2024 ACR Health Policy Statements

The ACR will advocate for and encourage the implementation of policies that will improve healthcare outcomes. The ACR's advocacy will support legislative and regulatory policy initiatives that will:

- Expand patient access to the care of rheumatologists and rheumatology interprofessional team members and alleviate the burden of utilization management policies on rheumatology professionals.
- Improve patient access to the most effective treatments and therapies.
- Support appropriate and sustainable reimbursement for rheumatologists and rheumatology interprofessional team members.
- Increase federal funding for rheumatology research.
- Broaden opportunities in and support the rheumatology workforce.

I. Overview

Expand Patient Access to Care by:

- Supporting adequate, affordable, and continuous health insurance for all Americans.
- Reducing the administrative burdens on healthcare professionals that detract from patient care.
- Promoting efficiency and interoperability of Electronic Health Records (EHRs).
- Modifying antitrust restrictions that bar practices from collectively negotiating with insurance carriers to support the viability of small medical practices.
- Reform of Recovery Audit Contractor practices and guidelines to effectively identify fraud.
- Revisit aspects of medical liability law to reduce costs to the system of "defensive medicine" while protecting patients who have been harmed.
- Prioritizing patient care through network and formulary adequacy and effectively regulating managed care systems.
- Protecting patients from surprise billing without deterring reimbursement for care or incentivizing further narrowing of insurance networks.
- Expanding access to care through appropriately utilized and reimbursed telemedicine.
- Supporting initiatives that diminish racial and ethnic disparities in care delivery and clinical trials.

Remove Barriers to Patient Access to Treatment by:

- Limiting the use of specialty tiers and other methods of excessive patient cost sharing.
- Ensuring patient assistance programs work to the benefit of patients.
- Adequately reimburse providing treatments covered by Medicare Part B.
- Managing treatments under Medicare Part D without unduly burdening clinicians or limiting access to medications integral to the treatment of rheumatic diseases.
- Prioritizing patient safety during treatment.
- Reducing the cost of treatments by examining the practices of stakeholders for areas that may add substantial costs to accessing prescription drugs with no benefit to patients.
- Taking steps to reduce drug shortages.
- Increasing access to biosimilar options.
- Recognizing the cost of administrating complex treatments under Medicare Part B including the necessary time and skill needed to safely administer such treatments.
- Support the federal Comparative Effectiveness Research program.

Support Rheumatological Care in Medicare by:

- Promoting appropriate management of the Medicare Access and CHIP Reauthorization Act (MACRA) to facilitate effective care of patients by appropriately reimbursed practitioners.
- Reforming the Medicare Physician Fees Schedule (MPFS) to recognize the value of providing cognitive specialty care.
- Recognizing the actual cost to practices of administering osteoporosis testing (DXA).

- Considering broader reforms to Medicare that support clinicians treating vulnerable patients.

Funding Rheumatology Research through:

- Increased funding for research in the National Institutes of Health (NIH) including appropriate support for the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS).
- Adequate funding for the Agency for Healthcare Research and Quality, Department of Defense, and Veterans Affairs medical research.
- Dedicated arthritis research funds in the Congressionally Directed Medical Research Program at the Department of Defense.
- Increased funding for the National Arthritis Action Plan and other rheumatologic-related activities of the CDC.

Preserving and Growing the Rheumatology Workforce by:

- Restricting the use of noncompete clauses to restrict the medical workforce.
- Preserving physician autonomy in treatment decisions.
- Expanding education and training opportunities for future rheumatologists.
- Developing measures for the quality of care that are linked to meaningful clinical outcomes.

Expand Patient Access to Care

i. Health Care Reform

All three branches of the federal government continue to reform policies regarding insurance coverage. The ACR is concerned that reducing subsidies for health insurance, withholding cost-sharing reductions, and the repeal of the mandate that individuals maintain health insurance, could raise the costs of care, and reduce patients' ability to afford/access health insurance and therefore medical care.

The ACR Supports:

- Ensuring the availability of sufficient, affordable, and continuous insurance coverage that makes high-quality health care accessible for all Americans.
- Maintaining affordable health insurance premiums, deductibles, and cost-sharing, including ongoing support for cost-sharing subsidies.
- Prohibiting health insurance companies from excluding participants based on preexisting conditions.
- Allowing children to remain on their parent's insurance plan until age 26.
- Capping annual out-of-pocket patient costs.
- Banning lifetime limits on health care costs for payers.
- Continuing essential health benefits to ensure patients have access to robust health care services and refining the definitions of essential benefits further.

II. Expand Patient Access to Care

ii. Administrative Burdens

Administrative burdens on healthcare practitioners have dramatically increased in the past decade. The ACR is concerned about these administrative burdens coupled with rising costs to provide healthcare and the resulting uncertainty for physician practices.

While intending to improve access to and quality of care for patients, legislative mandates for electronic health records, MACRA, and prior authorization/utilization management reforms have created mounting levels of administrative burden for medical practices that reduce their bandwidth for patient care.

Physicians now spend up to twice as much time documenting and managing administrative requirements as directly caring for patients. It is counterintuitive to ask practices to become more efficient through participation in administrative activities that are time-consuming, confusing, and burdensome.

The ACR urges the reduction of administrative burdens associated with MACRA and prior authorization.

The ACR supports:

- A 90-day reporting window for all MIPS categories especially Promoting Interoperability (formerly Advancing Care Information).
- Initiatives intended to reduce the administrative and regulatory burden imposed upon healthcare professionals participating in the Medicare program.
- Allowing administrative set-up costs for advanced alternative payment models to count as the necessary financial risk, at least on an interim basis.
- Placing guardrails around Step Therapy policies including mandatory exceptions to “fail first” protocols to prioritize patient health and honor the rheumatologist/patient relationship.
- Streamlining prior authorization by:
    - Creating a universally accepted prior authorization form with the option to electronically submit.
    - “Gold card” legislation, which creates a continuous prior authorization exemption for physicians who earn a 90% approval rate on prior authorization requests for a given service over a period of six months.
    - Carrying prior authorizations for stabilizing medications over to new insurance plans.
    - Eliminating additional prior authorizations for chronic patients who are stable on a specific medication or therapy by making prior authorization approvals extend for the duration of the treatment without the need for additional or annual renewal.

- Eliminating prior authorization for medications that do not have an equally effective alternative.
- Codifying exceptions to prior authorization requirements where these policies threaten patient health.
- Requiring timely appeals of prior authorization denials with standardized and published processes and determination timelines.
- Increasing transparency by insurance companies through the publication of formularies, specifying which medications require prior authorization and the specific related requirements.
- Requiring insurers to report the prior year's prior authorization approvals and denials and the accompanying timelines to respond to prior authorization requests.
- Requiring peer-to-peer reviews for prior authorization to be assigned to a physician licensed in the same or similar medical specialty.

II. Expand Patient Access to Care

iii. Electronic Health Records

The transition from paper-based to electronic health records (EHR) in recent years has enhanced the ability of healthcare professionals to document patient visits and services provided during the visit. When properly applied, EHR may effectuate significant improvements in access to care, patient safety, quality and efficiency of care, patient-clinician communication, and care coordination among health professionals.

The increasingly complex EHR systems have proportionately increased the administrative burden for physicians and members of rheumatology care teams which takes time away from patient care. Additionally, the implementation of these complex EHR systems is directly correlated with clinician burnout, struggles with maintaining the workforce, and challenges in maintaining optimal patient care.

Many factors contribute to the inadequacies of the current EHR structure. The ACR supports measures designed to strengthen the impact of the EHR product provided by vendors to rheumatology professionals, encourage dialogue between EHR administrators and the practices, and apply standard practices and accountability measures to ensure that the EHR provides value to patient care.

