

The ERISA Industry Committee

Driven By and For Large Employers

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The Honorable Lamar Alexander Chairman U.S. Senate, Committee on Health, Education, Labor and Pensions (HELP) 428 Dirksen Senate Office Building Washington, DC 20510

Dear Chairman Alexander,

Thank you for the opportunity to participate in stakeholder discussions on specific legislative, regulatory, or subregulatory solutions for reducing health care costs. On behalf of large employers that provide health coverage to millions across the nation, The ERISA Industry Committee (ERIC) is committed to working toward proactive solutions to rein in the unsustainable trajectory of health care costs in the United States, make health insurance and health care more affordable, eliminate unnecessary administrative costs and burdens, inject choice and competition into the health industry, empower patients, drive quality, and make the system work better for everyone.

ERIC member companies span every industry sector and every part of the country, but they come together at ERIC exclusively as plan sponsors. They all agree on the critical nature of providing quality health benefits to their employees, their families, and often times to retirees as well. Their innovations in health plan design and administration improve the quality and lower the cost of health care in communities across the country. ERIC member companies provide wellbeing programs, telehealth services, and other measures that work to improve health and avoid unnecessary care. ERIC advocates for federal and state policies to support the ability of large employers to offer affordable health coverage. ERIC represents exclusively large employers that sponsor health plans for their employees – as well as retirement and other employee benefits plans – to preserve and improve the employer-based health care system.

As you are no doubt aware, ERIC member companies are able to offer comprehensive health coverage to beneficiaries in a national, uniform manner, no matter where an employee may live, work, or receive medical care. This is due to the protections afforded by the Employee Retirement Income Security Act of 1974 (ERISA). Before we can engage in any deeper discussions on the health care system, it is important to recognize that any changes which weaken or jeopardize ERISA's ability to provide one uniform set of rules for national plan sponsors would represent an existential threat to employee benefits. Unless the federal government is prepared to add to its responsibility the health care costs for the 181 million Americans currently covered by job-based insurance, every effort must be undertaken to maintain, secure, promote, and buttress ERISA's national framework and powerful preemption.

That being said, plan sponsors are currently under extreme pressure to put health care costs on a more sustainable course. We are required by the Affordable Care Act (ACA) to provide a minimal level of benefits or face steep, non-deductible fines. On the other hand, if we provide health insurance that costs more than a specified amount

ERIC is the only national association that advocates exclusively for large employers on health, retirement, and compensation public policies at the federal, state, and local levels.

we may soon be subject to a devastating 40% excise tax. This squeeze is already limiting what plan sponsors can offer to beneficiaries, limits innovation, and threatens the employer-based system. Every year that health care costs rise faster than inflation, employers get closer to having to make a tough choice about curtailing employee health benefits. Already paying, on average, 75% of health insurance premiums on behalf of beneficiaries – and offering plans with a very high actuarial value, in which the plan sponsor pays around 85% of overall beneficiary costs – ERIC members have more skin in the game than anyone, and a greater urgency to address costs than any other health system stakeholder.

ERIC's Top 3 Health Priorities for the 116th Congress

Although ERIC has many priorities and policy goals that can improve health care quality and lower costs, we recognize that not all priorities are achievable and meaningful in a given Congress, under a given political situation, at a given time. For the 116th Congress, spanning 2019-2020, we have identified three issues as the primary focuses ERIC will pursue regarding health policy. We ask you to consider these issues first, as they are perhaps the areas in which Congress is the most likely to succeed in improving the system for plan sponsors and beneficiaries. Later in this submission we will cover numerous other valuable policy changes Congress should consider, but first, here are ERIC's chief health priorities at this time:

(1) Eliminate the Cadillac Tax

As you are aware, the ACA imposed a 40% "Cadillac" excise tax on high-cost employer-sponsored health insurance. This tax has nothing to do with the generosity of a given plan; rather, it comes down hardest on plans for things outside of their control, such as:

- Beneficiary demographics (bias against women, minorities, and seniors); and
- Regional variations in health costs (bias against plans with beneficiaries in rural, high-cost markets)

Avoiding the Cadillac tax is absolutely imperative for plan sponsors, lest they waste valuable plan resources on unnecessary taxes instead of on the provision of health care. Plan sponsors are already doing everything they can to reduce costs and drive quality in health benefits. As such, the only options plan sponsors can currently engage to reduce exposure to the Cadillac tax are policies that make health coverage worse, more expensive, and less flexible for beneficiaries. These are the primary options currently available to avoid the Cadillac tax:

