



June 18, 2010

Department of Health and Human Services
200 Independence Avenue, SW
Room 736-E
Washington, DC 20201
Attention: MCC Strategic Framework

**RE: Federal Register/Vol. 75. No 96/Wednesday, May 19, 2010/Notices; 28023-28024 -
Solicitation of Written Comments on Draft Strategic Framework on Multiple Chronic Conditions**

To the US Department of Health and Human Services Interagency Workgroup on Multiple Chronic Conditions:

The COPD Foundation is the national not-for-profit organization solely dedicated to representing individuals with COPD in the United States. COPD, or Chronic Obstructive Pulmonary Disease, is an umbrella term used to describe progressive lung diseases, encompassing emphysema, chronic bronchitis, refractory asthma, and severe bronchiectasis. The COPD Foundation respectfully submits these comments in response to the above referenced FRN regarding the Draft Strategic Framework 2010-2015. The Foundation is surprised that upon reviewing the FRN COPD is not mentioned as a leading problem for multiple chronic conditions that will benefit from advances in the development and testing of new approaches to coordinated care and management, patient centered benefits, and quality measures. For too long, the serious issues faced by both patients and healthcare professionals dealing with MCC have been addressed in a piecemeal fashion and this new Department of Health and Human Services (DHHS) effort is a major step towards creating a coordinated and comprehensive approach. COPD will directly benefit from the MCC approach and should be included when designing and implementing programs that will achieve all of the goals outlined in the Strategic Framework.

We wish to note that COPD is characterized by increasing breathlessness and is preventable and treatable. Smoking is not the only risk factor for COPD; second-hand smoke, occupational exposure, air pollution and genetic risk factors like Alpha-1 Antitrypsin Deficiency also cause COPD. NIH estimates that 12 million adults have COPD and another 12 million are undiagnosed or developing COPD. **COPD is currently the fourth leading cause of death in the US and is estimated to be the third leading cause of death in the US by 2020.** Many believe that COPD is on the rise because it lacks a significant public health infrastructure and has not been a focus of the Chronic Disease Division at the Centers for Disease Control and Prevention. Individuals diagnosed with COPD are subject to multiple co-morbidities and therefore suffer from multiple chronic conditions which we address later in this document.

The COPD Foundation was established to speed innovations which will make treatments more effective and affordable, undertake initiatives that result in expanded services for COPD patients, and improve the lives of patients with COPD and related disorders through research and education that will lead to

prevention and someday a cure for this disease. The COPD Foundation is currently engaged in applied public health programs such as the Mobile Spirometry Unit and advocacy aimed at enhancing data collection through the addition of a COPD module on the BRFSS. The COPD Foundation has developed comprehensive provider and patient self-education tools and has collaborated with professional societies in the design of continuing education courses.

The Draft Strategic Framework presents a well thought out approach to ways in which DHHS can begin addressing the needs related to the care of people with MCC. In the following comments the COPD Foundation aims to identify strengths and weaknesses of the strategies presented using our experience with the COPD medical and patient community, as well as identify gaps in the approaches that can supplement the existing framework. We are puzzled that the draft framework is titled “2010-2015”; if this document is meant to inform programs that will be implemented by DHHS we would assume that it would be associated with the upcoming fiscal year to be appropriated and forecast five years out. For instance to have the appropriate federal response we would assume the document to be targeted at 2012-2017 so that funding can be allocated. If we have misunderstood the use of federal resources to target these programs we hope that this will be explained in the final Strategic Framework document.

Major research efforts in the past decade have attempted to better understand the pathogenesis and manifestation of COPD. What has emerged from these efforts is a clear recognition that the typical COPD patient is not just experiencing one chronic disease, but rather they mirror the growing trend of people with MCC. In a 2006 survey of 3,000 households with one reported diagnosis of COPD, 81% of respondents described having over 6 co-morbid conditions. The survey found that the higher number of co-morbid conditions corresponds to worse health status and correlates to the larger number of pills taken daily. Additionally the survey uncovered that despite significant symptoms, functional limitations, and health care utilization, surveyed COPD patients appear to be receiving less than maximal medical COPD therapy. COPD has been shown to be associated with a number of chronic conditions including heart disease, diabetes, osteoporosis, depression and anxiety among others. While the exact linkage between the conditions is not proven, there is increased evidence that there is systemic inflammation not just lung inflammation that may lead to the development of these other co-morbid conditions as well as hold keys to possible treatment targets.

