2017 ACR Health Policy Statements

Through its advocacy efforts, the ACR will advise and encourage government decision makers to consider policies that will improve healthcare policy outcomes. The ACR's advocacy will support legislative and regulatory policy initiatives that will:

- Improve patient access to rheumatologists and rheumatology health care professionals
- Support equitable and sustainable reimbursement for rheumatologists and rheumatology health professionals
- Improve patient access to therapies
- Increase federal funding for rheumatology research and training

Policy Objectives

Overview of Policy Objectives

I. Improve Patient Access to Care

- Ensure appropriate implementation of the Medicare Access and CHIP Reauthorization Act (MACRA) that protects rheumatologists in the following ways:
    a. Advocate that the components of the new Merit-Based Incentive Payment System (MIPS) use metrics that are clinically relevant, efficient, and promote quality of care.
    b. Advocate for creation and accreditation of a variety of Alternative Payment Models and demonstration projects that recognize the value of care provided by rheumatologists and rheumatology health professionals.
    c. Ensure that participation in a Qualified Clinical Data Registry such as RISE counts toward MIPS categories under MACRA.
    d. Advocate for simplicity and transparency in MIPS and APMs allowing practicing physicians to easily understand and implement these programs.

- Support adequate, affordable and continuous health insurance for all Americans.

- Minimize administrative burdens associated with Electronic Health Records including electronic prescribing, and promote efficiency and interconnectivity.

- Support improved payment for cognitive care services.

- Support relief from certain anti-trust restrictions that bar small practices from negotiating effectively with large insurance carriers.

- Support repeal of the Independent Payment Advisory Board.

- Support reform of Recovery Audit Contractor practices and guidelines.

- Support efficient evidence-based performance measures that improve quality of care and promote fair reimbursement for work done by rheumatologists in collecting and reporting administrative data.

- Support medical liability reform.

- Support legislation to increase transparency and reporting of insurance network and formulary adequacy and safety.

II. Improve Patient Access to Treatment

- Advocate for patient access to appropriate treatments by elimination of specialty drug cost tiering practices, including excessive cost sharing (Tier IV practices) by all payers.

- Support access to patient assistance programs for Medicare beneficiaries for Part B and Part D drugs, and elimination of the Part D "doughnut hole".
- Support improvements to the Medicare Part D program, including allowing Medicare to negotiate drug pricing with pharmaceutical companies.
- Reduce administrative burdens in obtaining coverage for Part D medications.
- Advocate to ensure patient protections, improved quality of care, and increased access to care through reform of managed care regulations.
- Urge a national policy requiring payment for administration of Part B drugs that fall within 'biologic' class of drugs to be reimbursed as complex.
- Advocate that all biologics approved for rheumatic conditions should be covered at an appropriate level by all health plans and considered highly complex for purposes of administration, monitoring, coding and reimbursement.
- Support policies to address the causes of drug shortages and reduce their impact on patients and physicians.
- Support removal of prompt-pay discounts from the "Average Sales Price plus six percent" formula.
- Support patient access to fracture prevention services through increased reimbursement for osteoporosis screening.
- Support distinct names for biosimilars, allowing them to be distinguished from each other and their reference products.
- Oppose payer policies that force patients doing well on current biologic therapy to switch to a biosimilar.

III. Increase Rheumatology Research and Training Support

- Advocate for enhanced funding for basic and clinical research by the NIH, CDC and DOD in areas of arthritis and rheumatic disease and related comorbidities (such as infections, malignancies and cardiovascular disease).
- Support repeal of the sequester and its cuts to research funding.
- Support increased funding for graduate medical education, additional rheumatology fellowship positions, and the Pediatric Subspecialty Loan Repayment Program.
- Support federal Comparative Effectiveness Research programs.

Patient Access to Care

Medicare Payment Reform under MACRA

In April 2015, the Medicare Access and CHIP Reauthorization Act (MACRA) eliminated the Medicare payment system based on the Sustainable Growth Rate formula and implemented a transition period intended to incentivize payments based on value. In late 2016, CMS finalized measures for the new Merit-Based Incentive Payment System (MIPS) to consist of Quality (based on PQRS), Advancing Care Information (based on Meaningful Use), Clinical Practice Improvement (a new program), and Resource use (based on the Value Based Modifier, but which will not be scored in the first year of MIPS). In 2017, providers' performance on MIPS measures will provoke payment adjustments in 2019 unless providers join an Alternative Payment Model (APM).

This framework forces providers to choose between the financial risk of joining an APM and the possibility of overwhelming administrative burdens from the MIPS system. Practices may see fewer Medicare patients or opt out of Medicare altogether if they are not able to succeed under these programs. Patients could be left with longer wait times and travel distance, or increased out of pocket cost to see a rheumatologist.

