



June 22, 2015

The Honorable Orrin Hatch
Chairman
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Johnny Isakson
United States Senator
131 Russell Senate Office Building
Washington, DC 20510

The Honorable Mark R. Warner
United States Senator
475 Russell Senate Office Building
Washington, DC 20510

Dear Chairman Hatch, Ranking Member Wyden, Senator Isakson, and Senator Warner:

The American College of Rheumatology, representing over 9,500 rheumatologists and health professionals, acknowledges the importance of the Finance Committee's proactive step to form a chronic care working group, and its efforts to develop policies that will improve outcomes for Medicare patients with chronic conditions. We appreciate this opportunity to provide specific suggestions that will incentivize the appropriate level of care for patients living with chronic diseases, facilitate the delivery of high quality care, produce superior outcomes, and reduce growth in Medicare spending.

Rheumatologists treat patients with serious chronic conditions that can be difficult to diagnose and treat, including rheumatoid arthritis, osteoarthritis and other debilitating and potentially-disabling rheumatic diseases. Rheumatologists primarily provide face-to-face, non-procedural care in which they evaluate and manage patients' complex chronic and acute conditions. Early access to a rheumatologist who can prescribe timely interventions have been shown in numerous well-designed studies to improve patient outcomes and prevent disability and costly procedures. Although many diseases are managed by primary care internists and family practitioners, some diseases require expertise beyond that of primary care providers and are best managed by specialists trained to diagnose and treat them. Rheumatologists constitute a specialty that provides ongoing care for Medicare beneficiaries with complex chronic and acute conditions that require expertise beyond that of primary care providers. Although rheumatologists are not primary care providers, we are trained in Internal Medicine and are the principal care providers for many of our patients.

Background: Rheumatic diseases are the number one cause of disability and lead to higher costs than cancer care

Inflammatory rheumatic diseases cause more disability in America than heart disease, cancer or diabetes. Over 11 million American adults suffer from inflammatory rheumatic diseases. Rheumatic diseases of this nature include the group of autoimmune and inflammatory diseases that cause the immune system to unleash an attack on a person's joints, muscles, bones and other organs. Rheumatic diseases are often lumped under the term arthritis — a term used to describe over 100 diseases and conditions.

Although the demand for rheumatology services is expected to increase by 46 percent through the year 2025, it is expected that the number of practicing rheumatologists in the same period will only increase by 1.2 percent. This shortfall in supply is unacceptable to the patients who suffer from rheumatic diseases and to the rheumatologists who treat them. It is expected to lead to significant increased cost because of greater health care spending on extended hospital stays and tests, not to mention the indirect costs of increased unemployment and disability payments. The latest figures show arthritis and rheumatic disease cost the U.S. \$127.8 billion, compared to \$124.6 billion in costs for cancer care.

A central challenge facing patients living with chronic diseases is access to health care, and there are two primary components of access which must be improved: (a) access to providers, and (b) access to treatments. We hope you will take further action to improve patient access in each of these areas. We recommend the following specific policies that will increase access to rheumatologic care and treatments, thereby improving outcomes and preventing costly procedures and costs associated with disability and the progression of rheumatic disease.

I. Access to Care for Patients with Chronic Disease

Increasing Access to Rheumatologists Will Improve Patients' Outcomes and Prevent Costly Procedures and Disability

The most recent workforce study conducted by the ACR examining the number of adult practicing rheumatologists in the United States estimated approximately 1.7 adult rheumatologists exist in the U.S. per 100,000 persons. With the aging U.S. population and lack of growth in the number of rheumatologists, experts projected that by 2025 there would be a severe shortage of 2,500 rheumatologists. Additionally, a 2010 study analyzed the distribution of rheumatology practices across the U.S. **The study found that several regions with populations of 200,000 or more have no practicing rheumatologist in the area.**

The ACR is concerned about growing shortages of rheumatologists, especially given the increasing population of Medicare beneficiaries who will need rheumatology care coupled with the influx of patients expected with continued implementation of the Affordable Care Act. **The expertise rheumatologists and other cognitive specialists provide to their patients should be more appropriately valued. If their expertise is not appropriately valued, then the numbers of these specialists will continue to dwindle along with Medicare beneficiaries' access to these specialists.**