Moving away from paper-based records to electronic health records is a natural evolution. These systems should improve efficacy and reduce redundancies in our healthcare system, but we are far from achieving those goals. While data collection is an important task these programs can perform, the most important goal behind them should remain to improve patient care, increase efficiency, decrease errors, and improve quality of care by increasing coordination among practitioners and communications between patients and their healthcare teams. In this pursuit, EHR systems have inadvertently increased the administrative burdens on healthcare teams which has reduced the time for direct patient care with no clinically significant outcomes to show for it.

Additionally, the burden of implementing and upgrading the EHRs should not be shouldered solely by physicians. Vendors should be expected to actively participate in the implementation and troubleshooting process and should be held accountable for failures in implementing their systems.

The ACR supports:

- Minimizing administrative burdens associated with EHRs including electronic prescribing.
- The interoperability of EHRs, together with other measures to streamline information sharing for clinicians; the use of qualified registries; and the prevention of information blocking by EHR vendors.

- Developing efficient, secure, affordable, and interoperable standard-based EHR systems, with federal financial support for medical practices to defray the cost of implementation.
- Timely implementation of bidirectional EHR data exchange capabilities among different health systems and medical practices. This will improve the continuity of care and decrease medical errors.
- Requiring that EHR compliance goals be shared with vendors and that vendors share in penalties when compliance goals are not met due to technology implementation problems.
- Preventing information blocking/data blocking regarding medical registries and the interoperability of EHR, and the provision of more credit for those who participate in specialty clinical data registries under MIPS (such as ACR RISE registry which uses EHR to improve patient care, outcomes, and practice efficiency).
- Requiring that vendors provide a robust interface to allow communication and data sharing from one EHR to another, including EHR compatibility for a uniform electronic prior authorization process.
- Decreasing the administrative burden on clinicians and improving redundancies in these programs through collaboration between the developers and practicing clinicians.

II. **Expand Patient Access to Care**

iv. Antitrust Reform

Current antitrust regulations strengthen the position of health insurance companies while threatening the viability of physician-owned private practices. These laws restrict private practices from negotiating as a special interest group with large insurance companies, creating a barrier to collaboration and integration of clinical services which would improve quality of care, benefiting patients, clinicians, and payers.

Previous investigations have shown a “revolving door” between state insurance commissioners and the health insurance industry, where some commissioners were previously employed by health insurance companies or sought employment after their term. This raises the question of the ability of these government officials to effectively regulate the insurance industry.

The ACR supports:

- Amendments to the National Labor Relations Act and other appropriate federal legislation to ease antitrust restrictions, and permit physicians’ representatives to engage in collective negotiation with private payers, to promote a more level playing field.
- Legislation for regulation of state insurance commissioners and appropriate auditing.

II. **Expand Patient Access to Care**

v. 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 practitioners. This payment scheme is essentially bounty hunting. It is prone to abuse by overzealous contractors. The practitioner is often presumed guilty and often faces an arduous and expensive appeals process.

The ACR believes that RACs should be held accountable for reviewing claims based on CMS requirements and ensuring 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 the reform of audit practices and guidelines to:

- Eliminate fraud and abuse and promote the appropriate use of diagnostic and therapeutic modalities for the care of rheumatology patients.
- Oppose 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.
- Incentivize RAC identification of fraud, not errors.
- Replace financial penalties with a corrective action plan.
- Auditors should bear all costs incurred by individual practitioners due to RAC audits or other billing audits 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.

II. **Expand Patient Access to Care**

vi. 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 still 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 compared to those without such reforms. Additionally, lower malpractice risk has been shown to result in less "defensive medicine," with physicians ordering less invasive and expensive procedures, driving total healthcare costs down.

The ACR advocates for medical liability reform to reduce healthcare costs and preserve patients' access to care.

The ACR supports:

- A cap on non-economic damages.
- Standards for expert witnesses.
- A rigid statute of limitations from the day of discovery.
- The elimination of joint and several liability.
- Limits on contingency fees.
- Alternatives to traditional litigation such as arbitration and, in some cases, specialized medical liability courts.
- Establishment of state patient compensation funds.
- Establishment of state medical malpractice review panels consisting of physicians from the defendant's specialty that review malpractice claims before they may proceed to court, thus helping to discourage frivolous litigation.

II. Expand Patient Access to Care

vii. Network and Formulary Adequacy

Health insurance provider networks, including Medicare Advantage and formularies, are often overly restrictive, and unsafe, and can inappropriately limit patients' access to necessary care. Both public and private health insurance provider networks often contain incorrect or missing information, which makes it difficult for consumers to choose plans based on network adequacy.

Truthfulness in advertising health insurance plans is essential for both patients and healthcare providers. Patients expect to have access to the healthcare providers associated with the insurance plan when they initially selected which plan best met their needs. Patients should not be forced to lose or transfer care to a new provider when plans abruptly change networks and will no longer reimburse for care from the patient's previously chosen in-network provider. These changes can limit access to the already limited provider options in the geographic area accessible to the patient.

Changes in formulary components are also sometimes made outside of enrollment periods. An unexpected change could force a patient to change their treatment plan when their disease was previously well controlled on a different treatment. This disruption threatens patient health as well as trust in their care team. Payers should be restricted from changing drug formularies outside of open enrollment periods so patients and physicians can predict what treatments will be covered. An informed consumer should be able to rely on a payer's formulary for the entire year until the next open enrollment.

To ensure the quality of patient care, managed care systems should be regulated in a manner that ensures essential patient protection. The ACR advocates for issues affecting the quality of patient care, including managed care reform and access to care.

The ACR supports:

- Requiring insurers to set their provider networks in advance of open enrollment.
- Ensuring practitioners remain on a network unless the insurance company documents the cause for their removal.
- Requiring insurance provider networks to contain sufficient options and reasonable access to specialty physicians, including rheumatologists.
- Prohibiting overly restrictive drug formularies and creation of drug formularies solely based on financial expediency rather than a scientific basis.
- Prohibiting changes in drug formularies outside of open enrollment periods.
- Prohibiting indication-based formulary design and exclusion of protected drug classes.
- Prohibiting health insurers from incentivizing switching patients' treatments for any non-medical reason but specifically to a payer's preferred alternative.

Further, it is the ACR's Position 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.

  - Physicians, health professionals, and patients, rather than health plans, should make determinations regarding patient treatment options.
  - Patients covered by managed care plans should be provided with information on all treatment options and coverage available.
  - 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.
  - If participation between a health plan and health professional is terminated because of a 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.
  - Rheumatologists and other sub-specialists should be allowed to act as the principal care provider to patients with the chronic conditions they are specifically trained to treat.
- To coordinate care effectively, care management service codes should be simplified and available to physicians and specialists on the care team who are primarily responsible for disease management. Management of multiple chronic diseases requires team communication and should not be limited to only one physician per individual patient.

II. **Expand Patient Access to Care**

viii. Surprise Billing

Narrow provider networks utilized by insurance companies often necessitate or lead to patients receiving some care and services from practitioners who are out-of-network. The ACR supported the "No Surprises Act" which went into effect in 2022 to protect patients from responsibility for costs incurred above their in-network cost for any reason including emergencies, network coverage gaps, or lack of clarity regarding their network providers.

The ACR supports protecting patients from unexpected financial liabilities and resolving any payment disputes between insurance companies and out-of-network providers instead. However, the ACR is concerned that this policy change does not address and may exacerbate the lack of adequate in-network provider options in some payers' networks by disincentivizing insurance companies to maintain adequate provider networks.