During this transition, flexibility in the design of the MIPS programs and simplicity in implementation should drive the development of these new programs. Appropriate data and measurements should be used to develop these new programs to ensure there are no biases against certain patients and their physicians.

The ACR Supports:

- Simplifying the MIPS program through reduced reporting requirements and flexibility to account for practice variation.
- Continuing a 90-day reporting period rather than one year reporting for all MIPS requirements in future years.
- Preserving stability through the 0.5% updates promised by law through December 2019.
- Streamlining reporting systems for each MIPS category.
- Using caution when including the cost of expensive medicines in resource use formulas. Drug costs are unpredictable, variable, and derive from prices which rheumatologists are unable to control. Modifying physician payment based on drug costs can incentivize against following current treatment guidelines for use of biologic therapy. If drug costs are included in such formulas, the ACR cannot support including Part B drug costs without also including Part D drug costs.

- Ensuring that providers who participate in a Qualified Clinical Data Registry such as RISE can maximize credit in MIPS categories for doing so.
- Ensuring providers be informed of performance outcomes in real time in order to make changes prior to the next performance period.
- Minimizing barriers to forming virtual groups for the purpose of reporting performance.
- Prompt creation of a variety of alternative payment models which place adequate value on rheumatology care and are feasible for small practices.
- Ensuring new payment models include only those quality measures that are meaningful to patients and simple for providers to implement.

Patient Access to Care

Additional Medicare Reforms

In addition to initiatives related to MACRA, the ACR supports the following Medicare reforms:

- Realignment of payments to ensure an adequate supply of cognitive (nonprocedural) specialists who focus on managing patients with chronic conditions.
- Increases in reimbursement for E&M services, which are undervalued.
- Standardization of documentation requirements for billing E&M services, and greater transparency in reimbursement processes.
- Permanent repeal of the arbitrary Medicare therapy cap placed on outpatient rehabilitation services.
- Reevaluation of the Stark laws against physician self-referral because of changes in health care delivery as a consequence of the Affordable Care Act.
- Opposition to instituting a "user fee" tax on health care providers for participation in the Medicare and Medicaid program.
- Allowing the Congressional Budget Office to use dynamic scoring/longer time frames for scoring of healthcare legislation to more accurately reflect cost savings over time.

Patient Access to Care

Health Reform Efforts in the 115th Congress

Congress is currently considering efforts to reform national health care policy. During this time, the ACR is concerned that people with arthritis and rheumatic diseases may lose access to medical care. The following principles are critical to maintain and improve access to rheumatologic care in the US.

The ACR Supports:

- Sufficient, affordable and continuous insurance coverage that encourages access to high quality health care for all Americans.
- Prohibiting health insurance companies from excluding participants based on preexisting conditions.
- Allowing children to remain on their parent's insurance plan until age 26.
- Removal of excessive administrative burdens which prevent physicians from focusing on patient care.
- Caps on annual out-of-pocket patient costs and a ban on lifetime limits on health care costs.
- Affordable premiums, deductibles and cost-sharing.
- Continuation of the currently-required essential health benefits, in order to ensure patients have access to a robust set of health care services.

Patient Access to Care

Administrative Burdens

The ACR is greatly concerned about the administrative burdens of MACRA in this period of rising costs and uncertainty for physician practices.

The ACR urges reduction of administrative burdens associated with MACRA.

The ACR supports:

- Ensuring a 90-day reporting window for all MIPS categories especially Advancing Care Information.
- Initiatives intended to reduce the administrative and regulatory burden imposed upon health care providers participating in the Medicare program.
- Requiring payers to provide feedback regarding incorrect ICD-10 diagnoses and prohibiting payers from retroactively reclaiming payments due to lack of coding specificity. If a payer were to hold payment based on coding specificity, then a physician would not be paid.

Patient Access to Care

Electronic Health Records

Resources that help clinicians and health systems improve data management are playing a vital role in the transformation of health care. When properly applied, these technologies can lead to significant improvements in patient safety, quality of care, and the coordination of care among providers. Ideally, implementation of health information technology (HIT) systems create a more efficient health system with improvements in patient wait times, medical record documentation, prescribing errors, and communication among health care providers and their patients. Appropriate HIT implementation also provides decision-support for following preventive care and current best-practice guidelines.

The burden for implementing electronic health records (EHRs) should not be shouldered solely by physicians. Vendors are expected to be active participants in the implementation and troubleshooting process and should be held accountable for failures in systems implementation.

