

8.3. Verbatim Public Comments

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
1	6/28/11	COPD Mortality and Readmission	<p>The Consumer-Purchaser Disclosure Project is an initiative that is improving health care quality and affordability by advancing public reporting of provider performance information so it can be used for improvement, consumer choice, and payment. We are a collaboration of over sixty leading national and local employer, consumer, and labor organizations. We appreciate the opportunity to comment on YNHHC/CORE's measures of readmission and mortality following COPD hospitalization. We support CMS' efforts to develop measures of outcomes in this important area of care, and commend YNHHC/CORE's work in creating the cohort definition and exclusions for the proposed measures. However, we want to highlight the conflict between CMS' commitment to develop these measures "for use in national public reporting of hospital quality" (page 10 of the mortality report and page 11 of the readmission report) and the risk adjustment method being applied to the measures, Hierarchical Generalized Linear Modeling (HGLM).</p> <p>By publicly reporting hospital quality, CMS seeks to help consumers, purchasers, and others to make better decisions. However, for the information to be truly useful to these audiences, it must distinguish performance among providers. And as we have commented to CMS and YNHHC/CORE in the past, HGLM can wash away nearly all of the variation observed in the raw data because of the way in which it shrinks performance data towards the mean. The result is that most providers (i.e., individual hospitals) being profiled will be labeled as "average." In the case of the COPD measures, YNHHC/CORE's choice of risk adjustment method reduced variation across hospitals from observed rates of 17.9-25.7% to adjusted rates of 21.3-22.4% for readmissions, and from observed rates of 5.4-11.1% to adjusted rates of 8.0-9.1% for mortality. Regardless of which statistical test is used, the shrinkage in the distribution resulting from this HGLM will not allow for much differentiation of hospital performance, resulting in little or no information for consumers and purchasers (or for the hospitals themselves, for that matter).</p> <p>Consumer-Purchaser Disclosure Project Comments on COPD Readmission and Mortality Measures In the document summarizing the TEP evaluation of the measures, YNHHC/CORE states that HGLM is "consistent with guidance from NQF" (page 10).</p>	Christine Chen, Policy Analyst, Consumer-Purchaser Disclosure Project	CChen@pbgh.org	Private Company

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>However the developer did not raise a higher order question of whether the measure will meet NQF’s evaluation criterion of “usability.” Usability is the “extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and find them useful for decision-making.” In our conversations with other statisticians, we have found that which risk adjustment method is used is a matter of philosophy as there is no consensus about which is the “best.” As a result, we recommend that YNHHS/CORE also apply more traditional logistic regression approaches to their COPD data and share the results with CMS so that the agency can decide which risk adjustment method is best suited to its goal of publicly reporting how well hospitals care for their patients. The agency should be aware that its decision on which risk adjustment method to use impacts the public AND private sector. For example, many in the private sector use the information generated by CMS’ mortality measures because they lack data in this critical area and/or seek to foster standardization of performance information. In the spirit of promoting alignment between public and private sectors, we also encourage CMS to modify the measures to include the under 65 population so that other payers (e.g., Medicaid and commercial payers) can apply these measure to their data. On behalf of consumers and purchasers across the country, thank you for your consideration of our comments. If you have any questions, please don’t hesitate to contact [REDACTED] Deputy Director of the Consumer-Purchaser Disclosure Project.</p>			
2	6/29/11	COPD Mortality and Readmission	<p>The measures and cohorts for inclusion are appropriate. Nice work. I wish to comment on the value of this tool. While it is designed to measure hospital performance for 30 day readmission and 30 day deaths of COPD patients, there is one obvious gap here. No reimbursement is provided to hospitals that implement expensive educational programs that target this population to decrease hospitalizations and death. I would strongly urge CMS to consider providing reimbursement for targeted COPD education for this group of patients. As an example, CMS offers reimbursement for providing diabetes education and asthma education. As a result, several great education programs have been developed to lower health care costs associated in those two disease states. We need more than a tool to measure hospital performance. We need an infrastructure that supports preventative health care. This can be partially accomplished by providing reimbursement for performing COPD education in the acute care setting.</p>	Scott Cerreta, BS, RRT, Director of Education, COPD Foundation	scerreta@copdfoundation.org	Individual

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
3	6/29/11	COPD Readmission	Readmission risk is going to be closely related to the severity of the underlying COPD and the severity of the exacerbation. Risk adjustment will be an important part of a useful measure. GOLD is a well validated measure of underlying COPD severity. I have not seen a good metric that reflects the severity of exacerbation. It can range from URI, to bronchitis, to aspiration, to pneumonia. Associated comorbidity (especially CHF) is a frequent issue. If a readmission metric is going to become publicly reported and will influence hospital reimbursement, risk adjustment needs to be well validated and transparent. In addition, it would be useful to have a consensus on the best practice for COPD exacerbation management. Particularly problematic is appropriate dosing of corticosteroid in exacerbation management: The evidence is all over the place, ranging from initial doses of Prednisone 40 mg daily to Methylprednisolone 125 mg Q 6 Hrs.	John P Woodward, MD, Associate Chief Medical Officer, Jeanes Hospital	jpwoodward@mac.com	Individual
4	6/30/11	COPD Mortality and Readmission	These "30-day, all-cause..." metrics for mortality and readmission, are (like other 30-day, all-cause metrics) so detached from accountability to the inpatient facility as to be worthless. I am a pulmonologist...I admit the COPD patient for his umpteenth exacerbation...tune him up the best I can...he goes home, then 20 days later gets admitted to another hospital for his next exacerbation, and dies. Or he gets hit by a truck, or chokes on Brussel sprouts. How am I, or my hospital, in any way blameworthy? You might argue that such one-off scenarios will occur equally across all reporting facilities/doctors, and in any case be subsumed statistically into the 12-month average; and that careful use of the 95% conf interval will protect against this distortion. I'm not convinced. Choose something else; something that my hospital and I can really impact.	Peter M. Marvin, MD, VP Clinical Quality and Informatics, Baptist Health	Peter.Marvin@baptist-health.org	Individual
5	6/30/11	COPD Readmission	Readmission rate exclusion have to apply to patients who remain noncompliant or continue to smoke despite repeated warnings. Patients have to take some responsibility in their health care, and if they continue to smoke, thus negating all medication effects, physicians cannot be held accountable for their decisions which negatively impact their health.	Richard Harlow	rharlow3@kc.rr.com	Individual

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
6	6/30/11	COPD Mortality and Readmission	<p>On behalf of the American Association for Respiratory Care (AARC), I am responding to the request for comments on two hospital-level quality measures the Centers for Medicare and Medicaid Services (CMS) is proposing to use in future public reporting related to chronic obstructive pulmonary disease (COPD). The AARC is a professional association representing over 52,000 respiratory therapists nationwide who treat patients with COPD, including chronic bronchitis and emphysema, and asthma among other respiratory conditions. The AARC supports the two measures that CMS proposes to use: 30-day all-cause mortality following hospitalization for acute exacerbation of COPD and 30-day all-cause readmission following hospitalization for acute exacerbation of COPD. We particularly concur with the inclusion of diagnosis codes for patients with chronic obstructive asthma (COPD/asthma) in the cohort as recommended by the Technical Expert Panel and the rationale for including these diagnoses. We have no specific comments on the modeling approach and concur with the risk-adjusted measures as well as both the mortality and readmission exclusion criteria. We are pleased that respiratory therapists, including a member of the AARC, were among the Technical Expert Panelists who reviewed and provided feedback on the measures. We know that respiratory therapists can make a difference in the lives of the COPD patients they treat and, because of their expertise, can have a positive impact on patient outcomes. Approximately 70 percent of respiratory therapists nationwide work in the inpatient hospital setting. With the increased emphasis on hospital quality measures, including those COPD patients identified as part of the at-risk population under Medicare’s proposed shared savings program, we are confident that respiratory therapists can be a valuable partner in helping hospitals reduce mortality and readmission rates among the COPD patients identified in the proposed new measures. The impact respiratory therapists can have in reducing hospital readmissions was recently validated in a large one-year disease management study conducted at five VA medical centers and reported last year in the American Journal of Respiratory and Critical Care Medicine. The goal of the study was to determine if a simplified disease management program reduces hospital admissions and emergency department (ED) visits due to COPD. In the study, patients assigned to usual care received a one-page handout containing a summary of the principles of COPD care and the telephone number for the 24-hour VA nursing helpline, a service available to all VA patients.</p>	<p>Anne Marie Hummel Director, Regulatory Affairs American Association for Respiratory Care</p>	<p>ASHummel@aol.com</p>	<p>Medical Professional Association</p>

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>Patients assigned to the disease management arm attended a single 1 to 1-1/2 hour group education session conducted by a respiratory therapist case manager. The education session included general information about COPD, direct observation of inhaler techniques, a review and adjustment of outpatient COPD medications, smoking cessation counseling, recommendations concerning influenza and pneumococcal vaccinations, encouragement of regular exercise and instruction in hand hygiene. After one year, the primary outcome rate of hospitalization and emergency visits for COPD among the disease management patients was 48.4 per 100 patient-years compared to 82.2 per 100 patient-years among the usual care patients, a statistically significant 41% reduction. We believe this is an excellent opportunity for respiratory therapists in particular to address the needs of some of the very sickest COPD patients and educate them about the disease. We appreciate opportunity to comment on these important new outcomes measures.</p>			
7	6/30/11	COPD Mortality and Readmission	<p>The NewYork-Presbyterian Healthcare System's (NYPHS) Respiratory Diseases Council appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed readmission quality outcome measure for patients hospitalized with COPD exacerbation. The NYPHS consists of 23 acute care hospitals throughout the New York, New Jersey and Connecticut tri-state area. Over the past seven years, NYPHS's Respiratory Diseases Council has worked with its pulmonologists to assess and improve the management of COPD exacerbation in their hospitalized patients. Areas of system level focus have included the management of COPD exacerbation during the hospital stay, upon discharge and contributing factors for hospital readmissions. We applaud CMS's efforts to focus on COPD because of its high readmission rates, high morbidity and mortality, high resource use and significant consequences to the patient of poor quality. Our comments to the proposed measure focus on the following points: Cohort for inclusion in the measures We agree with the ICD codes listed in the sample except for ICD-9 code 493.21 Chronic Obstructive Asthma; Asthma with COPD, Chronic Asthma bronchitis, with status asthmaticus. We feel that this may broaden the population to include asthmatic patients rather than true COPD patients. Inclusion/exclusion criteria In addition to the exclusion criteria that are listed, we would strongly suggest that you exclude certain cases/conditions where there is a planned readmission as well as in cases where the readmission is totally unrelated to the index admission such as motor vehicle accidents.</p>	<p>Marcia Brinson MPH, RD Sr. Performance Improvement Specialist NewYork-Presbyterian Healthcare System</p>	<p>mab9108@nyp.org</p>	<p>Healthcare System</p>