The ACR supports the following principles regarding surprise billing:

- Protect patients from additional costs and payment disputes between their insurance company and an out-of-network provider when billing at out-of-network rates was not anticipated by the patient.
- Provide timely, upfront, commercially reasonable payment for out-of-network services and efficient implementation of the new independent dispute resolution process.
- Provide initial payment of a commercially reasonable rate that is fair to all stakeholders in the private market, including actual local charges as determined through an independent claims database.
- Ensure new imbalances are not created in the private healthcare marketplace through marketplace leverages to health insurers at the expense of providers.
- Establish strong, measurable, and enforceable network adequacy requirements. This is essential to ensure that insurers maintain adequate provider networks and do not force patients to go out-of-network to access the care that they need.
- Create balance in the system of arbitrating payments/dispute resolution of out-of-network care by ensuring that the cost of petitioning insurance companies for payment is not so high as to deter providers from pursuing reimbursement and therefore incentivizing insurers to further narrow their network of providers.

II. **Expand Patient Access to Care**

ix. Expanding Telemedicine

Telemedicine is the provision of health care services and education over a distance using telecommunications technology. The ACR recognizes that telemedicine is a tool that can increase access and improve outcomes for patients with rheumatic diseases when used as an adjunct to face-to-face assessments. The COVID-19 pandemic presented both challenges and opportunities to rheumatologists and rheumatology health professionals who have rapidly adopted telemedicine in routine practice.

Telemedicine's potential benefits in improving patients access to care both during and after the COVID-19 pandemic necessitate careful evaluation and investment for the continuity of telemedicine in the healthcare system and its successful implementation. Efforts on the part of rheumatology professionals to expand the use of telemedicine have been hampered by a multitude of factors, including federal and interstate licensing, state regulations, and reimbursement issues.

The ACR supports:

- The use of telemedicine along with in-office evaluations emphasizing that it should not replace essential face-to-face assessments conducted at medically appropriate intervals.
- Use of telemedicine to improve patient access and mitigate healthcare disparities through lessening geographic restrictions on telemedicine practice.
- Continued parity of reimbursement for in-office visits, audio-visual visits, and sufficient reimbursement for audio-only visits, by CMS, Medicaid, and commercial payers, after the declared COVID-19 public health emergency (PHE) has ended, if telemedicine services abide by the following principles:
    - The clinician-patient relationship should include both in-person and telemedicine services in accordance with the American Medical Association (AMA) Code of Medical Ethics, specifically Ethical Practice in Telemedicine.
    - Patients should have a choice of clinician for telemedicine services, as is required for all medical services.
    - The standards and scope of care provided remotely via telemedicine services should be consistent with related in-person services. The limitations of the relevant technologies should be recognized, and appropriate steps are taken to mitigate these limitations.
    - The provision of telemedicine services must be properly documented.
- The recommendation that telemedicine platforms provide an efficient mechanism to obtain informed consent for the delivery of telemedicine services, including information for patients or their surrogates about the distinctive features of telemedicine, the credentials of the healthcare professionals involved, and the limitations of the technologies.
- Appropriate protocols to protect the security and integrity of patient information, while balancing the need for access to telehealth services.
- Proposals that would reduce barriers to the interstate practice of telemedicine where appropriate.
- Fee structures for hospital telemedicine support based on a transparent and fair formula.

- The promotion of outcomes-based research regarding telemedicine use in the practice of rheumatology.

The ACR opposes:

- Geographical restrictions on telemedicine practice and supports the ongoing ability of patients to access telemedicine services from their home after the PHE had ended.
- Policies that mandate the use of specified telemedicine platforms or use telemedicine as a means of constructing restrictive networks or diverting patients to their “preferred” practitioners.

II. Expand Patient Access to Care

x. Recognition and Research for Health Disparities

The ACR recognizes that inequality and inequity are invisible undercurrents impacting the lives of many of our members and patients. The ACR condemns all acts that cause marginalization, discrimination, or harm to any person based on race, ethnicity, age, gender identity and expression, socioeconomic status, sexual orientation, religion, or disability.

From lupus morbidity and mortality to arthritis disability, and most recently to COVID-19 burden, severity, and deaths, people of color have suffered disproportionately. Physicians and healthcare professionals are bound to protect the health of all of humanity. The ACR pledges to be a leader for inclusion and change for our members, trainees, staff, and our patients.

The ACR supports:

- Initiatives that diminish racial and ethnic disparities for patients with rheumatic diseases including care delivery and clinical trials.
- Research and government funding to identify, recognize, and reduce racial, ethnic, and socioeconomic disparities in rheumatic disease diagnosis, care delivery, and outcomes.
- Targeting funding for research and the evaluation of clinicians' implicit bias and develop strategies and policies to address this.
- Recognizing the central role of social determinants on health disparities and health outcomes and the mobilization of resources and research funding to better understand and address these disparities.
- Increasing funding for rheumatology research workforce diversity.

III. Remove Barriers to Patient Access to Treatment

i. Specialty Tiers and Excessive Patient Cost Sharing

Patients face cost-based barriers to care often due to policies created and implemented by insurers to shift as much of the cost as possible onto the patient. This often comes in the form of "specialty tiers" for prescription drugs and policies preventing copay assistance funds from counting towards patients' cost-sharing requirements.

Many commercial health insurance policies put vital medications (mostly biologic treatments without alternatives) into "specialty tiers" that require a higher patient cost-sharing. These specialty tiers (Tier IV and higher) require patients to pay a percentage of the cost of these drugs (often 25 to 33 percent or more) as opposed to a co-pay, a difference that can cost patients hundreds or even thousands of dollars per month for a single medication. After patients reach the coverage gap or limit on what the patient or plan may spend on treatments in a year, the patient will pay 25 percent for all brands followed by 5 percent coinsurance even when their total out-of-pocket spending exceeds an annual threshold.

These coinsurance practices often put medically necessary treatments financially out of the reach of the majority of American patients. Proposed changes to Part B medications threaten to create similar issues.

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

The ACR supports:

- Placing restrictions on such tiering by insurance carriers.
- Reducing out-of-pocket costs for treatments by capping total annual patient out-of-pocket expenditures, allowing coinsurance to be spread over a plan year, and requiring health plans to include at least one option for pharmacy insurance that does not have a specialty tier.
- Allowing an expeditious exception and appeal process for Part B and Part D beneficiaries who are similarly affected by specialty tier practices.

III. Remove Barriers to Patient Access to Treatment

ii. Patient Assistance Programs

Biologics, cancer immunotherapies, and curative antivirals, have been recognized as revolutionary treatments for patients with a compendium of rheumatic diseases such as rheumatoid arthritis, systemic lupus erythematosus, vasculitides, and inflammatory muscle diseases among others.

For patients on Medicare, 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. Similar issues regarding high out-of-pocket costs also occur for patients with commercial insurance policies. As a result, many patients must forego life-altering 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 and other insurance policies to simply cover the cost of these essential treatments for chronic, non-curable diseases. However, in the absence of this type of 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. This is merely a band-aid approach and is a suboptimal way to address the high costs of therapies. While helpful in the short term, the ACR acknowledges concerns about these programs. When insulating patients from medication costs, these programs distort demand for lower-cost therapies and lead to increases in drug list prices. This problem is likely to become more pronounced in the coming years. Until more holistic measures can be implemented to reduce the cost of these treatments, patient assistance programs are needed and helpful but should be paired with measures that will spur a reduction in drug list prices to facilitate necessary change in the long term.

Both commercial payers and Medicare Part D restrict Patient Assistance Programs. Some commercial insurance carriers, for example, do not apply patient assistance program contributions towards patients' deductibles or out-of-pocket maximums (so-called "copay accumulator programs"). This essentially requires that a patient pay twice for drug costs: once with an assistance program and again with their own money. This creates an additional financial barrier to treatment.