- Goal 1: Provide better tools and information to health care and social service workers who deliver care to individuals with MCC

The COPD Foundation strongly supports this goal and recognizes the importance of Objectives A-C. Multiple guidelines and best practices have been developed for COPD and other chronic conditions. In COPD alone there are four sets of clinical guidelines that in some cases contradict each other. In order for Objective A to help achieve Goal 1, attention should be paid to harmonizing clinical guidelines and disseminating clear, concise information that will help physicians provide the best quality of care at the clinical level. Additionally, a set of guidelines designed for a particular disease must include specific details on how each recommendation may impact possible co-morbid conditions. A set of best practices related to all those with chronic diseases, such as vaccine recommendations, can be utilized to improve management. Attention should be paid to ensuring compliance with the tools that are developed but caution should be taken to ensure that the incentives provided do not interfere with the physician-

patient relationship. The COPD Foundation would ask that the voluntary health sector be looked to in order to facilitate the development and dissemination of the tools mentioned under Objective A.

The COPD Foundation also encourages the inclusion of MCC related education in health education curriculums including medical schools, physician assistant programs and nursing schools, and would suggest that methods of ensuring adequate knowledge on the subject be developed and incorporated into licensure and employment screening procedures as well as continuing education requirements.

- Goal 2: Maximize the use of proven self-care management and other services by individuals with MCC.

Self-management of chronic diseases, especially COPD, is a critical component to improving health status and quality of life; however, patients need education and simple tools to use for this purpose. The COPD Foundation encourages the inclusion of a strategy focused on communicating the availability of self-care management tools in Objective A. The tools that are developed will only be effective if the patient and provider community are aware of their existence and proven benefits.

Many valid tools have been developed by disease specific programs and voluntary health organizations, but efforts must be made to incorporate information on MCC management into existing resources. Collaborations can be formed to ensure disease specific management programs address the common co-morbid conditions in their materials.

The COPD Foundation supports the strategies outlined in Objective B but would caution that home health interventions must be performed by properly educated and trained professionals. Additionally, the inclusion of home health and community services by trained healthcare workers in reimbursement policies can dramatically improve the management of individuals with MCC. In the case of COPD, making the services of a Registered Respiratory Therapist available under the general supervision of a physician would provide patients and their caregivers with accessible education and maintenance services.

The COPD Foundation agrees with the strategies outlined in Objective C but would encourage an addition of a strategy detailing dissemination and education methods to patients to further clarify how the tools will be provided to patients. Further, a strategy aimed at utilizing trained allied healthcare professionals to ensure continued compliance outside of the hospital or office setting would help to accomplish the stated objective.

- Goal 3: Foster health care and public health system changes to improve the health of individuals with MCC

The COPD Foundation recognizes the shortfalls in the current payment mechanisms and delivery structures of the healthcare system and supports the Objectives of better care coordination and proven patient care management models. When evaluating changes and new care management models it is important to consider the setting where care is given, i.e. care models for hospital care may work differently based on the structures of the hospital itself. Additionally, attention should be paid to more efficiently coordinating the transition from hospital to outpatient care. It is important in individuals with

MCC who are hospitalized for complications from one condition to have communicated necessary information with providers addressing other co-morbid conditions in the outpatient setting.

The COPD Foundation recommends that attention be paid to properly constructing and evaluating any pilot programs mentioned in Objective A. Previous pilot projects in chronic disease management have not allowed sufficient enough time for evaluation and achieving the goal of cost neutrality is difficult to realize in the given time frame for demonstration projects. Many chronic conditions manifest over long periods of time and care management models may be effective at reducing long term costs when initial results did not suggest the same.

The COPD Foundation encourages the inclusion of reimbursement for education services provided by allied health care professionals prior to hospital discharge as a strategy under Objective B. Previous research efforts done in the VA medical system found a 41% reduction in hospitalizations for COPD when patients received a 90 minute education session from a Respiratory Therapist, followed by monthly follow up phone calls. The COPD Foundation endorses and supports the comments submitted by the American Association for Respiratory Care regarding Goal 3, Objective B, as respiratory therapists know first-hand the devastating effects to the quality of life of persons with multiple chronic conditions. Further, the AARC is more than aware that the readmission rate for such individuals is on the rise especially those with respiratory diseases such as COPD, who often present with multiple co-morbidities.

The COPD Foundation supports Objective C but stresses that any incentives developed for better care should not have the unintended effect of discouraging physicians from taking on complex patients with MCC.