The ACR supports:

- The development of efficient, secure, and interoperable standard-based EHR systems and federal financial support to medical practices to defray the cost of implementation.
- Vendors sharing in penalties when compliance goals are not met due to technology implementation problems.
- Preventing information blocking/data blocking with regard to medical registries and interoperability of EHRs.
- Requiring vendors to provide a robust interface to allow communication and data sharing from one EHR to another.

Patient Access to Care

Access to Complex Treatments under Medicare Part B

In 2014, certain Medicare contractors in California and many other states stopped reimbursing physicians at the higher "complex" rate for administering certain complex biologic medications that help prevent disability and death in rheumatoid arthritis and other diseases. The contractors now pay physicians as if routine medications have been given with less monitoring of patient safety. This conflicts with the official guidelines developed by the American Medical Association Current Procedural Terminology (CPT) Editorial Panel. Contractors did not consult physicians prior to changing reimbursement coverage as required by law. This reduction is in addition to the effect of sequestration of infusions. Without proper coverage of these treatments, access to therapy is threatened.

The ACR strongly supports the use of biologics in the treatment of rheumatic disease. Administering all biologics for rheumatic diseases requires advanced training by health care professionals and necessitates special handling of medications and increased monitoring of patient safety. Patients should not face threats to access to biologic treatment based on the region in which they live.

The ACR urges a national policy requiring payment for administration for Part B drugs that fall within 'biologic' class of drugs to be reimbursed as complex.

The ACR supports:

- Reimbursement of biologic infusions in accordance with CPT coding, as biologics for rheumatic diseases require advanced training by health care professionals to infuse and necessitate special handling and increased monitoring of patient safety.
- Enforcement of transparency in the way Medicare contractors consider reimbursement changes.
- Efforts by Congress to ensure seniors have access to medically-necessary biologics.

Patient Access to Care

Appropriate Reimbursement of Cognitive Specialties to Ensure the Viability of Rheumatology

Cognitive care is face-to-face, non-procedural care in which physicians see and speak with patients as they evaluate and manage patients' conditions. Like primary care physicians, rheumatologists and other cognitive specialists provide ongoing care to patients and primarily bill evaluation and management (E&M) codes.

Rheumatic diseases require management by a rheumatologist trained to diagnose and treat these diseases. Through early identification and treatment of these conditions, rheumatologists can prevent the need for costly procedures, and protect patients from disability which impacts quality of life and health care system costs. This is possible because of substantial additional training and expertise acquired by rheumatologists.

The additional training required to become expert in the specialty should be recognized by higher payments than provided to those without such training and expertise. The current payment methodology used by CMS, the resource based relative value system (RBRVS), explicitly precludes valuing expertise in the formula. If there is no differential, the relative numbers of cognitive specialists will continue to diminish and access to care will be further constrained.

Arthritis is the fastest growing health problem worldwide. As the U.S. population ages, it is critical that there be an adequate supply of rheumatologists to properly diagnose and manage care for the growing number of patients with arthritis, musculoskeletal and rheumatic diseases. In fact, the 2015 Rheumatology Workforce Study has identified a substantial shortage of rheumatology professionals predicted over the next 15 years. A lack of appropriate reimbursement exacerbates recruitment challenges and workforce shortages already faced by rheumatologists.

The ACR promotes appropriate reimbursement of cognitive specialties.

The ACR supports:

- The realignment of payment differentials between cognitive and procedure-based specialists to parity to help ensure an adequate long-term supply of rheumatologists.
- Development of distinct add-on codes to reflect specialty E&M work.
- The ACR continuing to work with the AMA CPT Editorial Panel to create new codes that accurately reflect the time and expertise of cognitive specialists who primarily provide E&M services.
- Urging CMS to perform research in the comprehensive understanding of cognitive physician roles to inform changes in payment models for E&M services.
- The modification the RBRVS formula to value expertise and training.

Patient Access to Care

Level Playing Field in Negotiations

The viability of private medical practice is threatened by several factors including an uneven playing field in negotiations with insurance companies. Currently, health insurance companies are exempt from antitrust laws, while physicians and groups of physicians are restricted under such laws from banding together or communicating for purposes of negotiating with these large companies. Increasingly, physician collaboration includes integration of clinical services and quality improvement that can result in a "win-win-win" for patients, providers, and employers/payers.

The ACR supports:

- Legislation to ease anti-trust restrictions to permit physicians' representatives to engage in collective negotiation with insurance carriers other than Medicare, thereby promoting a more level playing field.

- Legislation scaling back or repealing antitrust exemptions guaranteed for insurance companies in the McCarran-Ferguson Act.