The result is that many patients are faced with unexpected costs of thousands of dollars to get the medicines they need. 95% of medicines that are subject to programs like these do not have a less expensive alternative and 69% of those who depend on such assistance make less than $40,000 a year, leaving them at risk of losing access to necessary health care. Therefore, ACR takes the position that all payments, whether they come directly out of a patient's pocket or from the help of copay assistance, should count towards the out-of-pocket cost calculations of the patient, thereby removing a hurdle to access to prescribed treatments.

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 financial assistance, patients have difficulty receiving help if

they do not qualify or if the foundations' resources have been expended. The unintended consequence is that patients are forced off effective disease-modifying therapy when they become a Medicare Part D beneficiary.

The ACR supports:

- Increasing access to patient assistance programs for Medicare Part D beneficiaries if Medicare does not fully cover the cost of essential treatments - Patients should not be denied newly developed therapies such as biologics solely because of their cost.
- Allowing beneficiaries to accept financial co-pay assistance for specialty cost-tier drugs from pharmaceutical companies for Part B and Part D drugs.
- Legislation to reduce barriers to treatment for patients by requiring health plans to count the value of copay assistance toward a patient plan's cost-sharing requirements. This would ensure that all payments, whether they come directly out of a patient's pocket or from the help of copay assistance, count towards their out-of-pocket cost calculations.

The ACR opposes:

- Restrictions preventing the application of funds from assistance programs toward patients' deductibles and out-of-pocket maximum payments.

III. Remove Barriers to Patient Access to Treatment

iii. Access to Treatment under Medicare Part B

The ACR supports adequate reimbursement for providers of Part B drugs to maintain patient access to these treatments by covering the cost of providing them incurred by a specialty care team. These costs include drug acquisition, inventory maintenance, scheduling treatments, information technology, patient privacy protection, acquiring prior authorization (PA), appropriate storage of the medication, billing, and safe administration of these complex drugs. Multiple current and proposed policy changes threaten Medicare beneficiaries' access to Part B drug treatments by reducing reimbursement for treatment without reducing the cost of acquiring and providing the treatment. For example, CMS's decision to include the costs of Part B drugs when calculating the cost component of MIPS scores is likely to reduce patient access in this manner. 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 cost calculations, but Part D drug costs are not included, physicians may be penalized for providing medically necessary Part B drug treatments to their patients.

Unfortunately, due to a lack of appropriate reimbursement for the specialized care that rheumatologists provide, practices rely on income from Part B treatments. As such, the ACR is concerned that the variety of threats to reimbursement for physicians who provide Part B drugs to patients threatens the viability of rheumatology practices in the US, especially in this period during the Covid-19 pandemic, as practice solvency is at significant risk. As a result, many rheumatologists may be forced to cease providing these treatments because the payment rate does not cover actual cumulative costs. With limited access to in-office treatments, patients will be forced to seek treatment in hospitals where their physicians will not have direct supervision, as they would in the office setting, to monitor for adverse events including allergic reactions, they face higher copayments, facility fees, and often longer travel times. This unnecessarily increases healthcare costs and burdens on patients and the healthcare system. When the patient is forced to make a separate trip after seeing their healthcare professional to receive a medication infusion it puts an increased physical, financial, and logistical burden on the patient who is likely struggling with pain and inflammation, and in this set-up is required to spend additional money and time on travel and parking in addition to the extra time away from work and family.

The ACR supports adherence to the ASP + 6% reimbursement rate for in-office treatments as well as these policies to maintain access:

- Repealing sequester cuts to Medicare including the cuts to Part B drug reimbursements.
- 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.
- If Medicare changes reimbursement to a flat fee system, the fee must cover all the services required to maintain access to treatments as noted above. Also, this flat fee must rise with inflation as costs rise.

- Any Medicare reforms affecting the administration of biologic agents must protect patients' ability to receive them in a monitored healthcare setting with onsite supervision by a clinician with appropriate training in biologic infusions, preferably in the same location as the prescriber.
- Exclude Part B drug costs from the cost 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.

III. Remove Barriers to Patient Access to Treatment

iv. 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 clinicians, while others limit access to medications integral to the treatment of rheumatic diseases.

The ACR supports:

- Medicare negotiating with pharmaceutical companies to achieve more affordable pricing of drugs covered under Part D.
- Treating physicians deciding with a patient on the most appropriate, efficacious, and cost-effective therapy without Part D benefits influencing the choice of therapy.
- Patient assistance programs for Medicare beneficiaries for Part D drugs.
- Elimination of the Medicare Part D "donut hole".
- Where MIPS formulas impact providers, the most equitable formula would not include drug costs. Omitting or including both Part B and Part D drugs in the MIPS formula to ensure that providers who prescribe Part B drugs are not penalized or do not look "costlier" than those who mostly prescribe Part D drugs.

III. Remove Barriers to Patient Access to Treatment

v. Prioritizing Patient Safety

All classes of biologics used in autoimmune diseases have the potential to cause serious adverse events. Serious infections affect 2-5% of patients per year of exposure and adverse drug reactions associated with biologics occur in up to 30% of patients in clinical trials.

It is ACR's position that experienced clinicians, available on-site, are most capable of deciding whether it is safe to continue therapy in the setting of mild reactions and providing prompt treatment for moderate or severe reactions. Any financial considerations related to potential cost savings of home infusions should not override patient safety and standards of care.

This includes limiting payer-mandated "white bagging" drug acquisition systems where patients are required to purchase medications through specialty pharmacies that are owned by the PBM or insurer, thus allowing PBMs to make a large profit on the rebates they demand from drug manufacturers. This drives drug prices higher and has the potential to cause disruptions in care by adding a layer of red tape and financial burden to the patient.

The ACR Supports:

- Proper administration of biologic infusions taking place under close supervision in a practitioner's office, infusion center, or hospital rather than in a patient's home, unless the patient and clinician decide that home infusion is in the patient's best interest.
- Policies or pilot programs that reduce the price and cost of drugs while maintaining safe patient access to medically necessary treatment and ensuring the ability to administer and dispense treatments.
- Patient access to safe and cost-effective intravenous infusion therapy.
- Measures to preserve the long-term viability of and accessibility of patient access to infusion therapy in a variety of settings including infusion centers overseen by their private rheumatology professional.
- The traditional "buy and bill" model which over time reduces the cost of drugs, offers many benefits to patients and practices, allows for immediate availability of drugs, less waste to the system, safer handling and storage of drugs, and substantially reduced administrative burden.
- Equality in payment for identical intravenous therapy.
- Policies or pilot programs that reduce the cost of drugs to patients and the system while maintaining access to medically-necessary treatment and ensuring clinicians' ability to administer and dispense treatments including limiting payer-mandated "white bagging" drug acquisition systems.

The ACR opposes:

"Brown bagging", "white bagging" and or other similar attempts to limit access to infusion drugs.

III. Remove Barriers to Patient Access to Treatment

vi. Drug Pricing

The ACR believes that safe and effective treatments should be accessible to all patients at the lowest possible cost. Recent federal proposals to curb spending have included multifaceted approaches such as Medicare using its authority to negotiate lower drug prices and regulating additional utilization management (e.g., step therapy) by insurance plans. Also, payment models have moved towards holding physicians accountable for the cost of the care they provide, though physicians have little control over rising drug costs. The ACR supports shared decision-making between patients and clinicians, which decreases barriers to patients accessing treatment.

Pharmacy benefits managers (PBMs) are companies that manage prescription drug formularies on behalf of health insurers, Medicare Part D drug plans, large employers, and other payers with the intention to lower overall costs. PBMs are reimbursed partially on the rebates they obtain, which are calculated as a percentage of a drug's list price. Due to this, they are incentivized to favor coverage of medicines whose distribution provides PBMs with higher rebates, fees, spread pricing, and other profits. Although the ACR recognizes the need for cost control due to rising drug prices, it also stands by a practitioner's need for drug formularies to reflect evidence-based guidelines and clinical data, rather than profits derived from the drug distribution system.