The COPD Foundation is encouraged by the incorporation of health information technology as a tool in Objective D but would caution that the benefits of HIT will be limited by interoperability problems across the many settings in which individuals with MCC receive treatment. Additionally, a strategy addressing patient's fears related to HIT is warranted in order to encourage the greatest use and benefit of the technology.

The COPD Foundation believes there is a great deal of merit in the strategies under Objective E but would recommend the inclusion of strategies aimed at changing life-style related factors that contribute to the formation of new conditions in individuals with MCC. In addition the COPD Foundation recommends the development of a comprehensive vital sign list that is used in individuals with MCC to detect early any possible new conditions.

- Goal 4: Facilitate research to fill knowledge gaps about individuals with MCC.

In a 2007 survey by the COPD Foundation, 61.1% of primary care physicians reported that their education in COPD was inadequate for their needs. While education is a critical element in achieving improved care for patients with MCC the significant gaps that exist in research should be carefully constructed and conducted if they are to be meaningful. For instance, one of the most effective therapies in the treatment of COPD is the use of supplemental oxygen. However, oxygen therapy continues to be a target for cost containment within the Medicare system causing access problems for home oxygen patients. We have long advocated for studies that include evaluating oxygen saturation

levels for patients that are discharged from the hospital and placed on home oxygen therapy. An appropriate evaluation by a qualified allied health professional such as a respiratory therapist not associated with a DME company may avoid the continued payment for equipment that is not being utilized.

Comparative Effectiveness Research will also only be effective in bending the cost curve if the correct questions are posed and evaluation is based on the construct of proper matrix. Understanding and evaluating MCC may hold the key to appropriate research in the area of CER as the whole patient is taken into account.

We are encouraged by the acknowledgment in the draft Framework's review that the classic clinical research approach of eliminating those with significant co-morbid conditions creates a set of patients unlike those that health care providers deal with in real life situations. We feel strongly that this approach must change.

We would also stress again the need for research to develop guidelines that deal with the entire individual rather than disease specific instructions only dealing with one of the possible MCC. Further research into the concept of COPD as a systemic disease will help to uncover whether accelerated ageing or ongoing systemic inflammation play critical roles in the development of co-morbid illnesses. The concept that in COPD ongoing lung inflammation somehow leads to systemic inflammation which then leads to or contributes to endorgan damage has already generated a great deal of interest but clearly requires more research. Indeed this concept of importance of systemic inflammation leading to endorgan damage may well be critical in numerous disease states. We believe that COPD therefore may well be a prime area for investigation as a paradigm of chronic disease especially in view of its growing importance, morbidity, mortality and cost.

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Supplement 1: Summary of COPD Co-morbidities Survey

In 2006 at the American Thoracic Society's International Conference in San Diego, the COPD Foundation presented the results of the survey it took on COPD and co-morbidities. Dr. Byron Thomashow and John W. Walsh, presented the results of a survey conducted to 1,003 over the telephone (from an existing list of households in which at least one person reported a diagnosis of COPD), and 2,029 Internet surveys which were completed from COPD patients referred from national COPD organizations.

The Survey

The goal of this survey was to study the incidence of co-morbid diseases and impact on care received of individuals diagnosed with COPD. Previously this topic was relatively unstudied. The survey instrument had over 75 questions and addressed conditions such as diabetes, osteoporosis, depression, heart disease, and stroke, among others. Results of the study indicate co-morbidities are extremely common in the COPD population and add significantly to the complexity and cost of COPD care. The survey also suggested that despite significant symptoms, limitations, and health care utilization, surveyed COPD patients appear to be receiving less than maximal medical COPD therapy yet seem remarkably satisfied with the level of care. Those better connected to national COPD organizations appear to receive COPD care closer to suggested guidelines.

Co-Morbidity Findings

The main objective of the *COPD and Co-Morbidities Survey* was to explore what chronic diseases COPD patients suffer, the extent of these illnesses and whether the patient is taking medications for these additional illnesses. 81% percent of COPD patients in the household sample described having over 6 co-morbid conditions as compared to 69% in organizational sample. The breakdown revealed that 19% of the household sample reported 1 to 5 co-morbidities as compared 30% of the organizational sample, while 47% reported 6-10 co-morbidities in the household sample as compared to 53% of the organization sample. For those reporting 11-15 co-morbidities, over one-fourth (27%) of the household sample reported this number while only 14% of the organization sample reported 11 to 15 additional illnesses. Finally, 7% of the household sample reported over 16 co-morbidities while only 2% of the organization sample reported this number. The higher number of co-morbidities in the household sample corresponds to their worse health status. This greater number of co-morbidities also correlates to the larger number of pills taken daily as reported earlier: 59% of individuals in the household sample reported taking over 5 prescription medication per day compared to 48% in the organizational sample.