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>In either of those situations, the readmission would not reflect the quality of the care or hand-off that the hospital provided. Risk Adjustment Strategy The preliminary COPD risk models indicate that two significant risk factors related to 30-day readmissions are congestive heart failure (odds ratio=1.22) and pneumonia (odds ratio=1.10). Almost half of COPD patients readmitted have one or both comorbid risk factors (43.82% CHF and 51.42% pneumonia). CMS has already developed payment penalties for excess readmissions for both CHF and pneumonia, starting at 1% in FFY2013 and rising to 3% in FFY2015. If a patient with an index admission for COPD is readmitted within 30 days for CHF or pneumonia, will that readmission be treated as an index admission in either the CHF or pneumonia risk model? We urge CMS to clarify its policy such that hospitals are not unfairly penalized multiple times for readmissions that are considered index admissions for a separate clinical condition. NewYork-Presbyterian Healthcare System appreciates the opportunity to comment on this proposed outcome measure. We hope that you find our comments helpful as we share the same goals for improving the management of hospitalized patients with acute COPD exacerbation. If you have any questions, please contact [REDACTED]</p>			
8	7/1/11	COPD Mortality and Readmission	<p>AstraZeneca Pharmaceuticals (AstraZeneca) LP is a leading global healthcare company dedicated to the research and development of new medicines in therapeutic areas including cardiovascular, gastrointestinal, oncology, respiratory, and neuroscience. AstraZeneca is committed to the discovery of drugs that will allow patients to lead longer, healthier and more productive lives. AstraZeneca offers the following comments in response to the Center for Medicare & Medicaid services (CMS) public comment opportunity on COPD measures. As an active member of the National Quality Forum (NQF) and the Pharmacy Quality Alliance, AstraZeneca encourages the development and utilization of evidence-based, validated, performance measures for quality improvement. In the past, CMS has stated that they “generally prefer to adopt NQF-endorsed measures for CMS quality reporting programs,” however, consensus by other means is acceptable.[i] AstraZeneca recommends CMS use measures that have been endorsed by the NQF, as its endorsement process includes a rigorous evaluation of the measures by multiple stakeholders and provides an opportunity for public comment from those various stakeholders.</p>	Kathleen R. Gans-Brangs, PhD, AstraZeneca, Media Affairs	kathy.gans-brangs@astrazeneca.com	Pharmaceutical Company

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>This process is in contrast to the manner by which this measure development appears to have been performed which may not adequately represent consensus amongst all stakeholders. In addition, AstraZeneca requests an explanation of the rationale for using the broad term of “all-cause” as opposed to “COPD-related” within the following proposed measures:</p> <ul style="list-style-type: none"> • 30 day, all-cause mortality following hospitalization for acute exacerbation of COPD • 30 day, all-cause readmission following hospitalization for acute exacerbation of COPD <p>Since “all-cause” readmissions and/or mortality could be reflective of the patient’s overall disease burden and treatments and not necessarily specific to the COPD care specifically provided by a hospital, AstraZeneca recommends revising the proposed measures to state “COPD-related mortality” and “COPD-related readmission.” AstraZeneca thanks you for the opportunity to comment on the proposed COPD quality measures. We look forward to continuing to engage in a thoughtful dialogue around this important component of the future of our healthcare delivery system in the US.</p> <p>Please feel free to contact [REDACTED]</p>			
9	7/1/11	COPD Mortality and Readmission	<p><i>Cohort:</i></p> <ul style="list-style-type: none"> • A high percentage of patients that are HF readmits could potentially fall into the COPD 'bucket' as well. • I am curious as to the methodology that will be used in determining how subsequent readmits for HF and COPD will be handled (duplications so to speak). <p><i>Exclusion/Risk adjustment:</i></p> <ul style="list-style-type: none"> • Agree with including AMA for exclusion in COPD. • I would also like to see the code V15.81 (noncompliance with medical treatment) used; if not part of the exclusions, then at least consider as part of the risk-adjustment. <ul style="list-style-type: none"> ▪ These patients are extremely difficult to manage and continually re-visit the ED and meet medical necessity for a full admission status. 	Julie Irwin, RN, BSN, RN-BC, Director of Performance Improvement and Physician Information Systems, Southern Ohio Medical Center	irwinj@somc.org	Individual

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
10	7/2/11	COPD Mortality and Readmission	Kaiser Permanente requests that all measures developed by CMS, whether in-house or via contractors such as Yale, utilize data from all Medicare beneficiaries, including Medicare Advantage patients. Not doing so unfairly characterizes the performance of our hospitals and clinical care teams due to the fact that over 95% of our Medicare days are from MA members. We have been requesting that CMS change the policy of only including Part A MedPAR data in these analyses and would be willing to work with you on alternatives. Thank you.	Jed Weissberg, MD SVP, Hospitals, Quality and Care Delivery Excellence Kaiser Foundation Health Plan and Hospitals Kaiser Permanente	jed.weissberg@kp.org	Hospital
11	7/4/11	COPD Mortality and Readmission	The Yale-New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (CORE) and all the experts that participated in the development of the proposed COPD measures are to be commended for their efforts to enhance this valuable performance measurement tool. We at GlaxoSmithKline recognize and applaud CMS's willingness to elicit broad external input and CORE's consideration of this input. We appreciate the opportunity to comment on the draft COPD measures "30-Day Risk-Standardized All-Cause Mortality" and "Readmission in Acute Exacerbations of Chronic Obstructive Pulmonary Disease (COPD)." As do you, we recognize the importance of designing performance measures that reflect scientific evidence and sound clinical practice. To develop our comments, we circulated the proposed technical specifications to a wide variety of individuals here at GlaxoSmithKline, including clinicians, research scientists, healthcare delivery experts, pharmacoeconomists and statisticians. Included with this letter is a list of references for the articles cited in our comments. <u>General Comments</u> GSK supports the development of outcomes-oriented measures such as hospital readmissions and mortality measures because they address fundamental issues in care delivery. We also appreciate CMS's choice of conditions for the readmission measures: AMI, heart failure, pneumonia and now COPD. GSK strongly supports the focus on COPD because of its high impact and cost. COPD is the fifth most common reason for hospitalization of Americans over 65 ¹ and the fourth-leading cause of death. ⁸ COPD affects an estimated 24 million adults in the United States, with 12 million diagnosed and an estimated 12 million undiagnosed. ⁹ In 2007 the cost of COPD treatment in the United States reached an alarming \$42.6 billion,	Rae Gulick, GlaxoSmithKline	Rae Gulick <rae.h.gulick@gsk.com>	Pharmaceutical Company

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>with \$26.7 billion in direct costs.¹⁰ Published literature has shown that physicians often do not follow clinical guidelines.^{2,8} For example, a comprehensive international survey of adults with COPD found that only 46% of respondents underwent spirometry.⁹ These findings underscore the need for performance measures to motivate adherence to nationally recognized practice guidelines. Further, COPD is associated with multiple co-morbidities. Heart failure accounted for the largest portion of cardiovascular disease hospitalizations in people with COPD.^{10,11} COPD significantly increases the risk of pneumonia, osteoporosis, respiratory infection, myocardial infarction, angina, fractures and glaucoma.¹² Women with COPD are at increased risk of developing diabetes compared with women without COPD.^{13,14} Over 60% of people with COPD also had depression and/or anxiety.^{15,10} COPD also has a significant financial impact. The mean 2008 cost of ED visits was \$647. Simple COPD admissions averaged \$7242, while complex admissions were \$20,757. Intensive care/intubation admissions incurred the highest costs (\$44,909).¹⁶</p> <p><u>Methodology</u> We support the proposed methodology. However, we recommend testing several possible enhancements to the risk methodology:</p> <ul style="list-style-type: none"> • Incorporate Part D data to help differentiate the treated versus non-treated population. • Calculate previous “health care resource use” as a proxy for prior exacerbations and as an adjustor in calculating readmission rates and mortality rates 30 days post discharge. • Stratify the population by diagnosis code (e.g., COPD versus chronic obstructive asthma versus respiratory failure) in order to apply differential risk adjustments. <p>We support the hierarchical generalized modeling approach as a valid approach to adjust for hospital case mix. We are pleased to see that “readmissions” are excluded from the original definition of “admission” to avoid double counting.</p> <p><u>Effectiveness of hospital care</u> We recommend that hospital effectiveness be measured along with these measures. We recognize that the proposed readmission and mortality measures are intended to be outcomes measures useful in evaluating coordination of care. Using these measures alone could obscure poor quality of care in the hospital that leads to readmissions and death. We recommend adding hospital-specific COPD measures of inpatient care such as comprehensive medication management and discharge with appropriate medications.</p>			

