

2018 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

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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 Merit-Based Incentive Payment System (MIPS) use metrics that are clinically relevant, efficient, and promote quality of rheumatologic 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.
 - e. Support approval of the ACR rheumatoid arthritis APM by CMS.
 - f. Support legislation excluding Part B drug costs from resource use component of MIPS score calculations.
 - g. Encourage smaller practices to participate in APMs by lowering the payment amount and patient count thresholds required to achieve qualifying participant status in an advanced APM, and by minimizing initial risks to which providers are exposed.
- Improve transparency and accountability of the processes by which Medicare Administrative Contractors implement Local Coverage Determinations, and ensure provider input on all new or revised policies.
- 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 interoperability.
- 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 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.
- Advocate for other legislative means to reduce out-of-pocket costs for critical treatments, such as caps on total annual out-of-pocket expenditures, allowing coinsurance to be spread over a plan year, and forcing health plans to include at least one option for pharmacy insurance that does not have a specialty tier
- Support legislation requiring pharmacy benefit managers to disclose rebates, fees, and other discounts received, including what percentage was passed on to the patient, pharmacy, and insurance company.
- Support access to patient assistance programs for Medicare beneficiaries for Part B and Part D drugs, as well as 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 that requires payment for administration of Part B drugs falling within the ‘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 to 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 with meaningful suffixes 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 the areas of arthritis and rheumatic disease along with 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, including additional rheumatology fellowship positions, ongoing support for the Public Service Loan Forgiveness Program, 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 (i) Quality (based on PQRS), (ii) Advancing Care Information (based on Meaningful Use), (iii) Clinical Practice Improvement (a new program), and (iv) Resource use (based on the Value Based Modifier, which was not scored in 2017). Providers' performance on MIPS measures will provoke payment adjustments, in the form of bonuses or penalties, two years later unless providers join an Alternative Payment Model (APM).

The ACR recently designed an APM for the management of rheumatoid arthritis. This APM will provide an initial framework for APMs for a variety of rheumatologic conditions. The ACR supports policies that will optimize use of this APM by rheumatology providers, including lower thresholds for participation and minimization of the risk associated with participation.

In late 2017, CMS decided to apply MIPS payment adjustments to the cost of Part B drugs, in addition to physician services. This was a serious departure from CMS' previous policy for applying payment adjustments only to physician services for quality programs. Applying the MIPS adjustment to Part B drugs would distort the intent of the MIPS adjustment and introduce severe volatility into reimbursement for these medically-necessary treatments. Therefore, the ACR strongly supported legislation that passed in February of 2018 and successfully eliminated Part B drug costs from MIPS payment adjustments.

At the same time, CMS plans to begin implementation of the resource use, or cost, category as a component of MIPS scoring for the first time. This is concerning as Part B drug costs will be included in the cost component and count toward a practitioner's score, though Part D drug costs will not be included. Additionally, CMS has not outlined sound methodologies for risk adjustment for physicians with patient populations at risk for high resource use, and cost measures necessary under MIPS are still under development. Work remains to ensure that the new measures are developed and integrated in a way that accurately reflects the complexities of cost measurement and does not inadvertently discourage clinicians from caring for high-risk and medically complex patients.

Overall, the MACRA framework forces providers to choose between the uncertainty and financial risk of joining an APM and the possibility of overwhelming financial 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 costs.

Flexibility in the design of the MIPS programs and simplicity in implementation should drive the development of these programs. Participation in APMs would be improved by lowering payment amount and patient count thresholds required to achieve qualifying participant status in an advanced APM and by minimizing initial risks to which providers are exposed. Appropriate data and measurements should be used to develop these programs to ensure there are no biases against certain patients and their physicians.

