



July 13, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
Room 445-G-Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Secretary Azar,

The American College of Rheumatology (ACR) represents over 9,500 rheumatologists and health professionals. We are committed to working with the Administration on policy proposals that increase access to high-quality health care for Americans. Rheumatologists provide ongoing care for Medicare beneficiaries with serious complex chronic and acute conditions that require specialized expertise and can be difficult to diagnose and treat. Early and appropriate treatment by a specialist can control disease activity and prevent or slow disease progression, improve patient outcomes, and reduce the need for costly downstream procedures and care.

Drug pricing policies have the potential to positively or negatively impact access to effective specialty care for our patients. We are deeply concerned about current and increasing barriers that limit the ability of patients with chronic diseases to access safe, affordable, high quality, and high value healthcare and treatments. If patients are unable to receive safe access to high-quality medically appropriate treatments to control disease activity, they will face disability, permanent damage to their joints and other organ systems, and increased risk of death.

As the federal government considers changes to America's drug pricing and delivery system, the ACR urges consideration of the unique care needs of Americans living with chronic illnesses, including the 54 million who live with rheumatic diseases. We appreciate the opportunity to provide input and suggestions to the agencies as health policies are developed. **We request and encourage the Department of Health and Human Services (HHS) to put any proposals through the formal rulemaking process so that stakeholders are able to weigh in on the details of the proposals.**

Executive Summary

The ACR believes that safe and effective treatments should be accessible to all patients at the lowest possible cost and that this should be a fundamental basis for any drug-pricing

policy. We support policies rooted in scientific evidence that support shared decision-making between patients and their health care team and that decrease barriers to patients accessing treatment. We respectfully request that the following patient protections and proposed solutions be carefully considered by HHS as drug pricing proposals are developed:

A. Increasing Competition

1. The ACR supports policies that will improve FDA capacity and manufacturer ability to bring safe, effective biosimilars to market to maximize access to treatment by lowering costs.

B. Better Negotiation

1. Patients must have access to the most appropriate and effective therapy as determined by their health care team and the patient, including reasonable and unfettered access to the prescriptions patients and their doctors agree upon.
2. Patients who are stable on their current therapy should be able to remain on that therapy and must not be required to switch for any economic or non-medical reasons.
3. "Fail first" policies must be limited. Fail first, or step therapy protocols means that a patient must try a treatment other than what their physician determines is necessary for their condition, and failing that required treatment means that disease may progress in the meantime. For a patient with a rheumatic disease, this can mean irreversible joint or organ damage.
4. As we cannot predict the outcomes and the impacts new programs or demonstrations on patients and practices, any such programs or demonstrations must be voluntary until their impact has been established.
5. Any drugs with no cheaper and equally effective alternatives should be excluded from mandatory demonstration projects or other programs or policies that would reduce patient access to those drugs.
6. Proposals that make effective drugs less accessible and less safe for patients must be avoided. For example, moving Part B treatments to Part D would makes Part B drugs less accessible and safe due to utilization management access barriers and lack of physician monitoring and safety controls in Part D.
7. HHS policies must avoid creating needless clinical challenges or allowing inappropriate patient safety risks such as having patients transport intravenous medications to their provider, the dangerous practice known as "brown bagging".

8. The ACR has serious concerns regarding recreating a competitive acquisition program (CAP) for Part B drugs, and would oppose a CAP program if it were unchanged or similar to the previous unworkable program, particularly if it would not ensure adequate protections for patient access to medicines.
9. Any new health delivery program must not provide vendors, PBMs, or any other suppliers or entities the ability to impose Part D-like utilization management practices such as prior authorization and step therapy, or other formulary tactics that restrict patient access, on Part B drugs.
10. We recommend HHS continue to facilitate development and voluntary uptake of alternative payment models (APMs) that could address challenges such as drug distribution and affordability problems. To this end the ACR is actively developing an APM for rheumatoid arthritis. This APM includes treatment pathways that have demonstrated potential to significantly reduce treatment costs (including drug spending) while improving outcomes.
11. In order to enhance patient access, the ACR recommends that eligibility for the 340B program should not be reliant on being a hospital; i.e. “hospital-based” should be removed from the eligibility requirements so that any entity could qualify based on their own disproportionate share status.