Rheumatologists are cognitive specialists. Cognitive specialists are physicians with additional training who primarily provide face-to-face, nonprocedural evaluation and management (E/M) services to people with complex medical conditions. **On average they bill more than 60 % of their charges to Medicare under the same E/M codes as primary care physicians, have similar incomes and face the same recruiting problems.**

Frequently, cognitive specialists are able to prevent patients from having costly procedures by identifying and appropriately treating patients early. Examples include providers who treat complex chronic conditions such as rheumatologists who manage patients with rheumatoid arthritis; neurologists treating multiple sclerosis and epilepsy; and endocrinologists managing diabetes and its complications. Congress has recognized a crisis in primary care. But the profound difference in the payment between the care provided by procedural and cognitive specialists has

consequences— namely, **limiting the access to care from a rheumatologist where superior outcomes may come lower costs.**

Proposals to improve the practice climate for PCPs continue to focus on specialty designation rather than care provided to patients. Not including cognitive specialists in the Primary Care Bonus and similar proposals can leave cognitive physicians with lower reimbursement than PCPs for patients that the PCP is referring to the cognitive specialist, even though they bill the same E/M codes and the patient is receiving expert specialty care, and despite the additional years of education and training required. **Continuing to focus on specialty designation rather than care provided by physicians will further erode the supply of rheumatologists and other cognitive specialists.** Until action is taken to more appropriately value E&M services, the workforce challenges in rheumatology and other cognitive specialties will negatively impact the care of patients with complex chronic conditions, such as rheumatoid arthritis and lupus.

Recommendation 1: Create new evaluation and management (E&M) codes that accurately reflect the time and expertise of cognitive specialists who primarily provide E&M services.

Over the last twenty-five years, the expectations for optimal care of chronic illness have caused a paradigm shift for Medicare beneficiaries. New and complicated diagnostic and treatment algorithms have emerged with the increased understanding of complex presenting symptoms and disease states, as well as the early identification and prevention of disease complications. There has been an explosion of treatment options with increasingly complicated interactions among specialists and . **Rheumatologists and similar specialists regularly treat patients with multiple coexisting chronic conditions, often utilizing multiple medications for effective care.** Physicians spend less of their time treating acute illnesses and more of their time, appropriately, trying to ensure optimal outcomes efficiently. This work involves brief, focused physical exams, the determination of patient goals, medication reconciliation, the assessment and integration of hundreds of data points, the effective coordination of multiple consultants, collaboration with team members, continuous development and modification of care plans, patient or caregiver education, and constant communication.

A byproduct of this transformation in care is that the CPT codes for outpatient E&M services no longer describe the work performed by physicians and their clinical staff. Specifically, the existing office codes (CPT 99201-5 and 9921-5) no longer accurately or adequately reflect the work currently provided to and required by Medicare beneficiaries. **As new payment models are implemented, it is critical that CMS create a new set of codes to describe the work involved in evaluation and management services provided by cognitive physicians.** We support CMS engaging in an evidence based research process to establish new codes better describing cognitive services. This will incentivize appropriate level of care for patients living with chronic diseases.

The E&M codes are significantly flawed and do not reflect the following:

- The increase in the complexity-density of E&M work resulting from the expansion of inputs and outputs from medical decision-making.
- Physicians' focus on caring for lifelong, chronic illnesses, preventing complications from these illnesses and/or exploring complicated diagnostic and therapeutic pathways.
- The post-visit work – including care coordination, patient counseling, and other necessary follow up - extends well beyond what is included in these codes. To properly address these issues, we proposed that CMS commission perform the necessary research to define new E&M codes and the accompanying documentation requirements. We estimate that this research would take two years

and cost approximately \$20 million (\$10 million per year). CMS has indicated it will do this work if the necessary funds are identified.

In summary, as long as the service codes used for fee-for-service payment remain the foundation for reimbursement in new payment models, the inequities of the current system will remain. Cognitive physicians routinely address more than one chronic condition in a single patient visit and coordinate and manage care for patients as a member of a multidisciplinary team outside of the face-to-face patient visit. This work is not adequately described by the current evaluation and management codes. The ACR, and other non-procedural physician societies, has been engaged in discussions with CMS leadership on this important issue, and we have proposed how CMS can create an evidence base for new E&M codes. It is critical that CMS hear of the support of the Senate Finance Committee regarding this important issue. **Revaluing E&M codes should be a primary focus of the Senate Finance Committee's efforts to bolster chronic disease management.**