Patient Access to Care

Patient Protection & Affordable Care Act Advisory Board Provision

Rheumatologists have concerns about the Independent Payment Advisory Board (IPAB) provision of the Patient Protection & Affordable Care Act. The IPAB is a 15-member appointed panel charged with determining cuts to the Medicare system to curb rising costs. The ACR believes that this is not the appropriate way to curb health care spending. The risk of harm is too great when responsibility for Medicare decisions is mired in additional levels of bureaucracy, particularly one that is immune from congressional oversight and not accountable to all stakeholders.

The ACR supports repeal or modification of the Independent Payment Advisory Board provision of the Affordable Care Act.

Patient Access to Care

Reform of Recovery Audit Contractor Practices

The ACR acknowledges that we must address the billions of dollars lost each year by the Centers for Medicare and Medicaid Services due to fraud and abuse. To help recoup those losses, Congress established a recovery audit system utilizing Recovery Audit Contractors (RACs) administered by CMS. RACs are private contractors that use CMS guidelines to review claims. RACs are currently paid in direct proportion to the amount of money recovered from providers. This payment scheme, similar to bounty hunting, is prone to abuse by overzealous contractors and the practitioner is often presumed guilty a priori.

The ACR believes that RACs should be held accountable for reviewing claims based on CMS requirements and ensure they identify fraudulent activities, not merely errors. They should be paid based on their performance in following these requirements, rather than paid on the monetary incentives they might receive.

The ACR supports reform of audit practices and guidelines.

- The ACR supports efforts to eliminate fraud and abuse, and promotes the appropriate use of diagnostic and therapeutic modalities for the care of rheumatology patients.

- The ACR strongly opposes the contingency fee system for RAC compensation. The contingency fee system encourages aggressive tactics based on payment of a percentage of the recovered dollars.

- The ACR believes that all costs incurred by individual practitioners due to RAC audits or other billing audits should be borne by the auditors unless willful disregard for CMS billing rules is subsequently established. These should include the extra costs associated with compliance with the auditors, such as printing and clerical time.

Patient Access to Care

Medical Liability Reform

Meaningful medical liability reform is a major step toward lowering the cost of health care, reducing the federal deficit, and improving patient access to quality physician care, while providing fair compensation to patients who are truly harmed by cases of medical negligence. Research has shown that patients have greater access to physicians in areas that have instituted tort reform than in those without such reforms.

The ACR advocates for medical liability reform in order to reduce health care costs and preserve patient access to care.

The ACR supports:

- A cap on non-economic damages.
- Standards for expert witnesses.
- A rigid statute of limitations from day of discovery.
- The elimination of joint and several liability.
- The limitation on contingency fees.
- An alternative to traditional litigation such as arbitration and specialized medical liability courts.

Patient Access to Care

Adequacy of Provider Network and Formularies

Health insurance provider networks and formularies that are overly restrictive, unsafe or inappropriate limit patients' access to necessary care. Health insurance provider networks often contain false or incorrect information that makes it difficult for consumers to choose plans based on network adequacy. This issue applies to both public and private sector insurance.

Truthfulness in advertising for health insurance plans is essential for patients and physicians alike. Patients expect to have access to those physicians associated with a plan at the outset when they select which health insurance plan best meets their needs. Physicians should not be in a position where they must turn away returning patients because the insurer will no longer reimburse for the cost of care. Patients also expect to have access to specialists in their geographic area whenever possible.

Further, 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 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.

The ACR supports:

- Legislation requiring insurers to set their provider networks in advance of open enrollment.
- Legislation ensuring providers remain on a network unless the insurance company documents cause for their removal.
- Requiring insurance provider networks to contain sufficient and reasonable access to specialty physicians, including rheumatologists.
- Prohibition of overly restrictive drug formularies.
- The prohibition of changes in drug formularies outside of open enrollment periods.

Patient Access to Treatment

Elimination of Specialty Tier Barriers to Treatment

Many commercial health insurance policies have moved vital medications (mostly biologic response modifiers) into "specialty tiers" that require high patient cost-sharing. These specialty tiers (Tier IV and higher) require patients to pay a percentage of the actual cost of these drugs — from 25 to 33 percent or more, often costing hundreds or even thousands of dollars per month for a single medication — rather than a fixed co-payment. These coinsurance practices often put medically necessary treatments out of the reach for average Americans.

The ACR strongly opposes the excessive patient cost sharing that results from specialty cost tiering practices utilized by insurance carriers resulting in excessive patient financial burden.

The ACR supports:

- Federal and state/local legislation placing restrictions on such tiering by insurance carriers.
- Legislation allowing an exception and appeal process for Part D beneficiaries who are similarly affected by specialty tier practices.