C. Creating Incentives to Lower List Prices

12. We urge HHS to institute policies that require PBMs to be more transparent about their payment practices, including transparency around the true cost of prescription drugs, as a necessary means of evaluating the efficacy of drug pricing and utilization policies.
13. We urge policies requiring more uniformity or standardization in the ways that PBMs structure and convey their rebate programs, including uniform definitions for terms used in disclosures by specifying what constitutes a rebate, discount, fee, and amount received from a manufacturer.

D. Reducing Patient Out-of-Pocket Spending

14. The ACR urges HHS to explore and prioritize ways to allow patients and their doctors to have better information in real time about therapy options and their coverage, the price of available drugs, and their cost sharing requirements, so that patients are empowered and in the drivers’ seat in making decisions with their physician about therapies.
15. 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. The ACR also supports allowing beneficiaries to accept financial co-pay assistance for specialty cost tier drugs from pharmaceutical companies for Part B and Part D drugs.

16. The ACR supports policies, including current introduced federal legislation in the Senate that would prohibit gag clauses that prevent pharmacists from proactively notifying patients how to pay the lowest price possible for their medications.

E. Additional Feedback

17. The ACR supports reevaluation of the Stark law policies against physician self-referral in order to align new health care delivery models with value-based and shared risk reimbursement models.

A. Increasing Competition

The ACR supports policies that will:

- Improve FDA capacity and manufacturer ability to bring safe, effective biosimilars to market to maximize access to treatment by lowering costs.
- Expand patient access to off-label therapies supported by guidelines and/or clinical studies by improving updates, access, navigation and readability of the Compendia.
- Facilitate alternative payment models (APMs) that could address challenges such as drug distribution and affordability problems.

Biosimilars development.

The ACR supports policies that will improve FDA capacity and manufacturer ability to bring safe, effective biosimilars to market to maximize access to treatment by lowering costs. We also support expanded patient access to off-label therapies supported by guidelines and/or clinical studies by improving updates, access, navigation and readability of the Compendia. We recommend and strongly support addition of dedicated staff at FDA that could help to move the approval process forward more quickly.

Resources and tools from FDA.

The FDA has already developed educational materials for providers that are easily accessible. We would like to see the FDA develop easily accessible patient friendly materials for distribution to patients in provider offices. The ACR also strongly supports the rigorous pathway for demonstrating biosimilar interchangeability that was proposed in draft guidance by the FDA in 2017, including requiring manufacturers to use studies to determine whether alternating between a reference product and the proposed interchangeable biosimilar multiple times impacts the safety or efficacy of the drug. We request that the FDA finalize the biosimilars interchangeability pathway outlined in its draft guidance “Considerations in Demonstrating Interchangeability With a Reference Product” with all due haste, so as to allow development and designation of interchangeable biosimilars to proceed, allowing transition to an era of less expensive biologics that provide safe, effective, and accessible treatment options for patients.

Educating providers and patients.

We believe 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. 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.

Interchangeability.

The ACR strongly supports clinical trial development to focus on markers of immunogenicity, such as trough drug levels and loss of clinical efficacy, as well as adverse effects due to switching between drugs. This data is critical for providers to be able to assess efficacy and need for changes in therapy. Data collection should continue through robust post-marketing surveillance. The ACR suggests that FDA allow ready access to pharmacovigilance data for investigators to analyze, and that the FDA promote and disseminate information about the program and the available data.

We also support the FDA’s draft requirement that manufacturers use robust switching studies to determine whether alternating between a biosimilar and its reference product three or more times impacts the safety or efficacy of the drug. The use of at least two exposure periods to each drug will simulate what our patients are likely to experience with changing formularies in a multi-payer, multi-state, and ever-changing market. The requirement for multiple switching studies to demonstrate interchangeability is particularly vital in light of the fact that providers will often not know that their patient’s medication has been switched.