The ACR Supports:

- Approval of the ACR rheumatoid arthritis APM by CMS.
- Legislation or regulation to exclude Part B drug costs from the resource use component of MIPS score calculations. If drug costs are to be included, the ACR cannot support including Part B drug costs without also including Part D drug costs.
- Simplification of the MIPS program through reduced reporting requirements and flexibility to account for practice variation.
- Continuation of a 90-day reporting period rather than one year reporting for all MIPS requirements.
- Preservation of stability through the 0.5% updates promised by law through December 2019.
- Streamlining of reporting systems for each MIPS category.
- Policy ensuring that providers who participate in a Qualified Clinical Data Registry such as RISE can maximize credit in MIPS categories for doing so.
- Policy ensuring that providers will be informed of performance outcomes in real time in order to enable them to make changes prior to the next performance period.
- Minimization of 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.
- Policy encouraging smaller practices to participate in APMs by lowering the payment amount and patient count thresholds required to achieve qualifying participant status in an advanced APM, and by minimizing initial risks to which providers are exposed.
- Policy 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.
- Study of improving the way cognitive work is valued in E&M codes, so that new codes can reflect the value of cognitive work and streamline adoption of value-based payment models.
- Standardization of documentation requirements for billing E&M services, and greater transparency in reimbursement processes.
- Reevaluation of the Stark laws against physician self-referral in order to align new health care delivery models with value-based and shared risk reimbursement models.
- Opposition to instituting a “user fee” tax on health care providers for participation in the Medicare and Medicaid program.
- Policy 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.
- Policy improving the transparency and accountability of the processes by which Medicare Administrative Contractors implement Local Coverage Determinations, and ensuring provider input on all new or revised policies.

Patient Access to Care

Health Reform Efforts in the 115th Congress

Congress is currently working to reform national health policies regarding insurance coverage, including recently repealing the mandate to own health insurance. The ACR is concerned that reducing subsidies for health insurance, repealing the mandate, and/or withholding cost-sharing reductions may reduce patients' access to medical care. Additionally, the United States faces a shortage of rheumatologists; therefore, adding health coverage for Americans without adding sufficiently to the workforce may not necessarily improve access to 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.
- Maintenance of an adequate workforce of rheumatology specialists to care for people with arthritis and rheumatologic diseases
- Prohibition of health insurance companies from excluding participants based on preexisting conditions.
- Allowance of 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 and expansion of services.
- Caps on annual out-of-pocket patient costs and a ban on lifetime limits on health care costs.
- Affordable premiums, deductibles and cost-sharing, including ongoing support for cost-sharing subsidies.
- Continuation of 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. MACRA's administrative burdens may prevent practices from reducing costs and increasing quality of care. It is counterintuitive to ask practices to become more efficient while at the same time demanding participation in administrative activities that are time-consuming and burdensome.

The ACR urges reduction of administrative burdens associated with MACRA.

The ACR supports:

- 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.
- Interoperability of electronic health records, prevention of "data blocking" and other measures to streamline information sharing for clinicians and use of qualified registries.
- Policy allowing administrative set-up costs for advanced alternative payment models to count as the necessary financial risk, at least on an interim basis.

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:

- Development of efficient, secure, and interoperable standard-based EHR systems and federal financial support to medical practices to defray the cost of implementation.
- Requirements that vendors share in penalties when compliance goals are not met due to technology implementation problems.
- Prevention of information blocking/data blocking with regard to medical registries and interoperability of EHRs.
- Requirements that vendors 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 recent years, a growing number of contractors have 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. These contractors now pay physicians as if routine medications, which require less monitoring of patient safety, were given. Many contractors also refuse to pay for continuation of therapy with biologic infusions, which interrupts patient care and places the patient at risk for flare or worsening disease burden. These changes in contractor policy conflict with the official guidelines developed by the American Medical Association Current Procedural Terminology (CPT) Editorial Panel. Contractors did not consult physicians, as required by law, prior to changing reimbursement coverage. This reduction in service reimbursement is in addition to the effect of sequestration of infusions. Reduced reimbursement and coverage for medically necessary care and treatment will force doctors to reduce services they offer. Therefore, 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 biologics for rheumatic diseases requires advanced training by health care professionals and necessitates special handling of medications as well as increased monitoring of patient safety. Patients should not face threats to access to biologic treatment based on the region in which they live or the contractor that covers their treatments.