CMS should hire a contractor to work with stakeholders to develop a comprehensive understanding of what physicians and their clinical staff do on a daily basis. This research would 1) describe in detail the full range of intensity for outpatient E&M services, 2) define discrete levels of service intensity based on this observational, electronically stored data combined with expert opinion, 3) develop documentation expectations for each service level that place a premium on the assessment of data and resulting medical decision making, 4) provide efficient, meaningful guidance for documentation and auditing, and 5) ensure accurate relative valuation as part of the Physician Fee Schedule. **Congress should ask CMS to execute this research over a 2-year period.**

Recommendation 2: Include in any per beneficiary Medicare primary care payment all physicians regardless of specialty designation who bill at least 60 percent of charges under qualifying codes (60% or more E&M)

This will incentivize appropriate level of care for patients with chronic rheumatic diseases and facilitate the delivery of high-quality care. Both the Primary Care Bonus and MedPAC's proposed per beneficiary payment are **profoundly unfair to millions of Medicare beneficiaries who rely on physicians other than primary care providers to coordinate the care of their chronic conditions.**

As drafted, the MedPAC per beneficiary payments for primary care would pay physicians a monthly fee for coordinating care for Medicare beneficiaries. Although we believe this policy is a good idea, MedPAC chose to restrict the payment only to the listed specialties of family medicine and general internal medicine. **This excludes many physicians which commonly coordinate care for patients with chronic diseases such as Alzheimer's, rheumatoid arthritis, diabetes, HIV, mental health conditions and many other serious, complex conditions and are in the principle providers of care and care coordination for their patients.** As the Committee considers this recommendation, it is important to understand there is no code in the fee schedule for "primary care services." Physicians who see patients face-to-face bill Medicare under new or established patient E/M visits. Primary care physicians (PCPs) and cognitive physicians bill identical codes and either may coordinate care for individual patients.

Distinctions made among providers should be between physicians who mostly provide evaluation and management services and those who mostly provide procedures, not primary care versus specialty care. In fact, the National Commission on Physician Payment Reform stated in March 2013, "[w]hile the discussion about reimbursement has generally focused on services performed by

primary care physicians, the commission believes that the real issue is not one of relative payment of specialists versus primary care physicians but, rather, of payment for E&M services as contrasted with procedural services.” While the Primary Care Bonus and per beneficiary payment envisioned by MedPAC seek to remedy these inequities, as currently proposed the policies will continue the inappropriate policy of providing reimbursement based on specialty designation, rather than services provided. **This will further compound the challenges already facing cognitive specialties, ultimately leading to even greater access to care problems for some of Medicare’s highest need, highest cost beneficiaries with chronic diseases who rely on cognitive physicians.**

Recommendation 3: Medicare Advantage: Prohibit Overly Restrictive Provider Networks

The ACR understands that both the federal government and the private payment sectors will need to identify innovative solutions to control costs. However, **overly restrictive provider networks, intended to control costs, are restricting access to care.** These include some geographic restrictions on crossing state lines for care, even when services are cheaper and closer in a neighboring state. They also include changing of provider networks after open enrollment periods end. Informed consumers shopping in the marketplace should be able to tell if the doctor they wish to see is included in that payer’s network for the entire year until the next open enrollment. The restrictive provider networks also create an access problem in which they do not include adequate numbers of certain types of physicians within a payer network.

Of particular importance to rheumatologists and patients living with chronic diseases are issues pertaining to access to care and treatments. The ACR is concerned that **insurance networks that are overly restrictive in order to control costs limit patients’ access to care, which in turn, can place patients at increased risk for progression of joint damage, disability and related comorbidities owing to substandard medical care.** Ill-advised restrictions on access to appropriate care lead to complications that increase health care costs over the long-term.

We also believe that truth in advertising for health insurance plans is essential for patients and physicians alike. Patients expect to have access to those specialists in their health insurance plan at all times. Patients should not be denied access to specialists because their plan will no longer reimburse physicians for the cost of specialty care. Patients also expect to have access to specialists in their geographic area whenever possible. Specifically, we recommend the following:

- Require insurers to set their provider networks in advance of open enrollment.
- Ensure providers remain on a network unless the insurance company can “show cause” for their removal.
- Encourage insurance networks to have sufficient, reasonable access to specialty physicians.
- We recommend that Medicare Advantage plans, as part of the MA application process, should be required to file with CMS the source and mechanisms used to update each piece of information in the directory. Should a plan be found to have an inadequate network directory, this filing would create an audit checklist that would help in determination of whether the plan was at fault for the erroneous data or if they must make improvements in their data validation methods. Additionally, if CMS understands how each plan approaches collection of provider data, it can provide a basis for the initial development of the nationwide provider database.
- Further, the ACR recommends that CMS utilize a uniform and centralized form or directory for providers to update which automatically pushes updated provider data to plans indicating they have an active contract with a provider. The form could be updated by providers when they

change any of the following: location, hours of operation, whether they are taking new patients, general availability as deemed appropriate by CMS, and if they opt out of a network.