Due to the complex manufacturing processes of biopharmaceuticals, biosimilars are not identical to their reference products nor to the biosimilars from other manufacturers. This may result in differences in adverse events and/or immunogenicity between originator and biosimilar products. Because of this, adverse event reporting with biologics, including biosimilars, should include the drug name suffix. Additionally, lot number should be included in the medical record of patients receiving biologic medications to allow for detailed post-marketing analyses and attribution of adverse events to the correct biologic. Pharmacovigilance is an important component to increasing the acceptance and uptake of biosimilars.

The ACR has significant concerns about non-medical switching, also known as forced switching, whereby payers force patients from one biopharmaceutical to another using formulary changes. This already occurs in the absence of interchangeable status and will no doubt accelerate with the advent of biosimilars. Individual treatment decisions should be

made by physicians and patients who are informed about an individual patient's unique condition, comorbidities and circumstances. Such decisions should be made in the best interests of the patient and should not be determined solely by population-based cost considerations. We encourage HHS and the FDA to consider the issue of non-medical switching as future guidance is developed.

Additionally, the ACR supports the following measures to improve safety and efficacy of biosimilars:

- Statements in each biosimilar FDA label indicating whether the drug is interchangeable (in addition to whether a drug is biosimilar)
- Inclusion of clinical data for biosimilars in FDA labels, via text or hyperlink
- Specific guidance for pharmacists to prevent inadvertent substitution of a noninterchangeable biosimilar as a stand-alone document and as a prominent message inside the "Purple Book" list

To further incentivize the use of biosimilars, commercial and government insurance programs could harmonize drug prices with patients' out-of-pocket costs and provider reimbursement. Currently, however, patients with commercial insurance are likely to have similar copayments for both biosimilars and originator biologics, due to Pharmacy Benefit Manager (PBM) or plan-mandated patient cost sharing.

B. Better Negotiation

The ACR supports policies that will:

- Protect patient safety as a paramount and central component of patient access to safe, effective, and affordable therapies.
- Ensure patients' safe access to Part B treatments in monitored settings. Proposals such as moving Part B treatments to Part D would make necessary Part B drugs less accessible and less safe for patients, due to utilization management access barriers and lack of physician monitoring and safety controls in Part D.
- Avoid creating needless clinical challenges or allowing inappropriate patient safety risks such as having patients transport intravenous medications to their provider.
- Minimize utilization management techniques, such as step therapy and prior authorization, which often delay or prevent patients receiving the right therapy at the right time.

Part B Competitive Acquisition Program.

The ACR emphasizes – most importantly – that any demonstrations must be voluntary, as we cannot predict the outcome and the impacts on patients and practices. Making any programs and demonstrations voluntary, rather than compulsory, is centrally important to protecting patients. If HHS plans to put forward a proposed program, we request that the Department provide parameters and proposals for how this could be done in a way that would not harm patients or patient access to the therapies they and their doctor decide are right for them. Therefore, like with any aspect of

HHS initiatives related to drug pricing, we urge HHS to put forward proposals through normal rulemaking so that stakeholders can review details and provide input, reaction, and recommendations.

We have concerns regarding recreating a competitive acquisition program (CAP) for Part B drugs that was previously unworkable. In fact, we would oppose a CAP program if it were unchanged or similar to the previous program, or if it would not ensure adequate protections for patient access to medicines. As just one example, in the past there have been functionality problems in how physicians had to order specific treatments with the CAP vendor in advance of the patient's visit, which limited their ability to adjust therapies or dosages based on different patient needs they might identify in the visit. The ACR urges HHS to put proposals and details of any new CAP or CAP-like program through the formal rulemaking process so that we and other stakeholders could review details of any proposed program in order to assess and comment on impacts to practices and patient access.

We are wary of creating new PBM-like middlemen in the Part B. **Any new health delivery program must not provide vendors, PBMs, or any other suppliers or entities the ability to impose Part D-like utilization management practices such as prior authorization and step therapy, or other formulary tactics that restrict patient access, on Part B drugs.** Patient access to Part B therapies is currently much greater than patient access to Part D therapies, where UM is imposed and patient cost sharing is higher.