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>These are similar to the NQF endorsed measure #549 (Pharmacotherapy Management of COPD Exacerbation: 2 Rates). <u>COPD ED Admissions</u> We recommend either including people with COPD emergency department visits in the base population or developing a separate COPD readmission measure for the population that had emergency department COPD visits. Even though ED visit costs are lower than inpatient costs, repeated ED visitation is a strong indication of poor patient care, poor coordination of care and poor outcomes.</p> <p>References</p> <ol style="list-style-type: none"> 1. O'Malley AS, Pham HH, Schrag D, Wu B, Bach PB. Potentially avoidable hospitalizations for COPD and pneumonia: the role of physician and practice characteristics. <i>Med Care.</i> 2007 Jun;45(6):562-70. 2. Bourbeau J, Sebaldt RJ, Day A, et al. Suboptimal medical therapy in COPD: exploring the causes and consequences. <i>Chest</i> 2000;117:33S-7S. 3. Kanner RE, Connett JE, Williams DE, Buist AS, for the Lung Health Study Research Group. Effects of randomized assignment to a smoking cessation intervention and changes in smoking habits on respiratory symptoms in smokers with early chronic obstructive pulmonary disease: the Lung Health Study. <i>Am J Med.</i> 1999;106:410-416. 4. Anthonisen NR, Connett JE, Kiley JP, et al. Effects of smoking intervention and the use of an inhaled anticholinergic bronchodilator on the rate of decline of FEV1: the Lung Health Study. <i>JAMA.</i> 1994;272:1497-1505. 5. Anthonisen NR, Connett JE, Murray RP, for the Lung Health Study Research Group. Smoking and lung function of Lung Health Study participants after 11 years. <i>Am J Respir Crit Care Med.</i> 2002;166:675-679. 6. Global Initiative for Chronic Obstructive Lung Disease. <i>Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease—Updated 2007.</i> xiv. http://www.goldcopd.org. April 6, 2009. 7. Rutschmann OT, Janssens J-P, Vermeulen B, Sarasin FP. Knowledge of guidelines for the management of COPD: a survey of primary care physicians. <i>Respir Med.</i> 2004;98:932-937. 8. Jemal A, Ward E, Hao Y, Thun M. Trends in the leading causes of death in the United States, 1970-2002. <i>JAMA.</i> 2005;294:1255-1259. 9. Rennard S, Decramer M, Calverley PMA, et al. Impact of COPD in North America and Europe in 2000: subjects' perspective of Confronting COPD 			

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>10. International Survey. <i>Eur Respir J.</i> 2002;20:799-805.</p> <p>11. Huiart L, Ernst P, Suissa S. Cardiovascular morbidity and mortality in COPD. <i>Chest.</i> 2005;128:2640-2646.</p> <p>12. Sidney S, Sorel M, Quesenberry CP Jr, DeLuise C, Lanes S, Eisner MD. COPD and incident cardiovascular disease hospitalization and mortality: Kaiser Permanente Medical Care Program. <i>Chest.</i> 2005;128:2068-2075.</p> <p>13. Soriano JB, Visick GT, Muellerova H, Payvandi N, Hansell AL. Patterns of comorbidities in newly diagnosed COPD and asthma in primary care. <i>Chest.</i> 2005;128:2099-2107.</p> <p>14. Rana JS, Mittleman MA, Sheikh J, et al. Chronic obstructive pulmonary disease, asthma, and risk of type 2 diabetes in women. <i>Diabetes Care.</i> 2004;27:2478-2484.</p> <p>15. Sin DD, Man SFP. Why are patients with chronic obstructive pulmonary disease at increased risk of cardiovascular diseases? The potential role of systemic inflammation in chronic obstructive pulmonary disease. <i>Circulation.</i> 2003;107:1514-1519.</p> <p>16. Kunik ME, Roundy K, Veazey C, et al. Surprisingly high prevalence of anxiety and depression in chronic breathing disorders. <i>Chest.</i> 2005;127:1205-1211.</p> <p>17. Dalal A, Manan S, D'Souza A, Rane P. Cost of COPD exacerbations in the emergency department and inpatient setting. <i>Respir Med.</i> 2011;105:454-460.</p>			
12	7/4/11	COPD Readmission	This is interesting data. I'm sure this would never be developed into a system to penalize physicians for patients that need to be readmitted, would it? A response would be appreciated.	Stephen Capizzi, MD	scap70@gmail.com	Individual
13	7/5/11	COPD Mortality and Readmission	"all cause" for mortality and for readmits is a constant headache. I believe "related" to COPD is much more meaningful and useful to quality improvement.	Richard Smith	RSMITH@midstatemedical.org	Individual

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
14	7/5/11	COPD Mortality and Readmission	Please be specific in the cohort i.e. use codes 496, 491.20-22, 492.8. Do not include patients with chronic bronchitis from other causes, the treatment is potentially different and will dilute the population desired. Include ambulatory patients, no upper age limit. Include patients in assisted living or adult family homes. Including concomitant dementia is ok. Exclude Nursing Home residents, and patients on Hospice. Risk adjust using HCC scores, but I have a question. As an example if patient has mild-moderate COPD and falls breaking a hip or is in an MVA, cost is up, mortality risk is up, and risk of exacerbation (and hence readmission) is up due to reduced mobility but not attributable directly to the COPD. Is the HCC score for hip fx or MVA with trauma high enough to correct for this? Thanks for the opportunity to comment	Peter Rutherford, Wenatchee Valley Medical Center, Wenatchee, Washington	prutherford@wvmedical.com	Individual
15	7/6/11	COPD Mortality and Readmission	To Whom It May Concern, Patients readmitted who are on ventilators should be excluded. Additionally, patients who receive palliative care should be excluded from the mortality measure.	Geraldine Koster, R.N., (Submitted on behalf of Harry Steinberg MD)	GKoster@nshs.edu	Individual
16	7/6/11	COPD Mortality and Readmission	Mayo Clinic appreciates the opportunity to comment on the COPD Outcome Measures the Yale-New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE) has developed on behalf of the Centers for Medicare & Medicaid Services (CMS). Mayo Clinic is concerned that the development of this outcome measures presumes that the patients will never die of this fatal disease. The industry often uses the crisis of hospitalization to further our discussions about goals of care and palliative care. The outcome measures could potentially impact institutions' readiness to make those necessary and appropriate referrals if they know they will have negative outcomes. Thank you for the opportunity to share our concerns and comments.	Teresa Beard, Mayo Clinic Rochester, Medicare Strategy Unit	Beard.Teresa@mayo.edu	Hospital

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
17	7/7/11	COPD Readmission	<p>Dear Dr. Rapp,</p> <p>On behalf of Novartis Pharmaceuticals Corporation (NPC), I am pleased to respond to the Centers for Medicare and Medicaid Services (CMS) request for comments regarding the proposed quality measure: 30-day, all cause readmission following hospitalization for acute exacerbation of chronic obstructive pulmonary disease (COPD). NPC is a leading global pharmaceutical manufacturer that is dedicated to the discovery, development and marketing of innovative products to cure diseases, to ease suffering, and to enhance the quality of life, including a number of orphan drugs developed to treat rare, often life-threatening diseases. We are invested and actively engaged in efforts aimed toward driving improvements in the healthcare delivery system. We applaud CMS' efforts at promoting high quality care by supporting the development and implementation of quality measures, particularly those measures of health outcomes such as the COPD readmission measure. Given that outcome measures help to assess the end results of care delivery processes and not simply whether those delivery processes were implemented, the use of outcomes measures is of critical value to determine areas along the care continuum that require quality improvement interventions. In addition, we support incorporating risk-adjustment into this quality measure since it accounts for wide variation in patient risk factors. This type of variation may influence the crude incidence and prevalence of clinical outcomes or events across providers who often have a different case mix. In incentive-based quality improvement programs, appropriate risk adjustment helps to avoid penalizing providers who care for patient populations with a higher clinical or demographic risk profile.^{i,ii}</p> <p>To maximize the impact of this and other quality measures in real-world settings, we offer the following suggestions regarding the COPD readmission measure:</p> <ul style="list-style-type: none"> • Reconsider the use of an 'all-cause' specification; • Explore the use of data from electronic health records and clinical registries; and • Consider the use of composite quality measures. <p>All-cause readmission specification While measurement of readmission rates is a valuable tool for evaluating healthcare outcomes, it is important to evaluate readmissions that are directly related to the initial hospitalization or could have been prevented. CMS should consider the use of potentially preventable causes as the numerator criteria in the COPD readmission measure. Though the majority of hospital readmissions are considered potentially preventable,ⁱⁱⁱ not all readmissions are reasonably under a hospital's influence.</p>	Usman Azam, M.D. Head, US Medical & Drug Regulatory Affairs, North America	usman.azam@novartis.com	Pharmaceutical Company

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>Tracking a COPD-specific readmission rate or potentially preventable causes of readmissions will allow providers to identify and correct gaps in their systems of care. Use of data from electronic health records and clinical registries Clinical data from electronic health records (EHR) and registries are more robust and are more likely to reflect true elements of healthcare encounters.^{iv,v} As such, clinical data from these sources can support more accurate case definition and risk-adjustment which are key elements of outcome measures. We therefore urge the development of alternate measure specifications that incorporate or link data elements from EHRs and/or clinical registries with administrative claims data. Given the increasing adoption of health information technology in healthcare, CMS should consider how these measures could be structured for electronic data capture, reporting and quality measure calculation. These suggestions have implications for the costs and burden of data collection required to support claims-based measures.</p> <p>Use of composite quality measures Provision of care to COPD patients like that of many chronic conditions is complex and involves the coordination of multiple stakeholders to achieve high quality results. While hospitals have a responsibility to provide high quality care during an admission and appropriate discharge planning services including smoking cessation counseling, assessment of vaccination status, as well as education about recognition of symptoms of exacerbation and appropriate use of medications^{vi}, they do not always have the structural systems or financial incentive to provide care-coordination services to patients after they are discharged into the community. In its 2010 consensus report, the Global Initiative for Obstructive Lung Disease (GOLD) noted that use of an integrative care approach that includes patient education, coordination among levels of care, and increased access to care reduced hospital readmissions.^{viii} It is also recognized that gaps in post-discharge care play a key role in increasing the risk of readmission within the first 30 days after a COPD hospitalization.^{vi} CMS should therefore consider the use of composite measures that assess the quality of care along the care continuum for an acute exacerbation of COPD. These composite measures could leverage existing measures that already assess different stages of care. Alternatively, CMS could consider the development of measures around episodes of care for COPD.</p>			