- If a plan terminates a physician's network status, it should be the plan's responsibility to update its directory.

II. Access to Treatments

Increasing Access to Treatments will Improve Outcomes and Prevent Costly Procedures and Disability

Better access to therapies will produce stronger patient outcomes and in the long run reduce growth in Medicare spending and costly procedures and comorbidities. With the introduction of biologics and other novel therapies, there have been dramatic improvements in our ability to care for patients living with chronic diseases. Patients with chronic rheumatologic diseases need access to these effective therapies to enable daily functioning and pursuit of their livelihoods. But these innovative medications are very expensive, often costing more than 20 thousand dollars per year. When insurers demand excessive cost sharing for these medications, it leaves the average American without access to affordable beneficial treatment.

Recommendation 4: Support better access to treatments under the Medicare Part D program.

The inception of the Medicare Part D program has greatly increased Medicare beneficiaries' access to medication by providing drug coverage. However, some aspects of the program are burdensome to providers, while others limit access to medications integral to the treatment of rheumatic diseases. We recommend the following:

- Support legislation that allows Medicare to negotiate with pharmaceutical companies to achieve more affordable pricing of drugs covered under Part D.
- Part D benefits should not limit, incentivize, or otherwise steer doctors or patients away from the medical therapy judged by the treating rheumatologist to be the most efficacious choice. Allowing the most appropriate and efficacious therapy as judged by the treating physician can also result in long-term cost savings.
- The ACR supports elimination of the Medicare Part D "doughnut hole".

Recommendation 5: Prohibit overly restrictive drug formularies

Health insurance provider formularies that are overly restrictive in order to control costs limit patients' access to care. Formulary restrictions and in-year formulary changes are resulting in restricted access to treatment. Payers should be restricted from changing drug formularies outside of open enrollment periods. Informed consumers shopping in the marketplace should also be able to tell if the medication they may need is included in that payer's formulary for the entire year until the next open enrollment.

Recommendation 6: Prohibit excessive patient cost sharing

Biologic drugs like those used to treat rheumatoid arthritis, psoriatic arthritis, lupus, and other rheumatic diseases, are breakthrough treatments that can prevent disability, save and improve lives, and allow patients to function and remain in the workforce. Biologics are FDA approved and

have no inexpensive, generic equivalents. They can prevent patients with rheumatoid arthritis, MS, lupus, hemophilia, and certain cancers, from becoming disabled, seriously ill, or even dying. **In RA patients, lack of access to these disease-modifying therapies can result in permanent joint damage and disabilities, and costly surgeries.**

A disturbing and increasingly common practice for payers is to charge co-insurance for these “specialty drugs” often at 30-40% of the total charge or several thousand dollars per month, creating a barrier to treatment access for many insured patients. This practice existed before the ACA but has accelerated in the marketplaces. Charging vulnerable patients excessive co-pays is an unnecessary step. **Data shows that small premium increases, around \$3 per beneficiary annually across a plan, would obviate the need for this practice and restore treatment access for patients with many chronic, disabling, and life-threatening diseases.** Enacting H.R. 1600, the *Patients’ Access to Treatment Act* (PATA) would accomplish this by limiting the cost sharing insurers may require of patients. H.R. 1600 limits specialty drug cost-sharing (Tier IV and higher) to the plan’s level of cost-sharing for non-preferred brand drugs (Tier III). PATA applies to the commercial insurance market. We recommend similar policies for Medicare Part D, in which specialty tier practices limiting treatment access run rampant.

Recommendation 7: Allow beneficiaries to accept financial co-pay assistance for specialty cost tier drugs from pharmaceutical companies, for Part B and Part D drugs.