If in a voluntary alternative Part B payment model there is a payment to physicians for managing and coordinating patient treatments, reimbursement to the provider must be sufficient to cover managing and coordinating that treatment and all of the time and costs that go into such management. This includes and is not limited to drug acquisition, transportation, storage, insurance against loss of drug and other overhead, scheduling, hardware and software for electronic documentation, and retrospective denials of reimbursement. Payments for treatment management and coordination should be in addition to the regular fee schedule payment for administering the drug, and should cover coordination not currently reimbursed under the fee schedule.

Multiple vendors must be available in any program, so that competition is created in the marketplace. Therefore we also recommend that in any voluntary alternative Part B payment model, that HHS consider allowing physician practices to bid to become vendors. Physicians have experience negotiating with manufacturers and other stakeholders, are ideally positioned to manage access and monitor outcomes, and have a demonstrated record of putting patient care above profit (that has not been seen with the current PBM middle-man model.)

We recommend HHS continue to facilitate development and voluntary uptake of alternative payment models (APMs) that could address challenges such as drug distribution and affordability problems. The ACR will be bringing forward an Alternative Payment Model (APM) for rheumatoid arthritis that will incorporate a management fee for coordination of patient care and use of a treatment pathway. We

would be pleased to discuss our model specifics with HHS as we go through the submission process. For example, a voluntary Part B demonstration could incentivize use of a rheumatoid arthritis treatment pathway based on specialty guidelines. This would control drug utilization while allowing for practices to continue to negotiate better overall drug spending through Part B than occurs in Part D, as suggested by HHS's new dashboard.

Value-Based Arrangements and Price Reporting.

In order to provide for greater patient access to treatment, the ACR recommends that eligibility for the 340B program should not be reliant on being a hospital; i.e. "hospital-based" should be removed from the eligibility requirements so that any entity could qualify based on their own disproportionate share status. We recommend and request that HHS consider and propose how to best define disproportionate share in a way that would make sense for community-based, outpatient care. Additionally, the ACR supports efforts to enforce current 340B regulations with a focus on ensuring participating entities are following the rules of the program.

Indication-Based Payments.

The ACR is an active supporter of comparative effectiveness research (CER) as this type of research has the potential to powerfully inform physician and patient decisions about the relative merits of one treatment compared to another. CER should not, however, be employed to limit therapeutic options and force patients toward therapies that are not medically appropriate. Ideally, CER would highlight the need for multiple treatment options to address heterogeneous groups of patients with individual and unique co-morbidities. Unfortunately, studies that lack long-term follow-up and do not take into consideration patient heterogeneity, co-morbidities, preferences and tolerances must be interpreted within their limitations.

Regarding indications based pricing we remind HHS that there is a large body of research demonstrating that each biologic therapy is unique in terms of its molecular structure, immunogenicity, mechanism of action, safety and efficacy. Between classes of biologics, there are enormous differences in therapeutic pathways and FDA indications. Even within the most commonly used class of biologics, the TNF inhibitors, differences in responses and adverse events are commonly observed. Again, individual patient considerations, overlapping medical and immune conditions, safety and other considerations will drive the clinician and patient's decision for appropriate therapy. While some biologics may have similar mechanisms of action, this does not confer equivalent adherence, tolerability, or safety profiles. Moreover, all biologics can differ in time to remission, need for concurrent oral DMARD therapy, frequency of administration, and frequency of infusion and injection site reactions. The ACR is concerned that current available reports that would inform indications based pricing, provide insufficient information on model structure and validation.

Moving Medicare Part B Drugs into Part D; or Imposing Medicare Part D Structures onto Part B Drugs

Nationwide, there are 59.2 million Americans enrolled in the Medicare Part B program - but only 43.4 million enrolled in the Part D program - meaning that there are over 15 million Americans at risk of having no coverage at all for drugs that are switched into Part D coverageⁱ. We have serious concerns regarding the drastic change represented by this proposal and request clarification on how this proposal would function. **We are very concerned that moving Part B drugs into Part D may lead to access issues and force patients into higher cost sites of care. Formulary structure and cost sharing is different between Part B and Part D, and we are concerned that out of pocket (OOP) costs for patients would be very high, especially with the biologics prescribed by Rheumatology.** Further, Part D has no supplemental coverage to help with OOP costs. We urge HHS to consider the impact this proposal would have on treatment access.