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>The use of composite or episode of care measures would be in alignment with payment reform models such as bundling and delivery reform models such as accountable care organizations which are designed to encourage coordination of care specifically appropriate care transitions. We appreciate the opportunity to provide comments on this important topic and we look forward to other avenues to contribute to CMS' efforts at quality improvement.</p> <p>i Epstein AM, Lee TH, Hamel MS. Paying physicians for high-quality care. NEJM.2004;350:406-410.</p> <p>izaslavsky AM, Hochheimer IN, Schneider EC et al. Impact of sociodemographic case mix on the HEDIS measures of health plan quality. Med Care. 2000;36:961-992.</p> <p>ii Medicare Payment Advisory Commission (MedPAC). (2007, June). Report to Congress: Promoting greater efficiency in Medicare. Washington, DC: MedPAC</p> <p>iy Keyser OJ, Oembosky JW, Kmetik K, Antman MS, Sirio C, Farley DO. Using health information technology-related performance measures and tools to improve chronic care. Jt Comm J Qual Patient Saf. 2009 May;35(5):246-55.</p> <p>v Engelberg Center for Health Care Reform at Brookings. How Registries Can Help Performance Measurement Improve Care. June 2010. Available at http://tw.Nw.rwjf.org/files/research/65446.pdf</p> <p>vi Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2010. Available from: http://tw.Nw.goldcopd.org/.</p> <p>vii Garcia-Aymerich J, Hernandez C, Alonso A, Casas A, Rodriguez-Roisin R, Anto JM, Roca J. Effects of an integrated care intervention on risk factors of COPD readmission. Respir Med.2007 Jul;101 (7):1462-9. Epub 2007 Mar 6.</p> <p>viii Stephen F. Jencks, M.D., M.P.H., Mark V. Williams, M.D., Eric A. Coleman, M.D., M.P.H. Rehospitalizations among Patients in the Medicare Fee-for-Service Program. N Eng! J Med 2009;360: 141 6-26.</p>			

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
18	7/7/11	COPD Mortality and Readmission	<p>To Whom it May Concern:</p> <p>Thank you for the opportunity to review two outcomes measures related to COPD: (1) 30 day, all-cause mortality following hospitalization for acute exacerbation of COPD (2) 30 day, all-cause readmission following hospitalization for acute exacerbation of COPD</p> <p>The Society of Hospital Medicine supports the measures as they stand currently. The rationale and methodologies are comprehensive and reflect a well thought out process. If you have any questions or concerns, please do not hesitate to contact me.</p>	<p>Wendy Nickel, Associate Vice President, Center for Hospital Innovation and Improvement</p>	<p>wnickel@HospitalMedicine.org</p>	<p>Medical Professional Society</p>
19	7/8/11	COPD Mortality and Readmission	<p>Dear Dr. Berwick:</p> <p>On behalf of Partners HealthCare and its acute member hospitals, we appreciate the opportunity to offer comments on the proposed methodologies for a 30-day All Cause Readmission Following hospitalization for acute exacerbation of COPD (Chronic Obstructive Pulmonary Disease) measure and a 30-day All Cause Mortality following hospitalization for acute exacerbation of COPD measure. As we have expressed during prior CMS comment periods for readmission and mortality measures, the use of administrative claims data sources for such calculations is limiting and raises several concerns. We share those and related concerns below:</p> <p>1) The measures are not NQF endorsed: Partners believes all measures used by CMS either for public reporting or payment programs should be evaluated and endorsed by a voluntary, consensus development organization such as the NQF. Failure to use a NQF consensus development process precludes incorporation of multiple stakeholder comments and the ability to blend clinicians, delivery experts and technical specialists needed for effective measure development.</p> <p>2) Denominator Considerations: The proposed denominator is constructed to capture patients with an ICD-9 discharge diagnosis of COPD exacerbation or respiratory failure with secondary diagnosis of COPD exacerbation. This second general category is very problematic, however, as there is little clinical or health service evidence to support such a broad capture. For example, a patient with pneumonia and COPD would meet criteria for index admission or readmission by virtually all clinical algorithms for risk stratification (PORT, Pneumonia Severity Index, etcL and there is no evidence to suggest that specific interventions can reduce readmission for patients with COPD exacerbation complicated by a secondary respiratory pathology.</p>	<p>Diane G. O'Connor PARTNERS HEALTHCARE Project Manager, Clinical Affairs</p>	<p>DGOCONNOR@PARTNERS.ORG</p>	<p>Health Care System</p>

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>3) Failure to exclude or account for high-risk populations: Partners specializes in the care of many complex patients who are carefully managed for many diverse co-morbidities that are not accurately accounted for in this measure. For example, patients with a history of major lung resection or Immune compromised status (HIV, prior transplant, or active management of a malignancy) represent populations at high risk of co-morbid COPD and high-risk of readmission and mortality without evidence to demonstrate specific interventions that can reduce readmissions. Furthermore, these populations are not well suited to risk adjustment as models do not reflect the unique care pathways used for many of these patients that frequently requires inpatient admission. Partners recommends exclusion of this small subpopulation as secondary diagnosis codes should capture this population fairly reliably.</p> <p>4) Mortality and Readmission measures must account for patient transfers: As a major referral center, Partners cares for many patients with complex presentations requiring higher levels of care or specialty consultation. We appreciate CMS's consideration of transfer patient exclusion, but we believe the current attribution method does not fairly evaluate centers accepting patients. For example, mortality is attributed to the initial admitting hospital, creating an incentive for tertiary centers to not accept patients with severe COPD or for referring hospitals to transfer a patient from the emergency department to the receiving hospital even if it is unclear if the patient will require a higher level of care, thereby incurring significant costs and worsening hospital crowding. Similarly with respect to the RSRR, an adverse incentive exists to transfer patients recently discharged from a referring center in-order to improve RSRR performance, which threatens effective care coordination. Partners would propose stratified measurement that separates transfer from non-transfer patients or exclusion of transfer patients from receiving hospitals and attribution methods that hold both the referring and receiving hospital attributable for readmission.</p> <p>5) Failure to include pulmonary embolism in risk stratification: Measures of condition specific mortality and condition specific readmission are challenging in patient populations with numerous high risk comorbidities. Neither the RSRR or the RSMR that are proposed account for pulmonary embolism as a covariate in risk-adjustment or as a denominator exclusion. This may significantly limit the clinical coherence of the measure as studies have demonstrated pulmonary embolism to be the etiology of unexplained shortness of breath in up to</p>			

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>25% of patients hospitalized with severe exacerbations of COPDi. This population is at high risk of readmission and mortality, failure to account for pulmonary embolism will inaccurately attribute patients for inclusion in this measure despite meeting high standards of COPD care.</p> <p>6) The proposed diagnosis coding algorithm requires chart validation: The proposed ICD-9 coding inclusion algorithm is based on expert consensus and involves both primary and secondary diagnosis codes in a population of patients frequently coded with other primary and secondary diagnosis codes for conditions such as pneumonia, congestive heart failure, and malignancy. The measure development project employed for these measures did not validate this measure using a "higher quality, clinically derived data" set to ensure reliability between administrative claims data and medical recordsii</p> <ul style="list-style-type: none"> • We recommend limiting this measure to only patients with a primary diagnosis of COPD based on the higher measure specificity that would presumably exist by using a narrower definition for inclusion until a chart validation project can demonstrate the importance of including a more heterogeneous patient population in the measure. We appreciate CMS's effort to develop thoughtful measures and methodology. If you have any questions about our responses, please feel free to contact [REDACTED] Project Manager, [REDACTED] <p>i Tillie-Leblond I, Marquette CH, Perez T, et al. Pulmonary embolism in patients with unexplained exacerbation of chronic obstructive pulmonary disease: prevalence and risk factors. <i>Ann Intern Med.</i> 2006 Mar 21;144(6):390-6.</p> <p>ii Krumholz HM, Brindis RG, Brush JE, et al. Standards for Statistical Models Used for Public Reporting of Health Outcomes. <i>Circulation</i>; 2006; 113: 456-462.</p>			

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
20	7/8/11	COPD Mortality and Readmission	<p>Dear Dr. Drye,</p> <p>The American Thoracic Society would like to comment on the Centers for Medicare & Medicaid Services (CMS) proposed quality measures for 30-day risk-standardized all-cause mortality and readmission in acute exacerbations of Chronic Obstructive Pulmonary Disease (COPD), developed by the Center for Outcomes Research and Evaluation. The ATS is a multidisciplinary professional society that represents over 15,000 pulmonary and critical care practitioners in the United States. We strongly support CMS's efforts to profile hospitals based on the quality of their care for patients with COPD, and offer the following suggestions for improving the proposed measures. Definition of the cohort Patients admitted with an acute exacerbation of COPD are identified using <i>International Classification of Diseases Version 9—Clinical Modification</i> (ICD-9-CM) codes. ICD-9-CM codes are inherently limited for patient identification, as they frequently lack the necessary sensitivity and specificity to identify the cohort of interest. Indeed, recent research demonstrates that different algorithms for identifying COPD admission yield widely differing cohorts.¹ Nonetheless, we recognize that at the present time there are no practical alternatives to ICD-9-CM codes for patient identification. We also acknowledge that the proposed codes have extensive face validity, at least for preliminary use. To address this problem, we request that CMS fund a validation study examining the sensitivity and specificity of this coding strategy compared other strategies, with the gold standard being a clinical diagnosis of an acute COPD exacerbation. Such a study is necessary to ensure that these codes reliably and validly identify the true population, helping to mitigate the possibility that observed variations in outcomes are due to variations in coding practices. Exclusion criteria The current exclusion criteria include an exclusion for patients who are transferred from another acute care hospital. We recommend broadening this criterion to also exclude patients who are transferred from long-term acute care hospitals (LTAC). LTACs are specialized hospitals that provide complex services to patients with chronic critical illness and other unique conditions. A significant portion of these patients have had tracheostomies and receive long-term mechanical ventilation, and their mortality is extremely poor.² These patients are systematically different from traditional COPD patients in a way that is unlikely to be captured by existing risk-adjustment, warranting exclusion. Risk adjustment The current risk-adjustment variables include a history of mechanical ventilation (ICD-9-CM codes 93.90 and 96.7X), as well as Condition Categories for respiratory failure (CC 77-78).</p>	Gary Ewart, Director, Government Relations, American Thoracic Society	gewart@thoracic.org	Professional Society