- **Direct cost shifts to the employee**. This could include increasing the portion of the plan premium employees pay, increasing deductibles, or increasing copays and coinsurance.
- Eliminate employer contributions to consumer-directed accounts. This includes Health Savings Accounts (HSAs), Health Reimbursement Arrangements (HRAs), or Flexible Spending Accounts (FSAs). It is likely employee contributions would be exempt, but money contributed by the employer may not.
- **Reduce access to care**. This includes tightening networks and excluding high-cost providers, implementing barriers to high cost treatments and providers (step therapy, prior authorization), moving expensive medicines deeper into Rx formularies, and eliminating coverage for some medications.
- Eliminate coverage for spouses and dependents, and separate out or eliminate excepted benefits. These include dental, vision, hospital indemnity, cancer-only, or other "add-on" benefits.
- **Drastic plan redesign**. For instance, ending preferred provider organization (PPO) or point of service (POS) plans and implementing a high-deductible health plan (HDHP) or a health maintenance organization (HMO).
- Eliminate investments in health. Investments that plan sponsors make to improve health may save money later, but the costs of those investments could be considered to add value to the plan, moving it closer to the Cadillac tax. As such, plans may consider eliminating on-site clinics, wellness programs,

telehealth benefits, health information technology investments, and other health improvement efforts that have up-front costs.

Last Congress, 32 (evenly bipartisan split) Senators signed on to the *Middle Class Health Benefits Tax Repeal Act*. The House companion bill had more than 300 cosponsors. Almost every Republican (including Chairman Alexander) has voted to completely repeal the Cadillac tax, as well as to delay and defang it. We are urging Senator Heinrich to soon reintroduce the Cadillac tax repeal bill, and <u>we respectfully request Chairman</u> *Alexander to consider being an original cosponsor and urge his colleagues on the HELP Committee to do so as well*.

As Congress considers repealing the Cadillac tax, which we believe is the most dangerous tax pursuant to the ACA, we ask that you also repeal the Health Insurance Tax, or "HIT." The HIT does not apply to self-insured health plans like the ones primarily offered by ERIC members. However, some ERIC member companies (1) offer fully-insured coverage to retirees (often through an employer-group waiver plan, or EGWP), (2) offer fully-insured options to certain beneficiaries (such as through an HMO option in certain markets or regions), or (3) are otherwise exposed to the HIT. For those employers, the HIT serves as a disincentive to offer these benefits – and keep in mind, there is no statutory requirement for employers to do so. <u>As such, we ask Congress to repeal the</u> HIT tax on fully-insured plans, alongside repeal of the Cadillac tax on self-insured employer-sponsored plans.

(2) Eliminate Surprise Medical Billing

ERIC recently <u>shared this letter</u> with a bipartisan Senate working group that is developing legislation to address "surprise" balance bills levied upon unsuspecting patients. As stated earlier, large employers have more skin in the game than any other health care stakeholder, especially when considering the hundreds of millions of our employees, retiree, and their families affected by surprise medical bills. We urge you not to be distracted by the input of those unaffected by surprise billing (such as providers who typically do not engage in the practice) and to use this opportunity to address the egregious billing strategies of the relatively few provider groups that are causing the current surprise billing crisis. Each surprise medical bill causes mental and financial trauma on beneficiaries and their families, and without a resolution that eliminates these bills, beneficiaries will continue to suffer and employers will be pushed further toward curtailing health benefits.

We believe that surprise billing legislation can achieve the goal of eliminating the vast majority of these bills without significantly raising premium costs for patients, and without enshrining the abusive practices that lead to most surprise bills today.