Patient Access to Treatment

Patient Assistance Programs

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 private insurance 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 effective disease modifying therapy when they become a Medicare Part D beneficiary.

- **The ACR supports increased access to patient assistance programs for Medicare Part D beneficiaries** and that patients should not be denied newly-developed therapies such as biologic response modifiers solely because of their cost.
- The ACR supports legislation that will allow beneficiaries to accept financial co-pay assistance for specialty cost tier drugs from pharmaceutical companies for Part B and Part D drugs.

Patient Access to Treatment

Access to Treatment under Medicare Part B

Physicians who administer in-office drugs under Medicare Part B are not receiving the full Average Sales Price (ASP) plus 6% that was mandated in the MMA 2003 legislation due to a flaw in the formula used to calculate ASP. Currently, prompt-pay discounts between drug manufacturers and distributors and insurance company rebates that reduce the reimbursement for drug acquisition to private practice physicians are included in the formula calculating ASP. In aggregate, these discounts and rebates decrease reimbursement on infusion drugs to an average of only 1-2 % above the acquisition cost rather than the intended 6 %. Insurance companies and wholesale distributors benefit from these discounts, not physicians.

The ACR is concerned that the current physician reimbursement based on ASP + 6 % makes it economically unfeasible for some physicians to provide in-office treatments. With limited access to in-office treatments, patients will be forced to use more costly hospital facilities for these treatments, thereby unnecessarily increasing health care costs and burdens on patients and the health care system.

Sequester cuts to Medicare payments disproportionately affect payment for physician-administered treatments, often delivered by infusion similar to chemotherapy. Many rheumatologists have had to cease providing these treatments because the payment rate does not cover actual costs. This forces patients to seek treatment in hospitals with higher copayments, higher facility fees, longer travel times, and without their physician's supervision.

The ACR supports adherence to the ASP + 6% reimbursement rate for in-office treatments.

- The ACR supports removing prompt pay discounts between drug manufacturers and distributors, which artificially reduces drug reimbursement rates to physician practices, from the reimbursement formula for administering in-office drugs under Medicare Part B.

The ACR urges repeal of sequester cuts to Part B drug reimbursements.

Patient Access to Treatment

Access to Treatment under Medicare Part D

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.

The ACR supports improvements to the Medicare Part D program.

- The ACR supports legislation that allows Medicare to negotiate with pharmaceutical companies in order 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".

- The ACR supports including Part D drug costs with Part B drug costs in resource use formulas used to calculate cost under MIPS. Rheumatologists and other providers should not be incentivized to force patients to receive self-administered medicines, which they may not be able to afford due to cost sharing, when the most appropriate treatment may be administered in-office through Medicare Part B, making costs appear to increase. An alternative would be to eliminate drug costs in these formulas.

Patient Access to Treatment

Preservation of Physician Autonomy in Treatment Decisions

The development of non-ACR guidelines by some insurance carriers often impairs or precludes the ability of the treating rheumatologist to prescribe what he or she deems the most appropriate treatment for a given patient. The ACR recognizes the integrity of physician-patient decision making.

The ACR supports:

- Reimbursement provisions for off-label use of drugs when available evidence supports such use.
- The access to and affordability of rheumatic disease medications through oversight and reform of insurance and formulary practices that preclude appropriate use of medications because of formulary restrictions or excessive co-payment/coinsurance requirements.
- Universal prior authorizations compatible with the EHR.
- Strategies for lowering the cost of expensive medical therapies, except for cost savings plans that compromise the standards of quality, safe clinical practice.
- Including rheumatologists in pharmacy review committees when formulary benefits programs are being developed.

The ACR opposes:

- Mandatory drug switching of stable medical therapy, which is inappropriate and potentially harmful to patients.
- Step therapies, fail-first policies, and tiering of biologics.
- Legislation or regulation that would permit prescription therapeutic substitution by pharmacists, including therapeutic substitution of one biologic or biosimilar for another, unless the pharmacist is acting in accordance with a collaborative practice agreement with the prescribing physician, nurse practitioner, or physician assistant.

Patient Access to Treatment

Managed Care and Quality of Patient Care

In order to ensure quality of patient care, managed care systems should be regulated in a manner that ensures essential patient protections.

The ACR advocates for issues affecting quality of patient care, including managed care reform and access to care.

- The ACR believes that patients covered by managed care plans should be provided with access via a point-of-service option, which would allow the beneficiary to seek appropriate out-of-network treatment.

- The ACR believes that physicians, health professionals and patients, rather than the health plans, should make determinations regarding patient treatment options.

- The ACR believes that patients covered by managed care plans should be provided with information on the range of treatment options and coverage available.