The ACR supports policies that:

- Require 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 the establishment of uniform definitions for terms used in disclosures by specifying what constitutes a rebate, discount, fee, and amount received from a manufacturer.
- Provide patients with reliable access to high-quality treatments to control disease activity as well as prevent premature death, disability, and permanent damage to joints and organ systems.
- Reduce and streamline utilization management tools in the drug distribution process, including Medicare Part D, which delay and/or prevent patients from accessing medicines.
- Provide transparent processes for justifiable overrides and a reasonable timeframe for the processes by a physician or rheumatology interprofessional team member for step therapy policies.
- Ensure patients' safe access to Medicare Part B treatments in monitored settings. Intravenous biologic agents should be administered in a monitored healthcare setting with onsite supervision by a clinician with appropriate training in biologic infusions. The ACR opposes forced relocation of infusion to patient homes or other sites not directly supervised by a licensed practitioner.
- Promote the use of evidence-based treatment guidelines, when available, adapted for individualized treatment decisions made by doctors and patients.

- Improve FDA capacity and manufacturer ability to bring safe, effective biosimilars to market to maximize access to treatment by lowering costs.
- Ensure all stakeholders, including pharmaceutical manufacturers, insurers, health IT vendors, and device manufacturers, share the burden of controlling healthcare costs.
- Limit or cap out-of-pocket prescription drug costs for patients,
- Promote transparency in drug pricing, including reporting of:
    - Formulas that pharmaceutical companies, pharmacy benefit managers, and health insurance companies apply to determine the cost of prescription medication.
    - Incentives given by drug companies to pharmacy benefit managers or health insurance companies related to the dispensing or promotion of their manufactured drugs.
- Oppose restrictive insurance company rules that prevent the application of copay assistance funds toward patient deductibles and out-of-pocket maximum limits (so-called copay accumulator programs).
- Reduce the cost of prescription drug treatments to patients and the healthcare system without threatening access to care by targeting provider payments without also reducing the cost of providing the treatment to providers.

III. Remove Barriers to Patient Access to Treatment

vii. Drug Shortages

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

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. These shortages can cause arthritis patients to experience additional pain and immobility, relapse of life-threatening diseases, and add to suffering and disability.

Additionally, the ACR is concerned that there is a lack of timely communication to physicians and the public of impending drug shortages.

The ACR Supports:

- Addressing the causes of drug shortages and reducing their impact on patients and physicians.
- Efforts of the FDA to minimize drug shortages.
- Creation of redundancy in the drug supply chain for critical drugs, including generics, by providing incentives to manufacturers for the production of these drugs.
    - FDA policies to further broaden reporting rules to ensure that manufacturers provide early warning of disruptions in the supply of a drug.

III. Remove Barriers to Patient Access to Treatment

viii. Biosimilars

Biosimilars are medicines that could be cost-saving alternatives for the specialty drugs called biologics, which are large, complex therapeutic agents given by 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 approved by the FDA in 2019. The FDA must ensure that biosimilars and interchangeable biosimilars are safe and effective.

The ACR recognizes increasing cost pressures may cause payers to push patients toward biosimilars. This is most appropriate when there is data available. In the absence of data, payers should provide transparent guardrails around “non-medical switching” which allow the patient and clinician to choose the best treatment for that patient with tenuous disease control. For patients with stable disease, transition to a biosimilar product may be reasonable if cost savings are available, though we remain concerned that pharmacy benefit managers’ (PBM) lack of pricing and rebate transparency leaves formulary decisions disappointingly opaque.

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 strongly believes that safe and effective treatments should be available to patients at the lowest possible cost. Decisions regarding the approval and use of biosimilars must be driven by sound science and consider several guiding principles, including:

- Appropriately reimburse all biologics approved for rheumatic conditions by health plans in which all biologics should be considered highly complex for purposes of administration, monitoring, coding, and reimbursement.
- When starting new biologic therapy, clinicians consider a variety of patient-specific factors which include the severity of the illness, the most appropriate route of administration, and mechanism of action. Should the appropriate medication have a biosimilar option, the ACR supports initial biosimilar use. However, if the most appropriate biologic does not have a biosimilar option, it should be approved by the patient’s insurer, and not be switched to a different biologic class.

- In patients on established therapy, the final decision to switch from a reference product to a biosimilar should rest with the prescriber and the patient. The ACR opposes insurer-mandated forced switching to biosimilars and is concerned over frequent non-medical switching with biosimilars. In jurisdictions where substitution by someone other than the prescribing professional is lawful, the prescriber and the patient should be notified immediately when a substitution is made.

III. Remove Barriers to Patient Access to Treatment

ix. Administration of Complex Treatments under Medicare Part B

Biologic medications are vital in preventing disability and death in inflammatory arthritis and systemic autoimmune diseases. In recent years, a growing number of contractors have stopped reimbursing for these treatments at the appropriate higher "complex" rates without regard for the necessary time and skill needed to safely administer such treatments.

When a patient is responding appropriately to treatment, therapy should be continued. An insurer's refusal of payment interrupts care risking flare up of symptoms and disease progression. These changes in policy conflict with the official guidelines developed by the American Medical Association Current Procedural Terminology (CPT) Editorial Panel. This reduction in service reimbursement adds to the effect of the sequestration cuts to infusion reimbursements, further limiting reimbursement and coverage which threatens access to medically necessary care and treatment.

The ACR strongly supports the use of biologics in the treatment of rheumatic disease when indicated. Administering biologics for rheumatic diseases requires advanced training and necessitates special handling of medications as well as increased monitoring for patient safety. Patient access to biologic treatment should not be threatened 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 appropriately 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 administer and necessitate special handling, storage, and increased monitoring for patient safety.
- Enforcement of transparency requirements for Medicare contractors considering reimbursement changes.
- Efforts by Congress to ensure seniors have access to medically necessary biologics.

III. Remove Barriers to Patient Access to Treatment

x. 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, care delivery intervention, or service relative to other treatments for the same condition. High-quality CER and cost-effectiveness analyses (CEA) can and should inform the individual provider and patient decisions about the relative value of diagnostic and therapeutic options.

Indeed, CER has the potential to enhance understanding of the pros and cons of different treatments, as well as highlight the need for multiple treatment options to address heterogeneous groups of patients. However, CER and CEA results must not be misconstrued or inappropriately applied to individual patients via inflexible insurer policies designed to control costs, thereby overriding medically appropriate, individualized decision-making by providers and patients.

The ACR supports:

- CER should be applied to common problems that impact rheumatology patients and providers. The ACR advocates that federal funding of CER research (such as the Patient-Centered Outcomes Research Institute (PCORI), the Agency for Healthcare Research and Quality (AHRQ), and the National Institutes of Health, etc.) should target rheumatic and musculoskeletal diseases with requests for applications from rheumatology researchers.
- The collection of anonymized patient data in registries such as RISE (Rheumatology Informatics System for Effectiveness), which can serve as powerful databases for CER if they are robustly populated with sufficient patient data.
- Ongoing funding of CER initiatives to follow up the initial $1.1 billion investment made in 2009 through the American Recovery and Reinvestment Act (ARRA), understanding that groups such as PCORI and AHRQ are subject to ongoing funding allocation and perennially at risk of underfunding.
- Ongoing transparency regarding oversight of the distribution of CER funds and communication of results.
- Collaboration between the FDA and drug manufacturers to increase the collection of CER data for inclusion in drug labeling.

