD, FACP; Medical Director; Meaningful Use; Office of the National Coordinator for Health Information Technology; U.S. Department of Health & Human Services	Public/Community Health Agency	Individual	General: I support both the inpatient hyperglycemia and inpatient hypoglycemia measures.	CMS appreciates the comment. No change is required.

*Comments appear verbatim and have not been edited for spelling, punctuation, grammar, etc.