- The ACR believes that all patients should have timely access to a review and appeals process, with an opportunity for independent review by individuals with appropriate expertise, when service is denied.

- The ACR believes that if participation between a health plan and health professional is terminated because of change in the terms of provider participation, the covered enrollee should be notified and should be able to retain the services of the provider, paid for by the health plan, if no other specialist is reasonably accessible.

- The ACR believes that specialists such as rheumatologists, who choose to do so, should be allowed to act as the principal care provider for those patients with the chronic conditions the physician is specifically trained to treat, and should be paid at least the same level as other physicians providing primary care services. Any payment bonuses or incentives available to primary care providers should also be available to rheumatologists and other cognitive specialists if they are providing the same services, regardless of specialty designation. Rheumatologists face similar workforce and recruitment challenges and often bill the same codes as primary care providers, and have additional expertise and training.

- Chronic care management service codes should be simplified and available to any physician who is primarily responsible for managing a particular chronic disease rather than being limited to only one physician per individual patient. Many patients have multiple chronic diseases which are best managed by various specialists each of whom spends considerable non-face to face time in order to appropriately coordinate care.

Patient Access to Treatment

Drug Pricing and Drug Shortages

The ACR believes that controlling the cost of healthcare is critically important to ensuring access for all Americans. Recent and proposed changes in physician payment models have moved strongly towards holding physicians accountable for the cost of the care they provide, though physicians have little control over many aspects, including health IT infrastructure costs, imaging device costs and rising drug costs. The ACR supports national and state level policy that ensures all stakeholders, including but not limited to insurers, health IT vendors and device and pharmaceutical manufacturers share the burden of controlling healthcare costs.

The ACR supports legislation to allow Medicare to negotiate with pharmaceutical companies to achieve more affordable pricing of drugs

Several drugs prescribed by rheumatologists have recently been in short supply, forcing patients to struggle to find pharmacies that have their medications in stock. Treatment programs have been interrupted. Injectable methotrexate shortages have been especially devastating. This low-margin injectable generic drug is the foundation of rheumatoid arthritis treatment and is frequently used as maintenance therapy in vasculitis and other rheumatic diseases, often at a fraction of the cost of biologic response modifiers. These shortages can cause arthritis patients to experience additional pain and immobility, and add to suffering and disability.

The ACR supports policies to address the causes of drug shortages and reduce their impacts on patients and physicians.

- The ACR supports the efforts of the FDA to minimize drug shortages.
- The ACR supports the creation of redundancy in the drug supply chain for critical drugs, including injectable generics, by providing incentives to manufacturers for production of these drugs.
- The ACR is concerned that there is lack of timely communication to physicians and the public of impending drug shortages. ACR encourages the FDA to further broaden reporting rules to ensure that manufacturers provide early warning of disruptions in the supply of critical drugs.

The ACR supports legislation promoting transparency and Medicare negotiation in drug pricing.

- The ACR supports increased transparency in how pharmaceutical companies, pharmacy benefit managers, and health insurance companies determine the cost of prescription medication.
- The ACR supports increased transparency of any incentives given by drug companies to pharmacy benefit managers or health insurance companies related to the dispensing or promotion of their manufactured drugs.

Patient Access to Treatment

Patient Access to Osteoporosis Testing

Appropriate reimbursement is essential to preserving patients' access to critical tests such as dual x-ray absorptiometry (DXA) testing of bone density. The reduction in reimbursement below the cost necessary to provide the test limits patient access to DXA. The reduction in DXA reimbursement has been greater on office based than hospital based DXA which prevents many offices from providing this service to their patients. Preserving patient access to DXA testing will help to restrain unnecessary costs to Medicare, Medicaid, and the private sector by permitting access to fracture prevention services and reducing hospitalization and other costly fracture-related expenditures.

The ACR supports appropriate reimbursement for preventive osteoporosis screenings (DXA).

- The ACR supports DXA reimbursement rates that realistically reflect the cost of providing this test for patients who are at risk for osteoporosis.

Patient Access to Treatment

Access to Safe, Effective Biosimilar Treatments

Biosimilars are medicines that could be cost-saving alternatives for the specialty drugs called biologics, which are large, complex agents given through an injection or infusion. The relationship between biosimilars and biologics is akin to the relationship between generic and "Brand" name medicines; however, biosimilars are not generic copies of the reference drug. Due to the complexity of biologics used in rheumatoid arthritis and other autoimmune diseases, a separate regulatory approval and dispensing pathway is required to ensure effectiveness and protect patient safety. This pathway must go beyond what is required to approve and dispense regular generic medications. Biosimilars have the potential to work less well than the reference biologic drug, cause side effects, or interact with the immune system in a way that could create immunity against the biosimilar. Fortunately, initial data and experience suggests that biosimilars currently in use are safe and effective.