The biologic infusion and injectable therapies covered under Medicare Part B are fundamentally different from the prescription drugs found in Part D since they must be safely administered in a monitored setting by a qualified health professional. In fact, at the time that the Medicare Part D program was created, a report to Congress recognized that Part B drugs carry safety concerns not seen with Part D drugs. **That 2005 report found that “the majority of drugs in Part B are not appropriate to shift to Part D because they are provided directly in offices by physicians.”** **Proposals such as moving Part B treatments to Part D would make necessary Part B drugs less accessible and less safe for patients, due to utilization management access barriers and lack of physician monitoring and safety controls in Part Dⁱⁱ.** We urge HHS to avoid creating needless clinical challenges or allowing inappropriate patient safety risks such as having patients transport intravenous medications to their provider, the dangerous practice known as “brown bagging”, engendering multiple risks to patient safety including inability to ensure proper temperature controls to protect patients from potential reactions and even death.

Moving Part B drugs into Part D, or imposing Part D structures and practices on Part B drugs, would expose patients to many of the same access issues they currently face in Part D. Our patients, like many other patients, rely on a very specific treatment regimen that their doctor knows is best for them; step therapy or “fail-first” policies can be very detrimental. Formularies that prevent patients from getting the right drug are very concerning. Many rheumatology patients with prescription drug plans experience frustrating delays in getting treatment while facing increasingly higher cost-sharing and out-of-pocket costs.

We urge HHS to enact concrete solutions that limit restrictive insurance and PBM practices such as step therapy, specialty tiering, and non-medical switching so that chronically ill Americans, including the millions who live with a rheumatic disease, are able to get the care they need and deserve. Overall, as HHS moves forward with drug pricing reforms, they should ensure that their policies improve treatment access rather than reduce it.

Biologics are some of the most expensive, but vitally important therapeutic options for patients with chronic diseases. Biologic response modifiers, cancer chemotherapies, and other medications have been recognized as breakthrough treatments for patients with diseases such as rheumatoid arthritis, psoriatic arthritis, multiple sclerosis, hemophilia, inflammatory bowel diseases, and some cancers. If a patient with rheumatic disease is unable to access critical biologic or biosimilar medications, they may face irreversible joint damage and disability.

Step therapy, or “fail first” protocols, for a patient with rheumatic disease, means that they must try a treatment other than what their physician believes is necessary for their condition, and failing that required treatment means that disease may progress in the meantime. For a patient with rheumatic disease, this can mean further irreversible joint damage. It is critical to note that for patients who are stable on a biologic treatment and who are then required to go off of that treatment to try a non-recommended treatment, the original biologic that was working and controlling disease may not work again for them upon stopping and restarting.

Most importantly, patients who are stable on their current therapy should be able to remain on that therapy and must not be required to switch for any economic or non-medical reasons. Additionally, patients must have unfettered access to the most appropriate and effective therapy for them as determined by their physician and the patient.

Further, the ACR was involved in multi-stakeholder group convened by the AMA that represented patients, physicians, hospitals and pharmacists and developed the a set principles on utilization management programs to reduce the negative impact they have on patients, providers and the health care systemⁱⁱⁱ. A full listing of the principles for utilization management may be found at <https://www.ama-assn.org/sites/default/files/media-browser/principles-with-signatory-page-for-slsc.pdf>.

These principles include the following:

- Utilization management programs should allow for flexibility, including the timely overriding of step therapy requirements and appeal of prior authorization denials.
- No utilization review entity should require patients to repeat step therapy protocols or retry therapies failed under other benefit plans before qualifying for coverage of a current effective therapy.
- Utilization review entities should provide detailed explanations for prior authorization or step therapy override denials, including an indication of any missing information. All utilization review denials should include the clinical rationale for the adverse determination (e.g., national medical specialty society guidelines, peer-reviewed clinical literature, etc.), provide the plan’s covered alternative treatment and detail the provider’s appeal rights.