The ACR urges a national policy requiring that payments for the administration of Part B drugs that fall within the ‘biologic’ class of drugs 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. However, current E&M codes do not reflect the highly specific and specialized knowledge, exam, and decision making which goes into specialty care for patients provided by cognitive subspecialists such as rheumatologists.

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 only possible because of substantial additional training and expertise acquired by rheumatologists.

The additional training required to become an expert in rheumatology or in other cognitive subspecialties needs to 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 to recognize the additional value of specialization, the relative numbers of cognitive specialists will continue to diminish and access to cognitive care will be further constrained. The current code valuation system also does not encourage seamless adoption of value-based and episode-based payment models.

Arthritis is the fastest growing health problem worldwide. New Centers for Disease Control and Prevention (CDC) data finds that all forms of arthritis have a startling economic burden in the United States - to the tune of over \$300 billion annually - resulting in higher medical costs and earnings losses among people with the disease. 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 musculoskeletal and rheumatic diseases such as arthritis. In fact, the 2015 Rheumatology Workforce Study identified a substantial shortage of rheumatology professionals 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:

- 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.
- Continuation of work between the ACR and 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.
- Research by CMS to achieve a comprehensive understanding of cognitive physician roles in order to inform changes in payment models for E&M services.
- Modification of 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 to scale back or repeal antitrust exemptions guaranteed for insurance companies in the McCarran-Ferguson 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 being paid based 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 and potentially inappropriate 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 costs 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, in some cases, 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, and should not be forced to lose or transfer care if plans change networks or formulary components abruptly. 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 or regulation requiring insurers to set their provider networks in advance of open enrollment.
- Legislation or regulation ensuring providers remain on a network unless the insurance company documents cause for their removal.
- Policies requiring insurance provider networks to contain sufficient and reasonable access to specialty physicians, including rheumatologists.
- Prohibition of overly restrictive drug formularies.
- 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. As of 2015, more than 80% of Part D plans required patients to pay coinsurance for these biologic agents, with an average cost of greater than \$2700 for patients before catastrophic coverage, with its 5% coinsurance, takes effect. 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
- Other legislative means to reduce out-of-pocket costs for critical treatments and specialty drugs, such as caps on total annual out-of-pocket expenditures, allowing coinsurance to be spread over a plan year, and forcing health plans to include at least one option for pharmacy insurance that does not have a specialty tier.
- Legislation allowing an expeditious 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 currently no less expensive generic equivalents available in the United States. 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 the expense to the patient. Ideally, the ACR would like for the cost of drugs to be reduced, and for 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. The ACR does, however, acknowledge concerns about these programs. By insulating patients from medication costs, these programs may distort demand for lower cost therapies and lead to increases in drug list prices. As options for lower cost biosimilar and generic products increase in the coming years, this problem is likely to become more pronounced. As such, these programs may be best paired with other measures to reduce drug list prices, and are suboptimal compared to basic cost coverage strategies.

Both commercial payers and Medicare Part D restrict patient access programs. Some commercial insurance carriers, for example, do not apply patient assistance program contributions towards patients' deductibles or out of pocket maximums. This essentially makes a patient pay twice for drug costs: once with assistance program, and again with their own money. This creates a financial barrier to treatment. Among those with Medicare Part D coverage, access to any assistance programs is highly restricted. 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.

- **As long as Medicare does not cover the cost of essential treatments, the ACR supports increased access to patient assistance programs for Medicare Part D beneficiaries.** 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.
- The ACR opposes insurance restrictions that prevent application of funds from assistance programs toward patients' deductibles and out of pocket maximum payments.