Other Findings

The study found that the majority despite preconceptions, COPD affected more women than men; in both groups, female respondents were more prevalent with 58% of household respondents being female as compared to 64% of organization respondents. Thus, overall 38% of survey respondents were male with 62% being female.

Results also showed that 30% of respondents in the household sample reported their health status as poor, 35% as fair, 25% as good and 8% as very good. This compares to only 21% of the organization sample as reporting their health status as poor, 35% as fair, 30% as good and 12% as very good. Thus, only 35% of the household sample views their health as good or better as compared to 44% of the organization sample.

Interestingly, while the household sample self-reported a relatively poor health status, they were less critical of the medical care they received while the organization sample was more critical despite better self-reported health. When asked how satisfied they were with the medical care they receive, over half of the household sample (55%) as compared to two-fifths of the organization sample (42%) said they were very satisfied. An additional third of the household sample and 45% of the organization sample said they were somewhat satisfied. Only 14% of the household sample and 13% of the organization sample were either somewhat or very dissatisfied with their medical care. It appears that overall these patients believe their health cannot be seriously improved.

COPD patients in both samples were asked how well informed they felt they were about their condition and treatment. Over 80% in both samples believed they were adequately or very well informed about their condition. Interestingly, nearly half of the household sample considers themselves very well informed as compared to only one-third of the organization sample. However other findings suggest the household sample is over-confident in their knowledge of COPD and its treatment. The most common sources of information were physicians (93% of the household and 86% of the organization sample), nurses (57% of the household as compared to 43% of the organization sample), books and magazines (46% household and 43% organization), television or cable (30% household and 13% organization) and the Internet (69% household and 90% organization). Of note only 12% of the household sample and 26% of the organization reported getting COPD information from patient organizations. Also of note, the Internet is the main source of information for the organization sample and the second most important source for the household sample.

Below is a table describing the prevalence of co-morbidities of those interviewed:

Survey Results: Incidence of Major Co-Morbidities

Co-morbidity	Household	Organizational
Arthritic Pain	70%	70%
Cancer	17%	17%
Cardiac	58%	45%
Diabetes	25%	12%
Depression	35%	35 %
Female Osteoporosis	39%	44%
Heartburn	65%	62%
Hyperlipidemia	52%	50%
Hypertension	55%	50%
Male Impotence	37%	43%
Sinus Disease	58%	58%
Sleep Apnea	26%	17%

Conclusion

Conclusions that were drawn from the survey findings could be described in three points:

1. Despite significant symptoms, limitations and health care utilization, surveyed COPD patients appear to be receiving less than maximal medical therapy yet seem satisfied with the level of care.
2. Those better connected to national COPD organizations appear to receive COPD care closer to guidelines.
3. Co-morbidities are very common and add to the complexity and cost.

In an era of increasing physician time restraints, these multiple medical problems plus overall patient satisfaction with COPD care may prevent COPD from receiving the attention it deserves. Therefore, it is important to address the knowledge gap issues in medical professional education, and in the patient population.

Supplement 2: Results from a COPD Disease Management Survey

**Disease Management Program for Chronic Obstructive Pulmonary Disease: A
Randomized Controlled Trial**

Kathryn L Rice, Naresh Dewan, MD, Hanna E. Bloomfield, MD, MPH, Joseph Grill, MS, Tamara M. Schult, MPH, David B. Nelson, PhD, et al.

American Journal of Respiratory and Critical Care Medicine, February 2010

Objective: To determine whether a simplified disease management program reduces hospital admissions and emergency department (ED) visits due to chronic obstructive pulmonary disease (COPD).

One year randomized, controlled trial at five VA medical centers. "To our knowledge this is the largest published randomized trial of disease management in patients with COPD"

Measurements: The combined number of COPD-related hospitalizations and ED visits per patient.

Control Group: 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.

COPD Management Group: "Patients assigned to the disease management arm attended a single 1 1/2 hour group education session conducted by a **respiratory therapist** case manager. The patient 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...."

We required only a single on-site educational session supplemented by monthly reinforcing telephone calls, all of which were performed by **respiratory therapists**.

Results: After 1 year the primary outcome rate of hospitalizations 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**.

Conclusions: A relatively simple disease management program reduced hospitalizations and ED visits for COPD. "Although a formal cost benefit analysis has not been done, this intervention shows potential for reducing health care costs in addition to improving quality