- If a utilization review entity requires prior authorization for non-urgent care, the entity should make a determination and notify the provider within 48 hours of obtaining all necessary information. For urgent care, the determination should be made within 24 hours of obtaining all necessary information.
- Health plans should restrict utilization management programs to “outlier” providers whose prescribing or ordering patterns differ significantly from their peers after adjusting for patient mix and other relevant factors.
- Health plans should offer providers/practices at least one physician-driven, clinically based alternative to prior authorization, such as but not limited to “gold-card” or “preferred provider” programs or attestation of use of appropriate use criteria, clinical decision support systems or clinical pathways.

Rheumatologists and their patients have few treatment options and the costs associated with these treatments do not vary widely. Formulary structure and cost sharing is different between Part B and Part D, and we know from experience that out of pocket (OOP) costs for patients are very high and often unaffordable for RA patients. There are also utilization management practices in place that delay care and create barriers to access for patients in the Part D program. Part D also has no supplemental coverage to help with patient OOP costs. Financial matters related to potential cost savings should not override the safety and choice of the patients and standards of practice.

Rheumatologists follow strict guidelines for the treatment of rheumatic diseases such as rheumatoid arthritis (RA). ACR RA guidelines^{iv} state that those patients who have never taken a disease-modifying drug (DMARD) should be started on therapy with a synthetic DMARD such as methotrexate – a low cost oral medication. It is only when the disease activity is uncontrollable by this therapy or if the patient is not a candidate for it that a biologic is prescribed. When a biologic is needed, the decision to choose one biologic over another and whether to prescribe a biologic available through Medicare Part B or Part D requires careful clinical evaluation and consideration by a physician and patient. Patient factors that strongly influence this choice include but are not limited to an individual patient’s age, gender, diagnosis and comorbid conditions, concomitant medications, specific organ manifestations, antibody status, disease severity and burden, physical or psychological abilities, access to transportation, personal preferences, and ability to tolerate a particular route of administration.

We acknowledge that biologics are costly medications and providers must consider this choice carefully. Given the high value of this class of drug in achieving disease remission and improvements in overall patient wellness and long term function, employer health plans, other payers, and pharmacy benefit managers must allow affordable coverage options for biologics. There are currently no less expensive generic equivalents for these therapies used by our specialists, and the expense of utilizing these treatments can quickly escalate.

We respectfully request that any drugs with no cheaper and equally effective alternatives be excluded from any mandatory demonstration projects or other programs or policies that would reduce patient access to those drugs. If patients are unable to receive safe access to high-quality medically appropriate treatments to control disease activity, they will face disability, permanent damage to their joints and other organ systems, and increased risk of death.

C. Creating Incentives to Lower List Prices

The ACR supports policies that will:

- Decrease the concentration in the pharmacy benefit manager (PBM) market and other segments of the supply chain.
- Limit the adverse impacts of mergers and acquisitions in the pharmaceutical, pharmacy, PBM and insurance industry that adversely impact patient access and market competition.
- Increase transparency in how pharmaceutical companies, PBMs, and health insurance companies determine the cost of prescription medication.
- Increase transparency of any incentives given by drug companies to PBMs or health insurance companies related to the dispensing or promotion of their manufactured drugs.
- Encourage prescription drug price and cost transparency among pharmaceutical companies, PBMs, and insurers.

Fiduciary duty for Pharmacy Benefit Managers.