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>It is unclear from the report whether or not these variables refer to episodes of mechanical ventilation respiratory failure that occur not only in past admissions but also during the index admission. If these variables include the index admission, we are concerned that this variable could represent a complication of care rather than true variation in illness severity on admission. Many patients are admitted without the need for mechanical ventilation but ultimately require it, possibly due to poor care. We are concerned that adjusting for this variable may adjust away true variations in quality. A similar concern arises though the use of the code 93.90, which represents noninvasive ventilation (NIV). Early use of NIV is known to improve survival in patients with COPD³, and adjusting for this variable may adjust away true variations in quality. We observe that the variable Respiratory Dependence/Respiratory Failure (CC 77-78) is associated with a decreased risk of 30-day mortality (OR=0.88). This finding is counterintuitive, since respiratory failure is typically indicative of a high severity of illness. Consequently, we suspect that within the context of the current model, this variable is acting as a proxy for a desire to receive ongoing life sustaining therapy or access to a post-acute care facility (such as an LTAC) that might facilitate prolonged life-sustaining therapy. Patients meeting criteria for this variable might simply be those that were committed to surviving at all costs, thereby making it appear to convey a lower risk of death. Prior to including this variable as a risk-adjustment, we suggest further examining hospital and regional-level variation in this variable to better understand its meaning and its implication in risk adjustment. Modeling strategy We agree with the approach of using a hierarchical modeling strategy to profile hospital performance. However, we note that a strategy of profiling COPD performance using administrative data has not been validated against a strategy using clinical data. We request that CMS perform a model validation study analogous to the study performed for acute myocardial infarction⁴ to determine if this approach is reasonably equivalent to an approach using clinical data. Thank you the opportunity to comment on these proposed measures. Again, the ATS is strongly supportive of these efforts and is happy to provide future assistance as necessary.</p>			

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>1. Stein BD, Charbeneau JT, Lee TA, et al. Hospitalizations for acute exacerbations of chronic obstructive pulmonary disease: how you count matters. <i>Journal of Chronic Obstructive Pulmonary Disease</i> 2010;7:164-171.</p> <p>2. Kahn JM, Benson NM, Appleby D, et al. Long-term acute care hospital utilization after chronic critical illness. <i>JAMA</i> 2010;303:2253-2250.</p> <p>3. Hill NS, Brennan J, Garpestad E, Nava S. Noninvasive ventilation in acute respiratory failure. <i>Crit Care Med</i> 2007;35:2402-7.</p> <p>4. Krumholz HM, Wang Y, Mattera JA, et al. An Administrative Claims Model Suitable for Profiling Hospital Performance Based on 30-Day Mortality Rates Among Patients With an Acute Myocardial Infarction. <i>Circulation</i> 2006;113:1683-1692.</p>			
21	7/8/11	COPD Mortality and Readmission	<p>The Federation of American Hospitals (FAH) is the national representative of investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching, short-stay rehabilitation, and long-term care hospitals in urban and rural America, and provide a wide range of acute, post-acute and ambulatory services. On behalf of our member hospitals, we are pleased to offer comments on the following CMS measures currently in development:</p> <p>(1) 30-Day, All-Cause Mortality Following Hospitalization for Acute Exacerbation of COPD</p> <p>(2) 30-Day, All-Cause Readmission Following Hospitalization for Acute Exacerbation of COPD</p> <p>General Comments The FAH has serious concerns with the use of a 30-day timeframe for these measures and for outcomes measures generally. We believe that clinically, a 15-day timeframe for measuring readmissions and mortality is more reflective of the quality of care a patient received during their hospital stay. By measuring beyond 15 days, CMS is potentially holding hospitals accountable for a range of circumstances, including poor community infrastructure and natural progression of disease, which are not within the institution’s control. 2</p> <p>Similarly, we have concerns with the continued focus on “all-cause” readmissions and mortality. Measuring all readmissions and mortality regardless of whether there is any clinical relationship between the initial admission and the subsequent readmission or death does not help hospitals meaningfully assess where process improvements can be made to achieve better outcomes for patients.</p>	Samantha Burch, Director Healthcare Policy & Research, Federation of American Hospitals	SBurch@FAH.org	Hospital System Association

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>For this to happen, we need to develop measures that look at related readmissions and mortality using a methodology that can be replicated by hospitals. As with the three readmissions and mortality measures (for HF, AMI, and PN) currently posted on <i>Hospital Compare</i>, hospitals will have to wait for CMS to calculate these measures utilizing data the hospital cannot access and then inform hospitals of their rates which currently occurs once a year. This data lag, resulting from hospitals' inability to replicate the measure calculations in-house, does not lend itself to continuous tracking and rapid-cycle improvement. The development of new readmissions and mortality measures for consideration for public reporting and/or eventual inclusion in the Hospital Readmissions Reduction Program or the Hospital Value-Based Purchasing Program presents an opportunity to look at methodologies beyond the 30-day, all-cause methodology used in the current condition-specific readmission and mortality measures. We believe that this represents a missed opportunity to test the effectiveness of other measure constructs in driving improvements in hospital readmission and mortality rates. Specific Comments As described in more detail above, the FAH has serious concerns about the 30-day timeframe for these measures and would ask CMS and the measure developers to strongly consider a 15-day timeframe instead, which we believe is far more appropriate for assessing hospital quality and performance. According to our clinical experts, unlike certain other conditions or procedures (<i>e.g.</i>, readmissions following vascular procedures), complications related to COPD are likely to occur within hours of discharge, not within days. Complications related to COPD occurring beyond 15 days are like to be unrelated to the care provided by the hospital during the initial admission. While we support the addition of chronic obstructive asthma to the cohort for these measures (because it is part of the disease spectrum), the infrastructure of outpatient care in the community will be a significant determinant in the patient's outcome for this condition. In a community with strong access to outpatient care, there is a greater likelihood that a patient will be treated for a mild attack in a physician office, rather than returning to the hospital for care. In addition, there are environmental factors that contribute to the exacerbation of COPD that are not within the control of the hospital. Ensuring appropriate exclusions for planned readmissions within 30 days is important not only to ensure fair assessment of the hospital, but also to avoid unintended consequences for patients.</p>			

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>To that end, we would generally support broader exclusions for “readmissions” within 30 days that are almost always planned (e.g., chemotherapy) to avoid any incentive to delay planned care. We believe that ultimately physician documentation at the time of the index admission is the best method for determining exclusions for planned readmissions. This could be achieved by instituting a coded flag in the record to indicate that a planned readmission for follow-up care has been scheduled. 3 The FAH strongly recommends that the specifications for the COPD mortality measure be refined to exclude patients with DNR status. We believe it is only appropriate to include these patients when no evidence exists of discharge planning to include palliative care. Finally, the FAH would like to briefly comment on the risk adjustment methodology for these measures. The question of whether to adjust for Socio-Economic Status (SES) has been a topic of great debate within the health care community for some time. While the FAH recognizes there is currently no standard, valid methodology for adjusting for SES, we believe this is an area that warrants continued attention and analysis to determine whether there is a set of SES indicators that should be adjusted for to capture certain characteristics, such as the patient’s ability to comply with discharge/post-procedure instructions, or community infrastructure to support the patient after discharge, while balancing the critical need to avoid unintended consequences. **** Again, we appreciate the opportunity to comment on these new measures in development and look forward to continuing to work with CMS and its contractors to develop additional outcomes measures that will drive meaningful improvements in hospital performance. If you have questions regarding our comments please do not hesitate to contact [REDACTED]</p>			
22	7/8/11	COPD Mortality and Readmission	<p>On behalf of the American College of Chest Physicians (ACCP) the ACCP Quality Improvement Committee (QIC) appreciates the opportunity to comment on these measures. On principle, the QIC agrees that COPD is an area of interest for performance measurement and outcome measures are a preferable method for performance measurement. However, the QIC mentioned that they would be more interested in seeing a pulmonary function test as a performance measure, rather than 30-day readmission rates.</p>	<p>Jeff Maitland, Senior Clinical Standards and Informatics Specialist, Senior Clinical Standards and Informatics Specialist</p>	<p>jmaitland@chestnet.org</p>	<p>Professional Society</p>

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>The QIC also cited Dr. John Heffner’s manuscript entitled “COPD Performance Measures: Missing Opportunities for Improving Care” as a potential bank of needed COPD performance measures. The QIC notes that patients who are discharged to other acute care facilities are excluded from these measures and would like to know whether or not acute care facilities include long term acute care hospitals. The QIC is concerned that an unintended consequence might be patients discharged to a long term acute care hospitals to avoid an increased 30 day mortality rate. We would recommend that LTAC transfers be included. In addition, time –delineated mortality rates, at say 30, 60, and 90 days might be considered. The QIC also noted that the inclusion of patients admitted with ICD-9 code 799.1 (cardiorespiratory arrest) is likely to contaminate the denominator with patients having a variety of disorders, only one of which need be called an exacerbation of COPD. In addition, excluding patients enrolling in hospice on the day of admission is appropriate, but it very often takes more than a day to reach consensus on that decision. Furthermore, not excluding patients who have “do not resuscitate” or “do no intubate” status is a problem. While the QIC understands the rationale behind this, when mortality is the outcome of importance and the most potent tool available to physicians is not available for use, the QIC feels that the physician should not be responsible. The QIC recommends treating “do not resuscitate” or “do no intubate” patients similar to patients enrolling in hospice. The QIC also feels that shock and sepsis should be included in the risk adjustment. The QIC questions why certain comorbid conditions are included for risk adjustment, for example, retinal disorders, mononeuropathy, dermatological disorders, etc. In addition, diagnoses that are new on admission should be included, as these will clearly affect outcome. The QIC also stated that coding methods for these airway disorders are notoriously inaccurate, unreliable, and irreproducible. While there are many coding errors of many diagnoses in medicine, the inaccuracies are much greater in the obstructive lung diseases field than in other conditions. For example, asthma, bronchiectasis and congestive heart failure are routinely and commonly coded as COPD. Finally, the QIC strongly urges continued evaluation, testing, and validation of the risk adjustment model (which has not been externally validated) as the measures are deployed.</p>			