Patient Access to Treatment

Access to Treatment under Medicare Part B

Multiple recent policy changes have threatened Medicare beneficiaries' access to Part B drug treatments. In late 2017, CMS changed the way reimbursement adjustments would be made in Medicare by applying the MIPS adjustment factor to the cost of Part B drugs given by providers. As a result, reimbursement for physicians would have been highly variable, and penalties would put a practice's viability at risk. Legislation passed in February of 2018 successfully eliminated this threat. CMS's decision to include the costs of Part B drugs when calculating the resource use component of MIPS scores is likely to reduce patient access to treatment. It is not clear how those costs will be attributed to specific physicians or groups, and whether or how Medicare will track Part D drug costs. If Part B drug costs are included in costs calculations, but Part D drug costs are not included, physicians may be penalized for providing medically-necessary Part B drug treatments to their patients.

Physicians who administer in-office drugs under Medicare Part B are already 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. As a result of the budget sequestration of 2013, payments of Part B covered drugs have been reduced by 1.6% to a total of ASP plus 4.3%. In addition, 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 all of these threats to reimbursement for physicians who provide Part B drugs to patients constitute a "perfect storm" that threatens the viability of rheumatology practices in the US. As a result, many rheumatologists have had to cease providing these treatments because the payment rate does not cover actual costs. With limited access to in-office treatments, patients will be forced to seek treatment in hospitals with higher copayments, higher facility fees, longer travel times, and without their physician's supervision, thereby unnecessarily increasing healthcare costs and burdens on patients and the health care system.

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.

The ACR supports legislation or regulation to exclude Part B drug costs from the resource use component of MIPS score calculations. If drug costs are to be included, the ACR cannot support including Part B drug costs without also including Part D drug costs.

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. The most equitable alternative would be to eliminate drug costs in these formulas.

Patient Access to Treatment

Preservation of Physician Autonomy in Treatment Decisions

The ACR recognizes the integrity of physician-patient decision making in the treatment process. The development of non-ACR endorsed guidelines by some insurance carriers impairs or precludes the ability of the treating rheumatologist to prescribe what he or she deems the most appropriate treatment for a given patient. It has become clear that patients' access to treatment is reduced not only by the high cost of medicines, but also the formulary restrictions that are created by intermediaries in the drug distribution system. Pharmacy benefit managers appear to favor coverage of medicines whose distribution provides PBMs with higher rebates, fees, spread pricing, and other profits. The ACR recognizes the need for formularies to reflect evidence-based guidelines and clinical data, rather than profits derived from the drug distribution system.

The ACR supports:

- Reimbursement provisions for off-label use of drugs when available evidence supports such use.
- Drug formularies based on standard of care and evidence-based practice standards.
- 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 electronic health records.
- Strategies for lowering the cost of expensive medical therapies, except for cost savings proposals that compromise the standards of quality, safe clinical practice.
- Inclusion of rheumatologists in pharmacy review committees when formulary benefits programs are being developed.
- Legislation requiring pharmacy benefit managers to disclose rebates, fees and other discounts received, including what percentage was passed on to the patient, pharmacy and insurance company. In addition, the ACR supports establishment of uniform definitions for terms used in disclosures by specifying what constitutes a rebate, discount, fee, and amount received from a manufacturer.

The ACR opposes:

- Mandatory drug switching of stable medical therapy, which for any reason is inappropriate and potentially harmful to patients.
- Step therapies, fail-first policies, and tiering of biologics into specialty-tier pricing, rendering them unaffordable for patients.
- 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 expeditious opportunity for independent peer-to-peer 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 despite 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, relapse of life-threatening diseases, 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. As a consequence, fewer office-based practices offer this screening service, leading to a rise in fractures and cost to the healthcare system overall. 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 such as long term nursing care.

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.
- In an effort to close the care gap for osteoporosis patients, the ACR supports hospital funding for fracture liaison services to identify those at highest risk of subsequent fracture for intervention.

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 therapeutic agents given by an injection or infusion. The relationship between biosimilars and biologics (at the regulatory but *not* biochemical level) 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, separate regulatory approval and dispensing pathways were created to ensure effectiveness and protect patient safety.