The ACR has concerns regarding the practices of pharmacy benefit managers (PBMs). The PBM industry is overly consolidated with the two largest PBMs covering more than 170 million Americans. This consolidation results in one-sided formulary negotiations with pharmaceutical manufacturers and an unfaltering demand by the PBMs, at the cost of the patient. As the intermediary hired by insurers to manage drug benefit programs, PBMs were originally created to control drug costs by negotiating discounts on the behalf of patients. However, PBMs have become increasingly effective at keeping much of the savings for themselves by often pocketing the difference between the fees they charge to pharmacies and the prices they negotiate from manufacturers – prices that exist behind a steel curtain. These practices drive up co-pays and out-of-pocket costs for patients while providing record profits to PBMs. **We urge HHS to consider policies that require PBMs to be more transparent about their payment practices, including transparency around the true cost of prescription drugs.**

The system would also benefit from policies requiring more uniformity or standardization in the ways that PBMs structure and convey their rebate programs, including uniform definitions for terms used in disclosures by specifying what constitutes a rebate, discount, fee, and amount received from a manufacturer. The current lack of uniformity can obscure how money flows through the system and can lead

to unfair competition and ultimately additional financial burden for patients. As we mentioned in our comments to CMS on the Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Program, and the PACE Program proposed rule, the ACR fully supports maximal reduction of patient OOP costs by passing rebates and other price concessions to the patient.

Further, the RFI asks whether PBMs should have a fiduciary duty to the entities that they are managing pharmaceutical benefits for. A fiduciary duty is a specific legal duty that is the highest duty one party can owe to another. There is a great deal of uncertainty about the economics of ascribing this duty to PBMs. Adding the layers of compliance and liability necessary to comply with a fiduciary duty could lead to significant increases in administrative costs that could be passed to consumers. Additionally, some recent comments by Secretary Azar may suggest that the administration could be seeking to impose a duty that is less than a fiduciary duty. Given this uncertainty, we request that the administration clarify the legal duty that it is seeking for PBMs. If it is a lesser duty than a fiduciary duty, then the administration should change the nomenclature to distinguish this duty. It should also clearly define the duty that it is seeking to impose to clarify what has become an increasingly unclear position. Given the weight of this subject, any further comments, as well as rules and regulations, should be withheld until the specifics of the duty are clearly defined.

D. Reducing Patient Out-of-Pocket Spending

The ACR supports policies that will:

- Allow Medicare, the health plans, and pharmacists to aide in providing more information and transparency to patients.
- Require insurers to provide clear and continuous information to pharmacists to not increase burden.
- Improve the electronic health systems interoperability, which will be key in taking a comprehensive information sharing approach. We strongly support interoperability of electronic health records, prevention of “data blocking” and other measures to streamline information sharing for clinicians and use of qualified registries.

Copay discount cards.

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, incurable

diseases. In the absence of such a basic solution, the ACR recognizes that copay cards and 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 also 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. We oppose insurance restrictions that prevent application of funds from assistance programs toward patients' deductibles and out of pocket maximum payments.

Inform Medicare beneficiaries with Medicare Part B and Part D about cost-sharing and lower-cost alternatives.

The most critical type of information that is needed in the system, but that is currently missing, is information for physicians and patients about drug costs and coverage at the point of prescribing. Therefore the ACR recommends and urges HHS to explore and prioritize ways to get patients and their doctors better information in real time about all of the available therapy options covered for them, the price of available drugs, and their cost sharing requirements, so that patients are empowered and in the drivers' seat in making decisions with their physician about therapies. **Pricing, coverage, and cost sharing information for patients and physicians at the point of prescribing would revolutionize the decision making process patients and physicians engage in when deciding on treatment.**

Chronic disease patients are often very sophisticated consumers who are accustomed to balancing the cost of everyday necessities with the cost of their prescriptions. When given the appropriate information they will make choices that save money. That is why the ACR favors the removal of the so-called PBM “gag clause”. It is also why we propose the inclusion of automated line items on pharmacy receipts that detail the amount of savings, or additional cost, that a patient incurs by utilizing their pharmacy benefit plan.

These line items would function much like the savings line items on grocery store receipts that inform customers how much is saved in a shopping trip by using coupons and taking advantage of in-store deals. Instead, these line items would tell patients in concrete terms how much their pharmacy benefit is saving them. Conversely, it would also tell them how much additional it is costing them if the copay required by utilizing their pharmacy benefit is higher than the cash price of a drug. This automated disclosure would provide transparency at the point of sale and empower patients to make more informed choices about purchasing medications, as well insurance policies.