Congress provides two pathways for biosimilar approval: 1) biosimilar agents that have equivalent safety, purity, and potency as original biologics; and 2) a higher level of interchangeable biosimilars in which alternating or switching between an original biologic and biosimilar would not be predicted to cause any changes in efficacy or safety. FDA must ensure that regular and interchangeable biosimilars fulfill these promises. Federal and state/local regulation must ensure appropriate dispensing and monitoring.

The ACR strongly believes that safe and effective treatments should be available to patients at the lowest possible cost.

Regarding the approval and use of biosimilars, the ACR supports decision making that is driven by sound science and that takes into account several observations and guiding principles, including the following.

- The size, complexity, and heterogeneity of biologics (and thus biosimilars) necessitate a greater degree of scrutiny in their analytical evaluation than what is required for small molecule generics.

- In addition to adequate pharmacokinetic and pharmacodynamics studies, clinical data are necessary to ensure the safety and efficacy of biosimilars, and to provide the necessary level of confidence for their use by patients and providers. Furthermore, the collection of long-term post-marketing data for each individual biosimilar is necessary to monitor for less common but nevertheless important adverse events.

- Post-marketing surveillance studies are needed in children as well as adults, as toxicities and long-term sequelae may be different in these disparate populations. The Best Pharmaceuticals for Children Act (BPCA), which reauthorizes the pediatric studies provision of FDA Modernization and Accountability Act to improve safety and efficacy of pharmaceuticals for children, should apply to biosimilars.

- **The decision to substitute a biosimilar product for a reference drug should only be made by the prescribing provider.** In jurisdictions where substitution by someone other than the prescribing provider is lawful, the prescribing provider and the patient should be notified immediately when a substitution is made. Providers must retain the right to write "dispense as written" for all prescriptions, including biologics.

- **The ACR does not endorse switching stable patients to a different medication (including a biosimilar) of the same class for cost-saving reasons without advance express consent from the prescribing provider.**

- Biosimilars must have distinct names allowing them to be distinguished from each other and their reference products. This is essential for post-marketing pharmacovigilance.

- Extrapolation of indications for biosimilars should not be routinely granted by the FDA based solely on FDA-approved indications of the reference product and in the absence of safety data specific to the biosimilar agent and the patient population in question. In contrast, off-label use of biosimilars, based on FDA-approved indications of the reference biologic and other data, may be appropriate when deemed by the prescribing provider to be clinically appropriate and in the best interests of the patient, but should be pursued with the same level of caution applied to off-label use of reference agents.

- FDA labels (package inserts) should clearly indicate whether a biosimilar is interchangeable with the reference (originator) biologic. FDA labels should also clearly delineate all indications for which a biosimilar is approved, and specify whether the supporting clinical data for the indication are derived from studies of the biosimilar or the reference biopharmaceutical.

- ACR opposes Medicare plans to reimburse all biosimilars of a reference biologic at the same rate. Allowing for variation in payment between biosimilars would foster increased competition. Having a separate payment code for each biosimilar would also improve safety monitoring.

- ACR supports increased FDA funding and bureaucratic and hiring reforms to ensure adequate resources are available for regulation and advancement of new biosimilars.

Rheumatology Research and Training Support

Funding for Medical Research

Reductions in funding for the National Institutes of Health (NIH) threaten jobs and our nation's status as a leader in medical innovation while slowing down lifesaving research. NIH awards and grants alone support over 350,000 jobs across the country. More than 83 percent of NIH funding is spent in communities across the nation, creating employment opportunities at more than 3,000 universities, medical schools, teaching hospitals, and other research institutions in every state.

Recent budget cuts have resulted in the lowest grant funding rates in history, slowing the progress of improved diagnostics, better prevention strategies and new treatments for arthritis, rheumatic diseases and their comorbidities (infections, cancer, and cardiovascular diseases), at a time when the number of people with arthritis and related diseases is steadily rising. Further cuts are threatened by sequestration. These cuts in health research funding limit the potential for new discoveries and damage our unsteady economy through losses in skilled, high-paying jobs, new products and industries, and improved technologies.

The ACR advocates for the funding of basic and clinical arthritis research, and actively collaborates with the Arthritis Foundation, NIH, and others toward this aim.

The ACR urges repeal of federal budgets sequestration to end ongoing automatic across-the-board spending cuts that have severely damaged America's research enterprise.