Biologic response modifiers, cancer chemotherapies and other medications have been recognized as breakthrough treatments for patients with diseases such as rheumatoid arthritis, multiple sclerosis, hemophilia, hepatitis C and some cancers. There are no less expensive generic equivalents. However, the expense of utilizing these treatments can quickly escalate, rapidly exceeding the cost that Medicare Part D will cover, but not reaching the range of catastrophic coverage in place for Part D. As a result, many patients must forego life-changing treatments solely because of their expense. Ideally, the ACR would like Medicare to simply cover the cost of these essential treatments for chronic, non-curable diseases. In the absence of such a basic solution, the ACR supports an alternative approach.

Patient Assistance Programs sponsored by pharmaceutical manufacturers provide access to critical treatments for patients who otherwise would not be able to afford such treatments. However, unlike assistance to other Medicare beneficiaries, **drug companies currently may not offer direct support to Medicare Part D patients because of certain anti-kickback laws.** While some companies have responded by supporting charitable foundations that provide assistance, many patients have difficulty receiving help because they may not qualify or because the foundations’ resources have been expended. **The unintended consequence is that patients are literally forced off disease modifying therapy when they become a Medicare Part D beneficiary.** Congress should modify anti-kickback laws so that Medicare beneficiaries can accept financial co-pay assistance for specialty cost tier drugs from pharmaceutical companies, for Part B and Part D drugs.

Recommendation 8: Provide fair reimbursement for Part B drugs and preventive services

There are significant problems with Medicare and Medicaid beyond those listed above. These include adequate reimbursement for Part B drugs provided in an office setting, such as those provided by infusion. Many patients depend on their rheumatologist to administer biologic drugs that help prevent permanent disability. Treatments provided in rheumatologists’ offices and other outpatient settings are less expensive than treatment provided in hospitals due to the lack of

hospital facility fees. Part B drug payments to physicians are based on the average sales price of the drug plus 6 % intended to help cover infrastructure and overhead including special temperature control and inventory monitoring, safe handling, and specialized staff to prepare the drugs and the patient. Medicare reimburses 80% of ASP plus 6%; the patient pays a 20% copayment.

Sequestration cuts 2% of Medicare's reimbursement for the drugs physicians purchase for their patients. The cuts have reduced reimbursement for the drugs to Average Sales Price plus 4.3%, a 28% cut. Even before the sequester, actual reimbursements for certain drugs were dangerously close to the purchase prices paid for the drugs, placing patient access at risk. These cuts make providing some treatments impossible, especially for smaller private practices. **In many cases patients are forced to seek ongoing treatment in hospitals, often with higher copayments, longer travel times, and without their rheumatologist to supervise complex treatment.** Moreover, it is more expensive for the health care system to provide these treatments in the hospital setting. To remove the threat to patients' access to drugs administered by their doctor, the ACR recommends passage of H.R. 1416, the Cancer Patient Protection Act, which would exempt physician-administered drugs from sequester cuts.

Adequate reimbursement for preventative services is also impairing patient access. For example, bone density testing is now reimbursed at a level below the cost of purchasing, maintaining and operating the machine. Reduced access to testing results in more osteoporotic fractures in the elderly and more cost to the system by having the testing done only in hospital settings. Reimbursement was addressed in the ACA, but the provision expired in 2011 and should be renewed.

Recommendation 9: Address the rising costs of prescription medications

The ACR, through its Rheumatology Research Foundation is the primary non-profit funder of arthritis research after the NIH. We therefore understand the expense associated with research and development, but the funding provided by ACR to its grantees pales in comparison to that expended by industry to support its research and development of new drugs. We recognize that companies deserve to derive profit from their research and development efforts, but we also recognize the burden that the rising costs of new drugs places on the healthcare system and on individual patients who often struggle to pay for the cost-sharing of their treatments. **Meaningful discourse and reform must take place to reduce the cost of medications**, and steps toward this goal could include modifications to discount and negotiating programs, reforms to the drug and device approval process that balance patient safety with the cost of bringing a device to market, and reforms providing transparency in how medications are priced.

The American College of Rheumatology commends your leadership and your commitment to improving outcomes for Medicare patients with chronic conditions. Please call on us as a resource for you as you continue to refine your approaches to this significant goal. If you have questions or if we can assist you, please contact Adam Cooper, senior director of government affairs, at (404) 633-3777 or acooper@rheumatology.org

Sincerely,



E. William St.Clair, MD
President, American College of Rheumatology