IV. Supporting Rheumatological Care in Medicare

i. 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. 2024 is the eighth year of the Merit-Based Incentive Payment System (MIPS), which scores providers based on (i) Quality (based on PQRS), (ii) Promoting Interoperability (formerly Advancing Care Information, and based on Meaningful Use), (iii) Clinical Practice Improvement, and (iv) Cost. Providers' performance on MIPS measures will provoke payment adjustments, in the form of bonuses or penalties two years after the reporting year unless providers join an Alternative Payment Model (APM).

In 2018, CMS implemented the resource use, or cost, category as a component of MIPS scoring. This is concerning as Part B drug costs are included in the cost component and count toward a practitioner's score, though Part D drug costs are not included. Under this system, rheumatologists may be penalized for providing medically necessary Part B drug treatments to their patients. The ACR supports new cost measures that 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. This will safeguard practitioners, especially specialists like Rheumatologists, where there is a higher use of necessary and effective yet expensive medications, like biologics.
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. A third option, the MIPS Value Pathway (MVP) has been instituted to help ease providers, especially the smaller groups and solo practitioners, from MIPS to APMs and began implementation in 2023. The initial reporting period is through 2025 and in 2026 multispecialty groups will be required to form subgroups. These three programs must allow for meaningful and streamlined quality measurement without placing an unnecessary burden on the provider. 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 distances or increased out-of-pocket costs.

Flexibility in the design of the MIPS and future MVPs and simplicity in implementation should drive the refinement 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:

- Appropriate management of MACRA and protecting access to rheumatologists and rheumatology interprofessional team members in these ways:

  - Use of metrics that are clinically relevant, efficient, and promote quality of rheumatologic care in the components of the Merit-Based Incentive Payment System (MIPS) and implementation of MIPS Values Pathways (MVPs).
  - Creating and giving proper accreditation to a variety of Alternative Payment Models and demonstration projects that recognize the value of care provided by rheumatologists and rheumatology interprofessional team members.
  - Counting participation in a Qualified Clinical Data Registry such as RISE toward MIPS participation under MACRA.
  - Transparency in MIPS, MVPs, and APMs, allowing practicing physicians to easily understand and implement these programs.
  - Improving 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.
- Maintaining the revised RVUs for evaluation and management codes that reflect the work and medical decision-making required by cognitive subspecialists.
- Maintaining appropriate reimbursement conversion factor for the work RVU's so that the change in the wRVU yields appropriate reimbursement to physicians as intended.
- PTAC's recommendation for implementing the ACR rheumatoid arthritis APM.
- Excluding Part B drug costs from the cost 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.
- Congressional action to control excessive drug price increases.
- Simplifying the MIPS and MVPs program through reduced reporting requirements and flexibility to account for practice variation.
- Continuing a minimum 90-day reporting period for MIPS domains of Promoting Interoperability and Improvement Activities.
- Streamlining reporting systems for each MIPS category.
- Ensuring that providers who participate in a Qualified Clinical Data Registry (QCDR), such as RISE, can maximize credit in MIPS for doing so.
- Ensuring that providers will be informed of performance outcomes in real time to enable them to make changes before the next performance period.
- Minimizing barriers to forming virtual groups to report performance.
- Development of APMs that place adequate value on rheumatology care and are feasible for small practices and specifically:
  - Approval of the ACR rheumatoid arthritis APM by the Physician-Focused Payment Model Technical Advisory Committee (PTAC) and implementation by CMS. Excluding Part B drug costs from the cost component of MIPS score calculations. Lower the payment amount and patient count thresholds required to achieve qualifying participant status in an advanced APM and minimize initial risks to which providers are exposed to encourage smaller practices, many of which are in under-served areas, to participate in APMs.
- 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.
- Implementing efficient evidence-based performance measures that improve the quality of care and promote fair reimbursement for work done by rheumatologists and rheumatology interpersonal team members in collecting and reporting administrative data.

IV. Supporting Rheumatological Care in Medicare

ii. Cognitive Specialty Reimbursement

Rheumatic diseases require specialized management by a rheumatologist who has completed substantial additional training to diagnose and treat these complex diseases with the necessary expertise. Through early identification and treatment of these conditions, rheumatologists and their interprofessional team members can effectively care for patients, while limiting the need for unnecessary or costly testing and procedures. This protects patients from disability, increasing quality of life and decreasing the cost to the health care system.

Cognitive care like rheumatology involves face-to-face, non-procedural medical care in which physician specialists examine and counsel patients as they evaluate and manage the patient's conditions. Additionally, primary care physicians, rheumatologists, and other cognitive specialists provide ongoing care to patients and primarily bill evaluation and management (E/M) codes.

The Physician Fee Schedule changes finalized by CMS in 2020 which took effect in 2021 increase reimbursement for E/M codes reflecting the specialized knowledge, physical exam skills, and expert medical decision-making that are required to provide rheumatologic care. This increase also takes into consideration the extra time required to assess and treat these complex diseases.

ACR advocated for the implementation of the G2211 code, which more appropriately captures the additional costs clinicians pay to deliver ongoing care to patients living with single, serious, or complex chronic diseases like rheumatic and musculoskeletal conditions. After a three-year delay as part of coronavirus-related legislation to ensure all specialties do not suffer negative E/M reimbursements in 2021, the G2211 code was implemented on January 1, 2024.

The ACR supports:

- Increasing reimbursement for cognitive care services commensurate with specialized care.
- Repealing the balanced budget requirement for the physician fee schedule.
- Appropriately valuing evaluation and management codes and other measures in the Medicare physician fee schedule (MPFS).
- Fighting cuts to the Medicare program and returning to previous funding/payment percentages.
- Repeal the sequester cuts to the MPFS.
- Maintaining the E/M improvements for care provided by cognitive subspecialists that took effect in 2021 and 2024.
- Avoiding or mitigating cuts to reimbursements for services provided by any member of the rheumatology care team under Medicare, including but not limited to rheumatologists, physical therapists, physician assistants, nurse practitioners, and occupational therapists.
- Continuing the 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.

- CMS research to achieve a comprehensive understanding of cognitive physician roles to inform changes in payment models for E/M services.
- Advocating the importance of the updated E/M codes for cognitive specialties, the changes to their Medicare reimbursements as a result, and the benefit to appropriately valuing cognitive specialty teams in their employ.
- Passing legislation that would update all reimbursements under the Medicare Physician Fee Schedule annually in accordance with the Medicare Economic Index.

IV. Supporting Rheumatological Care in Medicare

iii. Osteoporosis Testing (DXA)

Appropriate reimbursement is essential to preserving patients' access to critical tests such as dual x-ray absorptiometry (DXA) testing of bone density which is considered the "gold standard" for diagnosing osteoporosis. Osteoporosis is a silent disease that often is not discovered until a fracture occurs. One out of two women and up to one in four men will suffer an osteoporotic fracture in their lifetimes. Further, the cost to the system of fractures in the aging population is estimated to be more than $25 billion by 2025.

Bone density assessment via DXA can identify those at high fracture risk who may benefit from treatment. However, the reduction in reimbursement below the cost necessary to provide the test limits patient access to DXA. The reduction in DXA reimbursement has impacted office-based more than hospital-based DXA which prevents many offices from providing this service to their patients. Consequently, fewer office-based practices offer this screening service, leading to a decrease in treatment and a rise in fractures and costs 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 mortality rate after a hip fracture in a person over 65 years old reaches 25%. Improving access results in early treatment and decreases mortality.

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

- The ACR supports legislation that would increase DXA reimbursement rates to reflect the actual cost of providing this test for patients who are at risk for osteoporosis.
- To close the care gap for osteoporosis patients, the ACR supports hospital funding for fracture liaison services to identify those at the highest risk of subsequent fracture for intervention.