Congress authorized the FDA to provide 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. The ACR strongly supports the rigorous pathway for interchangeability proposed by the FDA in 2017. The FDA must ensure that regular and interchangeable biosimilars are safe and effective. Federal and state/local regulation must ensure appropriate dispensing and monitoring, including regulation that prevents the rebate-based pharmacy benefits management system from excluding lower-cost biosimilars. Payers and pharmacy benefit managers must ensure that biosimilars improve patients' access to biologic treatments, and that the financial savings are passed along to patients. The ACR has published a [White Paper](#) regarding biosimilars.

The ACR strongly believes that safe and effective treatments should be available to patients at the lowest possible cost. The ACR is committed to advocating for a smooth transition to an era of less expensive biologics that provide safe, effective treatments that are accessible to more people.

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.
- Biosimilars must have distinct names allowing them to be distinguished from each other and their reference products, and furthermore, the 4-letter suffixes which identify each drug should be meaningful. This is essential for effective post-marketing pharmacovigilance.
- Because some patients with rheumatic diseases may be more susceptible to adverse drug reactions, and because disease states in some organ systems respond differently to one biologic compared to another, extrapolation should be pursued with caution. Regulatory agencies and manufacturers, in consultation with clinical experts free of conflicts of interest, should identify a minimum slate of disease states in which biosimilars should be tested before extrapolation to additional indications is granted. 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.
- Support for Medicare’s 2017 plan to reimburse all biosimilars of a reference biologic at their own individual rate. Allowing for variation in payment between biosimilars will foster increased competition. Having a separate payment code for each biosimilar will also improve safety monitoring.
- 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.

Severe budget cuts in funding to the NIH in FYs 2013 to 2015 resulted in the lowest grant funding rates in history, slowing the progress of improved diagnostics, 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. Such cuts in health research funding limit the potential for new discoveries and damage our economy through losses in skilled, high-paying jobs, new products and industries, and improved technologies. Recognition of this grave problem prompted budget increases in FYs 2016 and 2017, which have helped restore funding to pre-sequestration levels (FY 2012), however as inflation-adjusted funding rates had already been declining since 2003, continued advocacy for NIH funding is paramount to ensure progress in rheumatology related biomedical research.

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 budget sequestration to end ongoing automatic across-the-board spending cuts that have severely damaged America's research enterprise.

The ACR supports:

- Sustained funding for the NIH budget at current levels or above.
- Adequate funding levels for the Agency for Healthcare Research and Quality, 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 (HRSA's) Pediatric Rheumatology Workforce report of 2007 as set forth by the Children's Health Act of 2000.
- Research by HRSA that includes trends in disease incidence and treatment, and workforce demographics to predict future physician workforce needs.

Rheumatology Research and Training Support

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. Recent figures suggest that arthritis may be even more common than previously estimated, with an estimated 91.2 million Americans affected in 2015 alone.

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 improving 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 2015 Workforce Study predicts a shortage of 3,845 rheumatologists in the U.S. by 2025, up from previous projections of 2,576. The need for rheumatology trained subspecialists will continue to rise despite the shortage of rheumatologists as the incidence of arthritis reaches its projected increase to 25% of the population by 2030.

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

Ten US states currently do not have any adult rheumatology fellowship positions and thirty US states do not have any pediatric fellowship positions. The ACR supports increased funding for GME positions to expand fellowship training to states that are disproportionately negatively impacted by the rheumatology workforce shortage.

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.

The ACR supports the Public Service Loan Forgiveness Act.

The Public Student Loan Forgiveness Act addresses the rheumatology workforce shortage in two ways. First, it encourages young physicians to choose rheumatology despite the relatively lower compensation than other areas of medicine. Second, it encourages new fellowship graduates to stay in medical education and train the next generation of rheumatologists rather than accepting a potentially higher paid position in private practice.

Rheumatology Research and Training Support

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:

- Development of physician performance measures that are linked to meaningful clinical outcomes.
- 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.
- Policies requiring that any data collection to support performance measurement be reliable and practical, driven by specialists rather than payers, 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.

Rheumatology Research and Training Support

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 funding for the Patient Centered Outcomes Research Trust Fund and its funding of comparative effectiveness research.