Rather than restate ERIC's recent letter, the following excerpts are ERIC's specific policy recommendations regarding surprise medical billing. Some or all of these policies must be included in any bill that attempts to protect patients from surprise bills:

- <u>Establish a federal benchmark rate</u> to be paid by plans and plan sponsors to providers who otherwise would have generated a surprise bill. This benchmark rate should be based upon a percentage of Medicare, or something akin to 80% of a given market's average in-network allowable amount. The benchmark should be designed to provide a financial incentive for the provider to participate in the network.
- Require that any physician or medical service provider who is practicing at, or participating in a contractual or other financial agreement with, an in-network facility, <u>accept the in-network rates for any patient affiliated with that network, for any care at or connected to that facility</u>.
- <u>Ban profit-sharing agreements between in-network hospitals and out-of-network providers or</u> <u>staffing companies</u>. It has been brought to our attention that many balance bills are generated by

outsourced emergency room companies that have contracts to exclusively operate emergency rooms at certain for-profit hospitals. These arrangements result in a perverse incentive wherein the in-network hospital profits from in-network patients who receive surprise -- and frankly obscene -- out-of-network emergency room bills. The practices may be legal under current law, but they're unfair and inappropriate, and Congress should ban them.

- Congress should consider <u>requiring providers to participate in at least one or two of the networks</u> <u>most popular among the insured population in their markets</u> as a condition of participating in government health programs such as Medicare.
- Require, to the greatest extent possible, that a <u>hospital match in-network patients with in-network</u> <u>providers</u>.
- Require hospitals to contract with providers in a way that ensures those providers agree to accept in-network rates when a patient in the hospital's networks is treated. Some state laws may be obstructing the ability of hospitals to either employ physicians directly, or to negotiate network agreements with those physicians. Congress should preempt and invalidate those laws.
- Require hospitals to post, prominently, on their website information about the network status of practicing providers.
- Require that hospitals accept in-network reimbursements for patients referred by a physician who practices at, or has an ownership or profit-sharing interest in, that hospital.
- Ban exclusive, profit-sharing, or kickback agreements between hospitals and ambulance or air ambulance providers.
- ERIC members cannot support legislation that requires them to pay a percentage of billed charges, whether sifted through binding arbitration or not. This constitutes a clear and present danger to overall network integrity, creating an incentive for even more providers to adopt an out-of-network strategy.

These are not simply policy principles or heady ideals to frame a legislative concept – ERIC is prepared to offer technical and drafting assistance to craft provisions to affirmatively enact each of the above proposals. Our member companies have beneficiaries in every state and experience with the practices that are leading to surprise billing. We caution against approaching this issue in a manner that will preserve the current behaviors of providers who have, for economic reasons, developed exclusively out-of-network strategies. These behaviors are causing extreme distress to patients, and rearranging the system around those practices will only entrench them and make the situation worse.

Surprise medical billing is an extremely solvable problem when focus is maintained on the patients and the payors of health care, rather than on preserving the high profits of a select few groups of specialty providers who are taking advantage of the current system. It is an opportunity to reform the health care system in a targeted way that will indeed improve the lives of patients across the country.

(3) Address Out-of-Control Rising Prescription Drug Costs

Although prescription drug costs are not the largest part of employers' health care expenditures – indeed, that dubious honor goes to in-patient costs like hospitalizations – the prescription drug spend is rising at an unsustainable rate. Even if cost increases appear to have slowed this year, the existing pipeline represents a

serious threat: the rise of personalized medicine (where every drug is increasingly an orphan treatment), extremely expensive specialty medications and gene therapies, and an increasing focus on management of chronic conditions that will entail life-long adherence to medications.

Last year, ERIC surveyed our member companies to gauge their support for various policy proposals to address prescription drug costs. Members showed little interest in heavy-handed government intervention (for instance, in striking Medicare's non-interference clause and instructing the government to negotiate directly for Part D drugs), and focused rather on solutions that are free-market oriented, preserve and continue to encourage innovation, and hold the pharmaceutical industry accountable for abiding by the compromises between exclusivity and generic competition that were reached under the *Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act*, and later measures such as the biosimilar pathway created in the ACA.

It is our belief that the current system has an intended balance that should reward pharmaceutical companies for inventing treatments and cures, but also provide a timeline that leads inexorably to affordability for all products and all patient populations. That balance is currently broken, and it is Congress's job to fix it. As such, the following are the **top five priorities** of ERIC member companies to reform the prescription drug system and restore affordability, accountability, and transparency:

1. Improve Transparency, Rebates, Bundling, and Accountability

Currently, a debate is raging in Congress over the future of rebates for branded prescription drugs. ERIC members largely align with health system stakeholders who have testified before the HELP Committee that rebates are not an ideal system for realizing prescription drug savings. However, this is the system that has developed thanks to a labyrinthine series of laws, regulations, court decisions, consent decrees, and other legal structures. We acknowledge that some stakeholders have pointed to rebates as the *raison d'etre* for high prescription drug costs. While we disagree, ERIC acknowledges that addressing this issue in a proactive manner is necessary in order to take the issue off the table and allow policymakers to continue isolating variables in order to get to the bottom of the problems that plague the pharmaceutical market.