IV. Supporting Rheumatological Care in Medicare

iv. Additional Medicare Reforms

ACR opposes the following Medicare reforms:

- Use of step-therapy in Part B drug distribution to protect patient access to treatment and minimize overhead inefficiencies on the part of health professionals.
- "User fee" tax on health care practitioners for participation in the Medicare and Medicaid program.

Additionally, the ACR supports the following Medicare reforms:

- Modernizing the Stark laws against physician self-referral to align new healthcare delivery models with value-based and shared risk reimbursement models.
- Allowing the Congressional Budget Office to use dynamic scoring/longer time frames for scoring healthcare legislation so that CBO scores accurately reflect cost savings over time.
- Improving the transparency and accountability of the processes by which Medicare Administrative Contractors implement Local Coverage Determinations and ensure practitioner input on all new or revised policies.
- Increased transparency of Medicare formularies and evidence-based decisions made with input from specialty-trained health professionals.
- Easing access to medical directors and more timely resolution of patient care issues including prior authorizations.
- Measures to ensure practitioner solvency during public health crises.

V. Funding Rheumatology Research

i. Medical Research Funding

Funding for the National Institutes of Health (NIH) supports our nation's status as a leader in medical innovation and accelerates lifesaving research, while also providing jobs in communities across the country. NIH awards and grants alone support over 350,000 jobs. 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. These cuts slow the progress of developing improved diagnostics, prevention strategies, and new treatments for arthritis, rheumatic diseases, and their comorbidities (cardiovascular diseases, cancer, and infections), at a time when the population is aging and the number of people with arthritis and related diseases is steadily rising. Such cuts in health research funding limit the potential for 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 through 2020, increasing the NIH budget by 40%, which has helped restore funding to pre-sequestration levels. Continued advocacy for NIH funding, both broadly focused on basic science as well as advancing clinical research relevant to patients with rheumatic and autoimmune diseases, is paramount to ensure progress in rheumatology-related biomedical research.

The ACR advocates for the funding of basic, translational, clinical, and outcomes research in rheumatologic diseases through the Rheumatology Research Foundation, NIH, Department of Defense, and Centers for Disease Control alongside other research-focused lay and professional organizations toward this aim.

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

The ACR supports:

- Sustained funding for the NIH budget at current levels or above.
- Within the NIH budget, the ACR supports:
    - Evaluation of funding allocation relative to the quantitate burden of specific autoimmune, inflammatory, and degenerative diseases.
    - Promotion of collaborative research across institutes to address the burden of multi-organ diseases requiring multidisciplinary research efforts.
    - Appropriate support for the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS).
- Adequate funding levels for the Agency for Healthcare Research and Quality, Department of Defense, and Veterans Affairs medical research.
- Implementation of $20 million of dedicated arthritis research in the Congressionally Directed Medical Research Program at the Department of Defense. This funding was included in the House's FY24 defense funding bill but has yet to be confirmed.

- The funding for a continued emphasis on patient-based research and clinical innovations in patient care.
- Increased funding for the National Arthritis Action Plan and other rheumatologic-related activities of the CDC.
- Continuous funding of the Patient-Centered Outcomes Research Institute (PCORI) to support the implementation of science research and to help implement improved care principles in rheumatology clinics.
- Research by the Health Resources and Services Administration (HRSA) that includes trends in disease incidence and treatment, and workforce demographics to predict future physician workforce needs.
- Funding of the current Loan Repayment Program and development of other research career development programs that support physicians and other health professionals in research careers to ensure an adequate research workforce.
- Increasing global collaborative research in rheumatic and autoimmune diseases that positively impacts population health.
- Enhance funding for basic, translational, clinical, and outcomes 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).

VI. Preserving and Growing the Rheumatology Workforce

i. Support the Current Medical Workforce

The U.S. faces a shortage of rheumatologists; therefore, expanding health coverage for Americans without also growing the medical workforce may not expand access to care as intended. According to recent projections, the U.S. will face a physician shortage of between 54,100 and 139,000 physicians by 2033, more than two of five currently active physicians will be 65 or older within that time and 40% of practicing physicians were feeling burned out at least once a week even before the COVID-19 crisis. The COVID-19 pandemic exacerbated this issue as we see more burnout, retirements, and career changes out of the medical field.

This is also when concerns about noncompete clauses in physician employment contracts became especially acute as physicians advocating for healthcare worker safety were threatened with termination. Because of noncompete clauses, this could have meant months or years of unemployment or geographic relocation. Unfair noncompete clauses are extensive in health care, affecting between 37% and 45% of physicians. They can be especially problematic for residents, fellows and young physicians by limiting their opportunities for career advancement and restricting their ability to provide care in economically or socially marginalized communities.

The rheumatology workforce also relies on medical professionals who need visas to treat American patients. The system of care in our country and the patient population benefit from easier access for these professionals.

The ACR supports:

- Providing incentives to maintain and attract an adequate workforce of adult and pediatric rheumatology specialists to care for people with arthritis and rheumatologic diseases.
- Banning noncompete contracts for physicians in clinical practice who are employed by for-profit or nonprofit hospitals, hospital systems or staffing company employers. Removing noncompete clauses is also seen as a way to improve patient access, enhance the availability of specialist coverage in a community and reduce health inequities by allowing physicians to work for multiple hospitals.
- Decreasing barriers to the American medical workforce for appropriately trained individuals requiring a visa to work in the U.S.

VI. Preserving and Growing the Rheumatology Workforce

ii. Preservation of Physician Autonomy in Treatment Decisions

The ACR recognizes the integrity of physician-patient decision-making in the treatment process. Non-endorsed guidelines adopted by insurance carriers can preclude a rheumatologist from prescribing what they deem the most appropriate treatment for a given patient, reducing access to treatment not just by prohibitive cost, but the additional barrier of formulary restrictions that are created by intermediaries in the drug distribution system.

Additionally, Artificial Intelligence (AI) has become a powerful computational tool that is being used for progressively more applications in medical fields. This has the potential to lead to more rapid diagnosis and personalized treatment plans, hopefully resulting in improved patient outcomes. AI has immense potential to facilitate care and may become an integral part of the evaluation and management of those with rheumatic disease. AI will be capturing data that occurs outside of the normal patient-practitioner encounter. Reimbursement for data review may be better covered under a value-based model as opposed to a fee-for-service model. AI does have limitations that raise concerns for the rheumatology community.

AI should not replace the expertise and clinical judgment of the rheumatologist or rheumatology professional. The role of the rheumatologist is to interpret and integrate the information provided by AI algorithms into the clinical context of each individual patient, considering their unique medical history, symptoms, and preferences. Moreover, AI should be used as a tool to support, not replace, the human interaction and communication between the physician and patient. Ultimately all decisions made are the responsibility of the care practitioner and not that of an AI algorithm.

The ACR is deeply concerned about the impact of the U.S. Supreme Court's Dobbs v. Jackson ruling as it interferes with patient-physician shared-decision making. It is medically necessary for many patients to delay pregnancy until an optimal time, and in some cases, it is advisable to terminate pregnancy to avoid life-threatening worsening of severe chronic inflammatory diseases. Planning for a medically safe pregnancy often requires contraception or the use of assisted reproductive technology.

The ACR supports:

- Reimbursement provisions for off-label use of drugs when available evidence supports such use.
- Drug formularies based on the standard of care and evidence-based practice recommendations.
- Reforming insurance practices that preclude appropriate medications due to formulary restrictions or excessive co-payment/coinsurance requirements in order to allow access to affordable rheumatic disease medications.
- Universal prior authorizations compatible with electronic health records.
- Strategies for lowering the cost of expensive medical therapies, except for cost savings proposals that compromise the standards of high quality, safe clinical practice.