The ACR supports:

- Increased and sustained funding for the NIH budget, beginning with a return of NIH funding to pre-sequestration levels.
- Adequate funding levels for the Agency for Healthcare Research and Quality, and Department of Defense, and Veterans Affairs medical research.
- Creation of a $20 million dedicated arthritis research program at the Department of Defense
- The Funding for a continued emphasis on patient-based research and clinical innovations in patient care.
- Maintenance of funding for the National Arthritis Action Plan and other rheumatologic related activities of the CDC.
- The principles presented by the Health Resources and Services Administration's Pediatric Rheumatology Workforce report of 2007 as set forth by the Children's Health Act of 2000.

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Education and Training to Ensure Future Access to Rheumatology Providers

There are currently many geographical areas of the United States experiencing shortages of rheumatologists, a trend expected to significantly worsen in the coming decades according to the latest Rheumatology Workforce Study. The availability of pediatric rheumatologists is at a crisis level, with fewer than 300 pediatric rheumatologists in the United States providing care at present. As a result, the hundreds of thousands of children and young adults with juvenile rheumatic disease have limited access to high-quality care for their conditions. Additionally, the number of patients needing adult rheumatologic care is expected to grow as the U.S. baby boomer population ages.

Despite the need to address these workforce shortages, Medicare's support for its share of graduate medical education (GME) costs has been effectively frozen since 1997. The ACR believes that graduate medical education is a necessary public good that must be protected. Any cuts in GME funding would further exacerbate the growing shortage of physicians across several specialties, including rheumatology.

In order to fulfill the goals of improving and expanding access to care, the ACR strongly endorses additional GME funding and support as well as other broad measures to increase the supply of rheumatologists. Funding for GME and expansion of fellowship programs are crucial steps to shoring up these deficiencies. Funding for the pediatric subspecialty loan repayment program can encourage more pediatricians in training to pursue additional specialty training in rheumatology. More broadly, structural changes in the reimbursement system addressing the undervaluation of E&M services and cognitive care are additional critical steps which can reverse the trajectory of this impending crisis.

The ACR supports increasing funding for Graduate Medical Education.

The ACR supports expansion of fellowship training positions, particularly in pediatrics in alignment with physician workforce needs.

The ACR supports funding the Pediatric Subspecialty Loan Repayment Program included in the Patient Protection and Affordable Care Act and as part of the National Health Service Corps loan repayment program to alleviate the severe shortage of pediatric rheumatologists.

Quality of Care

In recent years, many quality measures and programs have been developed to improve patient outcomes. These efforts encompass a broad array of best practices ranging from use of diagnostic tests, medications and procedures to physician practice protocols and hospital operations. These measures impact how physicians treat patients and how physicians are reimbursed for their services. Rheumatologists are taking the lead to ensure that the emerging systems provide evidence-based, patient-centered, physician-directed rheumatologic care, and that incentive programs do not conflict with quality medical practices of rheumatologists.

The ACR supports:

- The development of physician performance measures that are linked to meaningful clinical outcomes.
- The development of performance measures by rheumatologists and health professionals through the ACR, and assessment and focus on those elements of clinical care over which rheumatologists have direct control.
- Requiring that any data collection to support performance measurement be reliable and practical, and that it should not violate patient privacy or add to the administrative burden experienced by rheumatologists.
- Appropriate reimbursement of providers for work involved in the collection and reporting of quality measure data.
- The ACR believes that performance measures should not be used to penalize providers.

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Comparative Effectiveness Research

Comparative Effectiveness Research (CER) efforts were established by the Affordable Care Act to evaluate the safety, efficacy, and cost of a given medical treatment or service relative to other treatments for the same condition. Government support for CER helps to enable patients to receive the best and most cost-effective treatment. There are vast opportunities to study key comparisons within the field of rheumatology that could greatly enhance healthcare outcomes for large segments of the population and reduce costs to the system as a whole. The ACR has the expertise to conduct such studies.

Keeping in mind realistic expectations of the time and resources needed to conduct sound research, with proper funding and protection from inappropriate use of the resulting data, the quality of rheumatologic healthcare may be greatly enhanced by CER. It is, however, important to note that an individual patient may respond better to a different agent than the population of patients as a whole. There is a need to allow for individualization without insurance provisions dictating which drugs to prescribe, even if those provisions are based on CER.

The ACR supports:

- CER funding should be public and directed to professional societies such as the ACR to preclude investigator and industry bias.
- The US FDA and drug manufacturers should work together to create more CER data for inclusion in drug labeling

- CER should be viewed as a continuous and ongoing necessity for advancing and improving rheumatologic care.

- The ACR strongly supports maintenance of the Patient Centered Outcomes Research Trust Fund and its funding of comparative effectiveness research.