Plan sponsors agree that we would like to know the exact costs we are paying for a given product. We also would like to know that we are not overpaying for one product in order to underpay on another. And we would like to know what products actually cost, which products are the most valuable, and why some plan beneficiaries gravitate to one product rather than another, even when it can be against their (or the larger group of plan beneficiaries') financial interests.

As such, we support efforts to transition from the current rebate system, to a system of up-front negotiations, transparent drug prices, and value-driven arrangements when appropriate. However, we urge caution, as simply eliminating the current rebate system could cause a sharp increase in costs. If rebates are done away with, how will Congress ensure that plan sponsors continue to pay net prices, not in many cases the ludicrously high current list prices? Will Congress change the antitrust and anti-kickback laws as necessary to ensure that our service providers such as pharmacy benefit managers (PBMs) can still negotiate on our behalf and realize savings? Will protections be put in place to make public when a pharmaceutical manufacturer engages in egregious price increases? We commit to working with Congress as these questions will have to be addressed before we can support a proposal.

We understand that this is complicated – it probably spans four different committees in the Senate alone. But the risks of getting it wrong, engaging in dangerous half-measures (such as the *Drug Price Transparency Act*, S. 660), or otherwise making the system even worse than the status quo, are too risky to ignore. As such, <u>we ask the</u> <u>Committee to take a comprehensive approach on drug prices, pairing changes to the rebate system with</u> <u>provisions that will prevent unreasonable price increases, ensure cost-savings, clarify the ability to</u> <u>negotiate up front, and make other changes that realize the full potential of a realigned system</u>.

2. Lock in Exclusivity, Eliminate Patent Evergreening

ERIC members are rightly appalled at strategies designed to inappropriately extend patent exclusivity, and have identified restoring the balance between innovation/exclusivity and generic competition as a top priority. Numerous proposals have been put forward which would erode so-called patent thickets; some have focused on reining in orphan drug designations (which are rewarded with additional tax breaks and longer exclusivity), others at requiring patents to be exercised at the introduction of a drug, and still others at requiring more meaningful changes and improvements in order for a drug to extend its market exclusivity. ERIC is agnostic on which specific approach Congress should take; rather, <u>we ask that Congress choose solutions that balance innovation/exclusivity and generic competition, and move forward immediately to end the practices that have allowed certain drugs to maintain exclusivity literally for generations.</u>

Congress has heard in recent weeks from numerous patients, including those whose loved ones died specifically as a result of abuse of this system as it relates to insulin. ERIC urges Congress to curb the egregious practices that have led to extreme suffering for diabetics.

Another matter for consideration are the rules and practices concerning biosimilar medications. ERIC has been working state-by-state to ensure the ability of health plans to steer beneficiaries to safe, effective biosimilars for a given reference biologic medication. This practice has resulted in meaningful cost savings for generic drugs and we believe that the savings opportunities for biosimilar alternatives to biologics is even greater.

Today only seven biosimilars are actually on the market, with many more the subject of litigation between reference drug manufacturers and biosimilar manufacturers. In 2003, the federal government put a stop to similar endless 30-month stay litigation strategies that delayed generic competition. We urge Congress to legislate rules that clearly and fairly set an end date for market exclusivity of biologics to stop needless litigation that delays biosimilar competition.

Large employers are struggling with making biosimilar medications available to their employees and families. They tell us that even those biosimilars that are on the market may not be appropriately placed in health plan formularies, due to negotiating strategies that push branded biologics using tradeoffs of price increases on unrelated drugs produced by the same company. **Congress should address this practice and other strategies that prevent competition and choice.**

A critical reason why generic competition is so effective among small-molecule drugs is because of the ability of pharmacists to switch a branded drug for a generic unless specifically prohibited by a physician. Congress should reduce hurdles to biologics competition by eliminating the requirement for an additional interchangeability designation before biosimilars approved as safe and effective for a given reference product can be substituted for that medication.