- Including rheumatologists in pharmacy review committees when formulary benefits programs are being developed.
- Transparency around the derivation of algorithms regarding reliability, variability, and the freedom from bias that impacts patient care.
- Efforts to create rheumatology-specific tools to assist patients and health professionals at each step of rheumatologic care and assess the impact on the rheumatology workforce.
- Efforts to assess how the interpretation of AI-generated data from patients impacts reimbursement.
- Greater regulatory oversight of the use of AI in evaluating patient claims and prior authorization requests.
- Clear policies regarding how patients in some states can access critical treatments such as methotrexate, a necessary medication that is commonly used to treat many rheumatic diseases, due to its alternate use as a medication to terminate pregnancy – though in much higher doses.

The ACR opposes:

- Policies that force patients stable on a biologic therapy to switch to a payer-preferred biologic or biosimilar.
- Mandatory drug switching of stable medical therapy guided by insurance as such switching is inappropriate and potentially harmful to patients.
- Overly restrictive step therapies, fail-first policies and tiering of biologics into specialty-tier pricing which render them unaffordable for patients.
- Legislation or regulation that would permit therapeutic substitution by pharmacists, such as 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, or unless the substitution is of an interchangeable biosimilar, in which case the prescriber should be immediately notified of the substitution.
- Indication-based formulary design.
- Attempts to limit access to care through the use of computer algorithms.
- Policies that limit access to comprehensive reproductive healthcare.
- State restrictions that intrude on the practice of medicine and interfere with the patient-physician relationship, leaving millions with limited access to reproductive healthcare services.

VI. Preserving and Growing the Rheumatology Workforce

iii. Educating and Training future Rheumatologists

There are currently many geographical areas of the United States with limited or no access to a rheumatologist or other rheumatology care professional, a trend expected to significantly worsen in the coming decades according to the latest Rheumatology Workforce Study. There is a predicted shortage of 3,845 rheumatologists in the U.S. by 2025, up from previous projections of 2,576. Recent figures suggest that arthritis may be even more common than previously estimated, with an estimated 91.2 million Americans affected in 2015, and the cases are rising.

Additionally, the availability of pediatric rheumatologists is at a crisis level, with fewer than 400 pediatric rheumatologists in the United States providing care at present. Nine states do not have a single board-certified and practicing pediatric rheumatologist and six states only have one. As a result, many children and adolescents with pediatric rheumatic diseases have limited access to high-quality care for their conditions. Rheumatologists trained to care for adult patients do not have sufficient training to provide the highest quality care for pediatric patients while general pediatricians have not received adequate training to treat the intricacies of pediatric rheumatology conditions.

Medicare supports physician training by funding Graduate Medical Education (GME) training positions for specialty care including Rheumatology. Nine US states currently do not have any adult rheumatology fellowship positions and twenty-eight US states do not have any pediatric fellowship positions.

Pipelines suggest medical students are growing in number; however, filling of training positions varies by availability. In adult rheumatology, there are more applications than positions, and in pediatrics, most positions do not fill. In recognition of the need to address these workforce shortages, the 116th Congress lifted the cap on Medicare support for GME costs which had 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, and increased funding is necessary to support a healthcare workforce capable of meeting the needs of America’s patient population.

Funding for loan repayment programs that support physicians entering the workforce in rural or underserved areas and specialties promotes workforce expansion. In particular, pediatric subspecialty loan repayment programs can encourage more pediatricians-in-training to pursue additional specialty training in rheumatology.

The Public Student Loan Forgiveness Act (PSLF) addresses the rheumatology workforce shortage in two ways. First, the program encourages young physicians to choose rheumatology despite the relatively lower compensation than other areas of medicine. Second, it encourages

new fellowship graduates to remain at academic medical centers and train the next generation of rheumatologists rather than accepting a potentially higher-paid position in private practice. Unfortunately, in 2018 and 2019, in the first group of applications for forgiveness under this program, more than 99% were denied. However, recently, more applicants are receiving their loan forgiveness through the PSLF program, and policy makers must protect these programs.

Similarly, the Pediatric Subspecialty Loan Repayment Program (PSLRP) specifically addresses the pediatric rheumatology workforce by encouraging pediatricians to pursue additional subspecialty training, despite the lower compensation compared to general medical practice, through loan forgiveness opportunities. This program was funded in FY2022 by the 117th Congress for the first time since its authorization by Congress in 2010. With the approved $5 million, it is estimated that approximately 50 initial two-year awards. While this is an important first step, the ACR supports full funding at $30 million per year.

Lastly, rheumatologists and other cognitive specialties are excluded from most federal and state public loan forgiveness programs. The ACR supports establishing new state-based loan forgiveness programs that would encourage cognitive specialists to practice in underserved areas.

More broadly, structural changes in the reimbursement system addressing the balanced budget requirement for the Medicare Physician Fee Schedule, undervaluation of E/M services, and cognitive care services are additional critical steps that can mitigate this impending medical workforce crisis.

Training and teaching the future generation of rheumatologists is imperative. Program directors, associate program directors, and other faculty play an important role in this. While GME designates certain FTE requirements for formal roles such as program director and associate program director, the academic hospitals which employ these physicians often view these FTEs through the lens of a non-revenue generating FTE. When this FTE time is unprotected or pressured to be replaced by revenue-generating clinical duties, this can detract from the valuable and important time needed to teach the fellows. Ultimately, this lowers the quality of education the fellows receive during this critical period.

The ACR supports:

- Expanding the medical workforce by increasing funding for Graduate Medical Education (GME) training position expansion.
- Repeal caps on residency positions.
- Increasing funding for the Pediatric Subspecialty Loan Repayment Program (PSLRP).
- Legislation to defer student loan interest while physicians are in residency to reduce the financial barriers to entering subspecialty training.
- Maintaining the Public Service Loan Forgiveness Act with full funding.
- Establishing loan forgiveness programs for cognitive specialties in underserved areas at the state level.

VI. Preserving and Growing the Rheumatology Workforce

iv. 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 the 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 the quality medical practices of rheumatologists and rheumatology interprofessional team members.

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 of 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 and rheumatology interprofessional team members.
- Appropriate reimbursement of providers for work involved in the collection and reporting of quality measure data.

The ACR opposes:

- Performance measures being used to penalize providers.

VII. Abbreviations

ACR	American College of Rheumatology
AHRQ	Agency for Healthcare Research and Quality
AMA	American Medical Association
APM	Alternative Payment Model
ARP	Association of Rheumatology Professionals
ASP	Average Sales Price
BPCA	The Best Pharmaceuticals for Children Act
CDC	Centers for Disease Control and Prevention
CER	Comparative Effectiveness Research
CHIP	Children's Health Insurance Program
CMS	Centers for Medicare and Medicaid Services
CPT	American Medical Association Current Procedural Terminology
DEXA	Dual-energy X-ray absorptiometry
DOD	United States Department of Defense
DXA	Dual-energy X-ray absorptiometry
E&M	Evaluation and Management Codes
EHRs	Electronic Health Records
FDA	Food and Drug Administration
FY	Fiscal Year
GME	Graduate Medical Education
HIT	Health Information Technology
HRSA	Health Resources and Services Administration
IT	Information Technology
MACRA	Medicare Access and CHIP Reauthorization Act
MIPS	Merit-based Incentive Payment System
MFN	Most Favored Nation
MMA	Medicare Modernization Act
MVPs	MIPS Value Pathways
NIH	National Institutes of Health
PA	Prior Authorization(s)
PBMs	Pharmacy Benefit Managers
PQRS	Physician Quality Reporting System
RACs	Recovery Audit Contractors
RBRVS	Resource-based Relative Value Scale
RISE	Rheumatology Informatics System for Effectiveness
US	United States of America
VA	United States Department of Veterans Affairs