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
23	7/8/11	COPD Mortality and Readmission	<p>Founded in 1951, The Joint Commission seeks to continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value. The Joint Commission evaluates and accredits more than 19,000 health care organizations and programs in the United States, including more than 10,300 hospitals and home care organizations, and more than 6,500 other health care organizations that provide long term care, behavioral health care, laboratory and ambulatory care services. The Joint Commission also provides certification of more than 2,000 disease-specific care programs, primary stroke centers, and health care staffing services. Although accreditation is voluntary, a variety of federal and state government regulatory bodies recognize and rely upon Joint Commission decisions and findings for both Medicare and licensure purposes across all of the Joint Commission’s accreditation programs. The Joint Commission appreciates the opportunity to review and comment on the 30 day all-cause mortality and readmission following hospitalization for COPD measures. We have reviewed the proposed measures and have provided the following comments for your consideration. We are aware that the development of the risk models for the COPD measures are aligned with the statistical model standards utilized for public reporting of health outcomes, and use methodology similar to those developed for AMI, HF, and pneumonia, where each model:</p> <ul style="list-style-type: none"> • Employs a hierarchical logistic regression model to create a hospital level risk-adjusted outcome rate; • Accounts for variation between and within hospitals; • Adjusts the model for case differences based on the clinical status of the patient at the time of admission; • Obtains covariates for each patient from Medicare claims extending 12 months prior to and including the index stay; • Uses condition categories based on groupings of ICD-9 diagnosis codes; • Excludes complications from the risk model that arise during the course of hospitalization; and, • Is compared to a more comprehensive model developed from data found within the medical record. 	Crystal A. Riley, PharmD, R.Ph., Associate Director, Federal Relations, The Joint Commission	criley@jointcommission.org	Health Care Accreditation Organization

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>In spite of the caution exercised and the available wealth of administrative data used in the development of the risk models, the models are prone to the same shortcomings as other 2 administrative data-developed risk models. As compared to data obtained from medical record review, administrative data models use data intended for billing purposes and lack the clinical specificity that can be obtained from a medical record review. Administrative data is susceptible to upcoding, data inaccuracies and contain little information on the severity of the patient’s COPD exacerbation or the patient’s functional status at baseline, arguably two of the most important risk predictors. Consequently, the risk adjustment cannot be considered clinically valid. The model is also potentially biased toward patients that seek care during the one year period prior to the episode; the differing likelihood of patients to seek medical care is not adjusted for within the model. Using readmissions as a marker for quality is also problematic because of the difficulty in determining the “right” amount of readmissions, even after adjusting for risk. The relationship between risk-adjusted COPD exacerbation readmission rates and mortality rates should be evaluated before deciding whether to use COPD exacerbation readmission rates as a publicly reported measure. We appreciate the opportunity to comment on the proposed outcomes measures. If you have any questions or would like to discuss our comments, don’t hesitate to contact me at [REDACTED].</p>			
24	7/8/11	COPD Mortality and Readmission	<p>AGS is the nation's largest membership association of geriatrics healthcare professionals, with nearly 6,000 members. We, and our members, are dedicated to improving the health, independence and quality of life of older people through initiatives in clinical practice, professional and public education, research, and public policy advocacy. In regards to the two Chronic Obstructive Pulmonary Disease (COPD) measures under development, (all-cause mortality, and all-cause readmission), AGS’ comment is directed at the use of the ICD-9-CM codes, in particular 491.22, 493.21, and 493.22. The use of the above mentioned diagnostic codes could result in a heterogeneous cohort, which may neither have COPD (e.g. as defined by spirometry) nor a COPD exacerbation (e.g. as defined by the cardinal symptoms of sputum purulence and volume, as well as dyspnea). This is of concern to AGS, due to a limitation inherent to the use of ICD-9-CM codes, and may very well increase the likelihood of misdiagnosis among older persons, particularly those with multi-morbid conditions.</p>	Susie Sherman, Coordinator, Public Affairs & Advocacy, The American Geriatrics Society	ssherman@americangeriatrics.org	Professional Society

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			We suggest collecting additional historical data, which in turn may indirectly support a diagnosis of COPD (e.g. prior smoking status, chronic bronchitis, bronchodilator use, and spirometry, or actual respiratory symptoms on hospital admission, etc.). Thank you for allowing the American Geriatrics Society this opportunity to provide feedback on the COPD Outcomes Measures. If you have any questions, please do not hesitate to contact [REDACTED]			
25	7/8/11	COPD Mortality and Readmission	<p>On behalf of the Premier healthcare alliance serving more than 2,500 leading hospitals and health systems and 75,000-plus other healthcare sites, we appreciate the opportunity to comment on the measures currently in development by the Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE): 30-Day Risk-Standardized All-Cause Mortality and Readmission in Acute Exacerbations of Chronic Obstructive Pulmonary Disease (COPD). Premier, a 2006 Malcolm Baldrige National Quality Award recipient, maintains the nation's most comprehensive repository of hospital clinical, financial and operational information and operates one of the leading healthcare purchasing networks. Our comments primarily reflect the concerns of our owner hospitals and health systems which, as service providers, have a vested interest in the development of quality measures by the Centers for Medicare & Medicaid Services (CMS). CMS is specifically interested in receiving feedback for the measure cohort inclusion definition, inclusion/exclusion criteria and risk adjustment strategy.</p> <p>Definition of the cohort The cohort definition includes a principal diagnosis of COPD, principal diagnosis of chronic obstructive asthma, or a principal diagnosis of respiratory failure with a secondary diagnosis of acute episode of COPD or chronic obstructive asthma. Premier notes that one of the rationales for including the COPD/asthma patients would decrease incentives for gaming, as hospitals could code patients with the COPD/asthma to exclude patients from the measures. This rationale assumes that hospitals would deliberately incorrectly code patient episodes to avoid measurement. On behalf of our membership, we take exception to this statement, as hospitals must adhere to strict coding rules and procedures. If this is a concern for CMS, they have the ability to monitor the measure rates and identify any coding discrepancies. Prevention of "measurement gaming" should not be a rationale for defining the measure cohort. We are concerned with the impact of the upcoming implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) on the cohort definition.</p>	Christine L. Van Dusen, Senior Consultant, Clinical Standards and Quality, Premier, Inc.,	christinevan_dusen@premierinc.com	Healthcare Association

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>The specificity of ICD-10-CM codes may result in revisions to the currently defined cohort. Premier recommends modeling the cohort definition using the latest ICD-10-CM version. The results of this modeling will be beneficial to assess the impact of ICD-10-CM on these measures. Inclusion/Exclusion Criteria In addition to the stated readmission exclusions, we suggest further excluding conditions that may result in readmissions that are not “preventable,” including trauma, psychoses, substance use, maternity and neonatal, and end-stage renal disease. CMS should actively and quickly work with the National Uniform Billing Committee to enable CMS and other payors to track planned readmissions through claims and alter the measure specifications to exclude additional cases for which the hospital should not be held accountable in the readmission measure. Risk adjustment The risk adjustment methodology is the same model as the current AMI, Heart Failure and Pneumonia 30-day mortality and readmission measures. The intent of the following statement is unclear; “the models do not adjust for the patients” admission source and discharge disposition because these factors are associated with structure of the healthcare system, and not solely patients’ clinical risk factors. This statement seems to imply that because these factors cannot be attributed to the patient, the admission source and disposition are within the hospital’s control. This may not be true in all cases. We realize this statement is consistent with the NQF guidelines; however, there are valid factors that may be outside the control of the hospital and should be considered, even if they cannot be directly attributed to the patient. Additionally, socioeconomic status may be an important factor for risk adjustment for this measure. Patients may have underlying conditions that if not managed at home, can result in readmissions. Conclusion In closing, Premier appreciates the opportunity to provide these comments. As the measure development work by YNHSC/CORE and the TEP is not completed, CMS should provide another public comment period when the measure specifications are refined, or before finalized. Premier recommends that the information for a public comment period include the measure specifications, the risk adjustment methodology and results of all analyses.</p>			

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
26	7/8/11	COPD Mortality and Readmission	<p>Dear Administrator,</p> <p>The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to comment on two measures currently in development by the Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE): (1) 30 day, all-cause mortality following hospitalization for acute exacerbation of COPD; and (2) 30 day, all-cause readmission following hospitalization for acute exacerbation of COPD. AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members produce the majority of the health care technology purchased annually in the United States and a significant share purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies, including those that detect and treat pulmonary conditions, including COPD, worldwide. AdvaMed supports the development of relevant hospital-level quality outcome measures related to COPD and understands the potential problems and complex issues involved in meaningful development and data collection/analysis concerning these measures. While we support this effort, we have several concerns with both the proposed measures and several statements in the Technical Expert Panel (TEP). Our detailed comments address the following key issues:</p> <ul style="list-style-type: none"> • Risk Adjustment, including Socio-Economic Status, Admission Source/Discharge Destination, Coding Issues, and Use of Administrative Claims Data for Risk Adjustment • Cohort for Inclusion in the Measure <p>I. Risk Adjustment AdvaMed recognizes the importance of risk adjustment factors in the development and implementation of quality measurement. In the proposed measure sets for COPD, CMS is proposing to use variables derived from Medicare administrative claims data submitted by hospitals to CMS for payment purposes to create —clinical risk adjusters. Risk adjusters must be valid, reproducible, sensitive and specific. Any flaws that may be present in the methodology to examine risk adjustment can potentially lead to flawed conclusions and therefore compromise the validity of the resultant conclusions. Thus it is important to consider many relevant variables in developing these models. In addition to age, sex, race, other variables should be used.</p>	Amanda Wall, Research Associate, AdvaMed	AWall@advamed.org	Medical Device Trade Association