The ACR supports policy that will provide beneficiaries with clear information about cost-sharing and lower-cost alternatives. We believe utilization management processes should also be transparent in addition to information about cost sharing and lower cost alternatives. Prior authorization is a process whereby a prescriber must obtain approval from an insurance plan before a patient’s prescribed treatment is approved. This is a time-consuming process that often involves a patient going to the pharmacy only to be turned away because they have not obtained the proper authorization. Where treatment is delayed or the patient does not return and fails to comply with their physician’s treatment plan, the consequences can be devastating.

According to a 2017 AMA survey^v 92% of physicians reported that prior authorization caused delays in their patients’ care, and 78% reported that prior authorizations sometimes led to treatment abandonment. Prior authorization also creates a burden for physicians who are then required to spend extra time seeking approvals from insurers for medications they have already prescribed. This could be streamlined by tools such as electronic prior authorization, which allows prescribers to request, and insurers to grant prior authorization quickly through technology. Adopting an electronic process for Medicare and Medicare Advantage plans will help America’s seniors access needed medications more easily and efficiently and reduce physician burden.

Federal preemption of contracted pharmacy gag clause laws.

We do not believe gag clauses serve any other purpose than to require beneficiaries to pay higher out-of-pocket costs. **The ACR supports policies and current introduced federal legislation in the Senate that would prohibit gag clauses that currently prevent pharmacists from proactively notifying patients how to pay the lowest price possible for their medications.** The Patient Right to Know Drug Prices Act applies to plans offered through exchanges, private employers and sponsors, and the Know the Lowest Price Act applies to Medicare Advantage and Part D.

E. Additional Feedback

The ACR supports reevaluation of the Stark law policies against physician self-referral in order to align new health care delivery models with value-based and shared risk reimbursement models. The “Stark” self-referral policies that were enacted nearly 30 years ago now pose barriers to care coordination. The Stark Law prohibits payment arrangements that consider the volume or value of referrals or other business generated by the parties. These prohibitions can stifle care delivery innovation by inhibiting practices from incentivizing their physicians to deliver patient care more effectively and efficiently, because the practices cannot use resources in rewarding or penalizing adherence to clinical guidelines and treatment pathways.

We therefore support HHS having authority to waive the prohibitions in the Stark Law and associated fraud and abuse laws for physicians seeking to develop and operate Alternative Payment Models (APMs) as was provided to Accountable Care Organizations in the Affordable Care Act. We also recommend removing the “volume or value” prohibition in Stark policy so that physician practices can incentivize physicians to abide by best practices and succeed in the new value-based alternative payment models. This protection would apply to physician practices that are developing or operating an alternative payment model including, Advanced APMs, APMs approved by the Physician-Focused Payment Model Technical Advisory Committee, MIPS APMs, and other APMs specified by the Secretary.

In conclusion, the ACR is dedicated to ensuring that rheumatologists and rheumatology health professionals have the resources they need to work with CMS and provide patients with high-quality care. We believe that for HHS, clinicians, and patients to all achieve their objectives, payment programs must be designed to reflect the way practices treat patients.

The American College of Rheumatology appreciates the work that the agencies do and the opportunity to respond to this proposed rule. We look forward to being a resource to you and to working with the agency. Please contact Kayla L. Amodeo, Ph.D., Director of Regulatory Affairs, at kamodeo@rheumatology.org or (202) 210-1797 if you have questions or if we can be of assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "David I. Daikh". The signature is fluid and cursive, with the first name "David" being the most prominent part.

David I. Daikh, MD, PhD
President, American College of Rheumatology

ⁱ <https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/>

ⁱⁱ https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/RtC_PtbtoPtD_2005_4.pdf

ⁱⁱⁱ <https://www.ama-assn.org/sites/default/files/media-browser/principles-with-signatory-page-for-slsc.pdf>

^{iv} <https://www.rheumatology.org/Portals/0/Files/ACR%202015%20RA%20Guideline.pdf>

^v <https://www.ama-assn.org/sites/default/files/media-browser/public/arc/prior-auth-2017.pdf>