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>These include severity of illness and clinical covariates, socioeconomic status, other concurrent treatments/interventions and their associated intensity/complexity and sources of co-morbidity. The potential side effects and adverse reactions associated with the different therapies and interventions that may occur to patients may also need to be considered. And, notably absent from discussions on determination of risk stratification factors are functional status and other individual patient measures can play a very significant role in contributing to outcome measurement and potential readmissions. Therefore, AdvaMed recommends that CMS examine additional variables including patient-specific factors in the risk adjustment methodology. a) Socio-Economic Status (SES) The TEP Summary Report notes that the risk adjustment methodology was discussed and —the models do not adjust for socioeconomic status (SES), race, or ethnicity because risk-adjusting for these factors would hold hospitals to different standards of care depending on their case mix. AdvaMed recognizes that SES-based information, for example, educational level, literacy and language skills/abilities, can potentially alter the process of care of patients undergoing diagnosis and treatment for COPD and thus confound the results and conclusions in these measure sets. For example, some patients, while they may be literate, may not understand the complexity of their health condition and their care and treatment. This may influence their compliance and ultimately impact the quality of care that they receive which, in turn, will affect the outcome data. Additionally, there may be some hospitals where SES would have a significantly different impact on complication/mortality or readmission rates (e.g., hospitals in regions for which patient SES is incongruent with the average of all U.S. hospital regions). While this information may be difficult to elicit and collect, its omission 3 could have a significant impact on the validity of these measures. AdvaMed recommends that the YNHSC/CORE team perform additional analyses to determine the potential impact of SES status on these measure sets and consider stratifying the measures by SES; and AdvaMed Recommends that risk stratification should take into account a patient’s socioeconomic status, as this information potentially affects all aspects of health care delivery. b) Admission Source / Discharge Destination AdvaMed is also concerned that the proposed models do not risk adjust for patients’ admission source and their discharge disposition after the index event. Admission and post-acute services provided to the patient, such as those provided by a skilled nursing facility, may significantly impact the mortality and readmission rates.</p>			

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>Therefore, AdvaMed recommends that CMS risk adjust the readmission measure set to reflect a patient’s admission source and discharge destination. c) Coding Issues Changes in coding may impact the validity of the claims data and should be carefully considered. A recent TEP evaluation on a proposed stroke measure set by CMS (YNHHSC/CORE) highlighted this issue. The authors noted that recent change in the definition of stroke vs. transient ischemic attack (—TIA) based on imaging results, could be leading to a miscoding of some patients who actually experienced a TIA, but were coded as —stroke instead. The TIA patients (who had been miscoded as —stroke) were highly likely to experience better outcomes than those patients with a more severe stroke, thus introducing a significant source of unintentional bias into the outcome measure results. Therefore, AdvaMed recommends that CMS monitor the impact that any ICD-9 coding definition changes could have on these measures. d) Using Administrative Claims Data for Risk Adjustment The proposed measure uses administrative claims data to develop risk adjusted outcome measures for calculating readmission rates. AdvaMed has serious concerns regarding the use of solely administrative claims data in setting these quality measures. Administrative claims data lacks robust clinical information and other pertinent patient data—such as those contained in medical records — which are necessary to assess details related to patient complications and other variables that are used in determinations of these measures. In the —Stratification or Risk Adjustment sections of the <i>Measure Information Forms – (MIF)</i> for each measure, CMS states that condition categories (CC’s) -- or groupings of ICD-9-CM codes -- will be used to adjust for case mix differences based on the clinical status of the patient at the time of the hospital stay. However, CMS does not plan to risk-adjust for CC’s that are possible adverse events of care recorded in the index admission or include complications that arise during the course of the hospital stay in the determination of the risk adjustment. Without these adjustments, a significant amount of unintentional bias could be introduced into the measure set. Therefore, AdvaMed strongly recommends that adverse events and complications of care be factored-in as part of the planned risk adjustment analyses in these measures. e) COPD Patient Population Medical and Psychosocial Circumstances These proposed outcome measures, while attempting to adjust for certain candidate variables, fall short of considering factors that affect the needs of patients following discharge after an acute exacerbation of COPD. ¹</p>			

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>Information from focus groups with this condition indicate that these patients may be especially vulnerable for subsequent morbidity/mortality as they: (1) are reluctant to seek help in an exacerbation; (2) have fear and anxiety associated with acute attacks of breathlessness and frustration with healthcare providers concerning the lack of shared concern over when to administer oxygen; (3) express concerns over the lack of discharge planning and medical and social support at home, including the feeling of isolation; (4) express the need for more education concerning what to do when their symptoms deteriorated; and (5) have high levels of depression and anxiety which is associated with the fear of another —attack as well as uncertainties about social and medical care provisions, especially the provision of oxygen. Therefore, AdvaMed recommends that the impact of patient-centered circumstances post-discharge should be assessed by the YNHSC/CORE in the risk analysis of these proposed readmission/mortality COPD outcome measures. II. Cohort for Inclusion in the Measure AdvaMed agrees with the TEP comments which recommend that CORE also include patients in the cohort with a diagnosis of chronic obstructive asthma (COPD/asthma):</p> <ul style="list-style-type: none"> • 493.20 Chronic obstructive asthma; Asthma with COPD, Chronic asthmatic bronchitis, unspecified; • 493.21 Chronic obstructive asthma; Asthma with COPD, Chronic asthmatic bronchitis, with status asthmaticus; • 493.22 Chronic obstructive asthma; Asthma with COPD, Chronic asthmatic bronchitis, with (acute) exacerbation; and • Patients with a principal discharge diagnosis of respiratory failure (ICD-9 codes 518.81, 518.82, 518.84, 799.1) with a secondary discharge diagnosis of COPD (ICD-9 codes 491.21, 491.22, and 493.21, 493.22). <p>AdvaMed shares the concerns of the TEP that coding can be inexact for these patients since it is often challenging for physicians to differentiate between asthma and COPD patients. It is likely that patients in the COPD/asthma group include many patients with COPD, who may be misclassified as having asthma, and may include specific groups which could be more likely to be misclassified as having asthma, (e.g., women > age 65 or low-SES patients). In addition, inclusion of this group would likely reduce bias due to variation in diagnostic, documentation and coding practices. Therefore, AdvaMed commends CORE for their decision to include patients in the cohort with a diagnosis of chronic obstructive asthma (COPD/asthma).</p>			

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>AdvaMed greatly appreciates the opportunity to provide these comments to CMS. We would be pleased to answer any questions regarding these comments. Please contact [REDACTED] we can be of further assistance.</p> <p>1 K. Gruffydd-Jones, <i>et al.</i> What are the needs of patients following discharge from hospital after an acute exacerbation of chronic obstructive pulmonary disease (COPD)? <i>Prim Care Resp J</i> 2007; 16(6): 363-368.</p>			
27	7/8/11	COPD Mortality and Readmission	<p>Dear Dr. Berwick,</p> <p>On behalf of Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI), I am pleased to submit comments on the recently developed draft measures, “Risk-Standardized Mortality Rate (RSMR) following COPD Hospitalization” and “Risk-Standardized Readmission Rate (RSRR) following COPD Hospitalization.” BIPI believes that performance measures in quality reporting programs are an important mechanism to advance high-quality patient care, and we support the efforts of the Centers for Medicare & Medicaid Services (CMS) to implement quality improvement programs. As such, we appreciate the opportunity to provide comments on the draft measures which will potentially be used in CMS’ acute inpatient public reporting programs. Our comments focus on the following areas</p> <ul style="list-style-type: none"> • COPD is a Priority Area for Outcomes Measure Development • Strengthening the Proposed COPD Mortality and Readmissions Measures • Additional Areas for New Measure Development and Testing <p><u>COPD is a Priority Area for Outcomes Measure Development</u> BIPI supports CMS’ efforts to develop, test, and adopt readmissions and mortality measures for chronic obstructive pulmonary disease (COPD), which were previously proposed in the FY 2012 Inpatient Prospective Payment System proposed rule. COPD currently affects over 12 million people in the United States.¹ COPD is the fifth most common reason for hospitalization of Americans over age 65² and is the fourth leading cause of death in the United States.¹ COPD also poses a major economic burden in the United States, accounting for \$38.8 billion annually in direct and indirect costs³, a substantial portion of which are associated with inpatient hospitalizations.⁴ In addition, there are gaps in care for patients hospitalized with acute exacerbations, particularly around medication use, smoking cessation counseling, and vaccinations.⁵</p>	Nicole C. Quon, Associate Director, on behalf of Dr. Christopher Corsico, Senior Vice President, Boehringer Ingelheim Pharmaceuticals, Inc.	nicole.quon@boehringer-ingelheim.com	Pharmaceutical Company

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>Focusing on COPD represents a significant opportunity to improve both quality of care and reduce systemic costs in the Medicare program, and we support the use of evidence-based performance measures as a strategy to improve COPD outcomes. However, although it is a high-burden condition that often requires care in the inpatient setting, there are no current COPD measures in CMS' Inpatient Quality Reporting (IQR) program. Testing and subsequently adopting these outcomes measures in the IQR and other reporting programs will foster greater accountability for inpatient care for COPD patients. We recognize that the proposed all-cause readmission and all-cause mortality measures were constructed using existing hierarchical logistic regression models for risk adjustment, previously developed for similar readmission and mortality measures for acute myocardial infarction (AMI), heart failure, and pneumonia. While we believe that the proposed measures should be ultimately updated with risk adjustment methods tailored for the COPD patient population, these draft measures represent an important step forward in developing outcomes measures for COPD. Relative to other types of existing measures, outcomes measures are best able to demonstrate the meaningful results experienced by patients with a particular condition, making them a valuable metric for assessing care performance, as there is a general paucity of outcomes measures in COPD. Therefore, we support CMS' prioritization of COPD as an area for new measure development, and we support the continued development of these measures so they might be considered for adoption in future CMS program updates. <u>Strengthening the Proposed COPD Mortality and Readmissions Measures</u></p> <p>We encourage CMS to work toward refining these outcomes measures in the future, particularly with the objective of strengthening the risk adjustment methodologies. CMS may consider incorporating new data sources, such as a registry or electronic health records, rather than administrative claims alone. Collecting clinical data will help narrow attribution of the outcomes being measured to the care received, consequently improving the accuracy of any public reporting or financial incentives that may be tied to use of these measures by CMS or other entities. There are also several elements of the technical specifications that can be revised to strengthen these measures in the short term. Specifically, we suggest that CMS include patients enrolled in the Medicare Hospice program as a denominator exclusion in both the COPD readmission and mortality rate measures; currently it is listed as an exclusion only in the mortality rate measure.</p>			

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>Since these patients are likely seeking palliative care only, they may not have been given treatment intended to slow disease progression or prevent exacerbations. Additionally, we recommend that the age cohort for each of these measures be expanded to include all eligible Medicare patients (including high-risk and disabled adults aged 18 and older and Medicaid dual eligibles), rather than limiting them to patients aged 65 and older. COPD is not limited to the elderly population and can affect any adult with a history of smoking, long-term exposure to harmful air pollutants, or genetic alpha-1 antitrypsin deficiency.⁶ We also recommend that CMS include all ICD-9 discharge diagnosis codes with a base of 491, 492, and 496, since limiting the patient cohort to the ICD-9 codes listed in the draft measure specifications and the additional codes proposed by the Technical Expert Panel could exclude some COPD patients. For example, the “Pharmacotherapy Management of COPD Exacerbation” measure developed by the National Committee for Quality Assurance (National Quality Forum #549) uses these ICD-9 codes to define COPD. <u>Additional Areas for New Measure Development and Testing</u> Finally, we recommend that CMS develop, test, and adopt process measures, as well as outcomes measures, for this condition. Adherence to processes of care that support the desired patient outcomes evaluated in these metrics should be measured in addition to the outcomes themselves to comprehensively encourage improved patient care for this condition. In particular, there are opportunities to improve transitions of care for COPD around patient discharge, medication reconciliation, and medication adherence through activities, such as enhanced patient education and better physician communication. Developing and adopting appropriately designed measures for these healthcare processes can lead to provider and patient behavior changes that would positively impact COPD patient readmission and mortality rates. We also encourage CMS to conduct rigorous field testing that will speak to the reliability and validity of both the proposed readmission and mortality rate measures, as well as any other COPD measures developed in the future, and submit them for endorsement to the National Quality Forum. This process will ensure that their methodological rigor is properly vetted and encourage adoption in quality reporting and pay-for-performance programs beyond CMS. <u>Conclusion</u> We appreciate the opportunity to comment on these measures. A transparent measure development process is important for ensuring that all stakeholders affected by performance measurement can contribute to their design and use.</p>			

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>We look forward to continuing to work with CMS to improve quality of care and outcomes for patients.</p> <p>1 National Heart Lung and Blood Institute. COPD Learn More Breathe Better. Accessed on 6/23/11 at http://www.nhlbi.nih.gov/health/public/lung/copd/index.htm</p> <p>2 O'Malley AS et al. "Potentially Avoidable Hospitalizations for COPD and Pneumonia: The Role of Physician and Practice Characteristics." <i>Medical Care</i> June 2007;45(6):562-70.</p> <p>3 Foster TS et al. "Assessment of the Economic Burden of COPD in the U.S.: A Review and Synthesis of the Literature." <i>COPD</i> Dec 2006;3(4):211-8.</p> <p>4 Halpern MT et al. "The burden of COPD in the U.S.A.: results from the confronting COPD survey." <i>Respiratory Medicine</i> March 2003;97(Supplement C):S81-S89.</p> <p>5 Yip NH et al. "Analysis of Hospitalizations for COPD Exacerbation: Opportunities for Improving Care." <i>COPD</i> April 2010;7(2):v85-92.</p> <p>6 National Heart Lung and Blood Institute. COPD Learn More Breathe Better. Accessed on 6/27/11 at http://www.nhlbi.nih.gov/health/public/lung/copd/index.htm</p>			
28	7/11/11	COPD Mortality and Readmission	<p style="text-align: center;">American Medical Group Association Managing Chronic Obstructive Pulmonary Disease Learning Collaborative Comments to COPD Outcomes Measures</p> <p>The American Medical Group Association (AMGA) represents medical groups and organized systems of care, including some of the nation's largest, most prestigious integrated healthcare delivery systems such as the Mayo Clinic, Cleveland Clinic Foundation, Ochsner Clinic Foundation, Lahey Clinic, Johns Hopkins University School of Medicine, Vanderbilt Medical Group, Harvard Medical Faculty Physicians, Henry Ford Health System and the Permanente Federation. More than 113,000 physicians practice in AMGA member organizations, providing healthcare services for 110 million patients in 49 states (nearly one in three Americans). AMGA's member services include a number of means to assist member groups in enhancing their performance levels in quality, patient-centricity, care coordination and improved outcomes at lower costs. Learning Collaboratives are one of these services.</p>	<p>Danielle Flowers, MBA</p> <p>Manager, Quality Programs, American Medical Group Association</p>	<p>dflowers@amga.org</p>	<p>Medical Group Association</p>

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p><u>Background of AMGA’s Learning Collaboratives</u></p> <p>AMGA’s Learning Collaboratives are shared-learning programs that compile evidence of best practices and are designed specifically for member medical organizations that are striving to improve the care of patients with chronic conditions. The goal of the collaboratives is to create a community of knowledge that can help participants accelerate systematic change and make lasting breakthroughs in quality patient care and service that meet or exceed patient expectations. During a standard one or two year membership in the collaborative, participants are invited to attend meetings during which expert faculty guide attendees in how they can achieve their goals. Between these meetings, participants learn from one another, invited guest faculty and implementation experts through interactive Web-based conference calls.</p> <p><i>Past Best Practices Learning Collaboratives include:</i></p> <ul style="list-style-type: none"> ▪ Transforming Systems of Care Delivery: Learning Collaborative and Knowledge Exchange ▪ Models of Excellence Collaborative ▪ Safety Collaborative for the Outpatient Environment or SCOPE ▪ Best Practices in Managing Diabetes Learning Collaborative ▪ Best Practices in Managing Hypertension Learning Collaborative ▪ Best Practices in Managing Diabetes Learning Symposium ▪ Best Practices in Managing Hypertension Learning Symposium <p><i>Current Best Practices Learning Collaboratives include:</i></p> <ul style="list-style-type: none"> ▪ Managing Patients with Chronic Obstructive Pulmonary Disease (COPD) ▪ Best Practices in Managing Patients with Multiple Chronic Conditions <p><u>Regarding AMGA’s COPD Learning Collaborative and Comments</u></p> <p>The Managing Chronic Obstructive Learning Collaborative is for organizations that are striving to improve the care of patients with COPD. The participating medical groups are working together to develop an optimal care framework that includes a comprehensive, patient-centered, value-based approach to chronic care. There are 12 groups participating in this AMGA Collaborative presently. Two of the COPD Learning Collaborative member medical groups have volunteered to provide comments to the request of The Centers for Medicare & Medicaid Services (CMS) and Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE) to develop two hospital-level, quality outcomes measures for patients with chronic obstructive pulmonary disease (COPD).</p>			

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>Please find below their individual comments: -----</p> <p>University of Michigan Hospital and Health System Response to Potential CMS COPD Quality Measures:</p> <ul style="list-style-type: none"> (1) 30 day, all-cause mortality following hospitalization for acute exacerbation of COPD (2) 30 day, all-cause readmission following hospitalization for acute exacerbation of COPD <p>The concept of measuring 30 day all-cause mortality and readmission rates following hospitalization for acute exacerbations for COPD is unfortunately an idea ahead of its time. Currently, mortality for patients in the first year following a hospitalized exacerbation is already fairly high, 21% (McGahan, et al. Chest 2007;132:1748). The biggest risk factors for hospitalized exacerbations are older age, low lung function and duration of COPD which are unalterable (Niewoehner, et al. Chest 2007;131:20). We really only have two treatments for COPD exacerbations, steroids and antibiotics. While steroids may shorten hospital stay (Cochrane Database Syst Rev 2009), there is no evidence that they reduce mortality or readmission rates. Studies for antibiotics in hospitalized exacerbations indicate even less effectiveness. In a recent report randomizing patients to antibiotics for hospitalized AECOPD, no difference in clinical outcome was seen at day 30 (Daniels, et al. AJRCCM 2010; 181:150). Thus we believe it is highly problematic to use an outcome measure where most of the variance will be due to the underlying patient population itself and not the care provided by the individual hospitals. Finally, even if risk stratification strategies are attempted, lung function measures will be most important in that risk stratification. Only about 1/3 of patients diagnosed in this country with COPD even have had spirometry performed (Han, et al. Chest 1007;132(2):403), and obtaining spirometry during the hospitalization is impractical and likely impossible. These measures appear to be more than anything else a measure of baseline disease severity. While we are very much in favor of trying to improve quality of care and outcomes for this patient population, it is unclear that we have tools at our disposal at the current time to meaningfully impact these very short term outcome measures.</p> <p>MeiLan K. Han, MD, MS, Fernando J. Martinez, MD, MS, DeAnn VanSickle, BSN, RN</p>			

Comment #	Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
			<p>Indiana Internal Medicine Consultants/Center for Respiratory and Sleep Medicine Response to Potential CMS COPD Quality Measures:</p> <ul style="list-style-type: none"> (1) 30 day, all-cause mortality following hospitalization for acute exacerbation of COPD (2) 30 day, all-cause readmission following hospitalization for acute exacerbation of COPD <p>Our cohort for inclusion will include all patients admitted to the hospital with a diagnosis of acute exacerbation of chronic obstructive pulmonary disease. Patients eligible for inclusion will be those admitted to the hospital with acute exacerbation of chronic obstructive pulmonary disease. Exclusion criteria will include a concomitant diagnosis of congestive heart failure exacerbation, unstable angina, patients with multiple morbid illness with expected survival of less than 6 months, patients with an active diagnosis of lung cancer, and patients with advanced dementia. Our strategy to decrease hospital readmissions and improve quality of life in these patients will be close follow-up, within 1 week after discharge. Also, we will stress protocolised management of COPD including the COPD action plan and extensive education.</p> <p>Khalil Diab, MD, Christina Ashworth, NP, Tina Elliot, CMA, Bob Daly, Aaron Bruns</p> <p><u>In Conclusion</u></p> <p>AMGA's Learning Collaborative programs represent creative, promising solutions to better management of chronic illnesses. Over the years, through their participation in these Collaboratives, AMGA members have been able to demonstrate dramatic improvements in patient outcomes, document their successes, share lessons learned, and change the way by which they deliver care.</p>			