A functioning biosimilars market is absolutely critical to putting the specialty drug market on a sustainable path forward. It appears that other countries, including the European market, have been more successful at this than the U.S. has been. While we recognize that the European system is not the same as the U.S. and want to express our support for a market-based system that rewards innovation but also provides for affordability, there is still much to learn from it.

3. Completely Ban Pay-for-Delay Agreements, and Other Competition-Delaying Tactics

At the time of this writing, the Supreme Court and various Administrative agencies have taken numerous steps toward ending the practice of branded manufacturers paying generic competition to stay off the market,

effectively extending branded products' exclusivity – a clear undermining of *Hatch-Waxman*. We applaud these positive steps but urge <u>Congress to affirmatively end pay-for-delay immediately</u>.

We also urge Congress to address two more common practices. First, Congress should take affirmative steps to end the abuse of patient safety protocols (such as Risk Evaluation and Mitigation Strategies, or REMS) to deny samples (or access to tracking databases, etc.) to generic or biosimilar competitors. Generic drug manufacturers are required to do bioequivalency testing of their product as part of the FDA approval process and need the samples to do so. Denying the samples effectively prevents the competition from obtaining approval. In a 2017 report from Premier, it was found that this restricted access to samples costs the health care system \$5.4 billion each year, and if this expands to the biosimilar market, it could cost \$140 million in savings for every billion in biologics sales.¹ To address this, Congress should take up and immediately pass the CREATES Act of 2019 (S. 340).

We also urge Congress to look into the use of "citizen petitions" at the FDA, which can be used to block generic drugs from coming to market. Citizen petitions are submitted by stakeholders outside the FDA to ask it for particular action in a generic drug approval application. The intent is for the petition to bring valuable information to the FDA's attention, such as suggesting a certain way to test for bioequivalency. The petitions have been abused by brand drug manufacturers who have filed them without merit, causing delay in the approval process. A study by a Rutgers University Law School professor found that between 2011 and 2015, 92% of the citizen petitions were from brand drug manufacturers.² The FDA moved in this direction recently, cracking down on some of the frivolous or improper citizen petitions.³ Now Congress should finish the job, and give the FDA authority to deny and ignore any and all petitions that are obviously the product of intra-drug company rivalries, or otherwise do not meet the original intent of Congress in allowing this avenue of advocacy before the FDA.

4. Ban Pharmaceutical Companies from Engaging in Abusive Couponing

One way that plan sponsors have been successful in managing prescription drug costs for plan beneficiaries has been engaging in medication and medical management. We build choice infrastructure into our plans, including our prescription drug formularies, and this infrastructure rewards patients for being smart shoppers, which in turn reduces overall plan costs, allowing plan premiums to stay affordable for all participants. This is especially important in the case of young, healthy individuals who are not on expensive specialty medications – if plan premiums rise sufficiently, these individuals will opt out, and the result will be significantly higher costs for the sick. Economists refer to this cycle as a "death spiral."

This management of formularies includes incentives that have repeatedly proven to be successful under normal circumstances. For instance, when a generic drug is available for free or for a nominal amount, compared to an expensive branded product with a meaningful patient copay or coinsurance, adoption of the generic is nearly universal.

The use of couponing by branded pharmaceutical manufacturers undermines formulary management by steering patients to significantly more expensive drugs, resulting in higher costs for the plan and beneficiaries. One way couponing works is by providing actual coupons, or copay assistance cards, to patients, with the manufacturer paying the patient's out-of-pocket costs. Other times the manufacturer may reimburse the patient, bypassing the ability of the plan to even know who is receiving assistance. This can in effect transfer the rest of their costs on to all of the other plan beneficiaries.

¹ <u>https://www.premierinc.com/newsroom/education/drug-roadmap2017</u>

² <u>https://awards.concurrences.com/articles-awards/academic-articles-awards/article/citizen-petitions-long-late-filed-and-at-last-denied</u>

³ <u>https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm622252.htm</u>

In a recent hearing in the Senate Finance Committee with representatives of branded drug companies there was recognition that this practice should be curtailed, especially when it coincides with a branded drug that has generic competition on the market. <u>ERIC requests that Congress outlaw couponing or manufacturer</u> reimbursements related to any drug with generic or biosimilar competition. Further, Congress should require that all drug patient assistance programs – whether run directly by a drug company or their contracted service providers, or by a patient group that receives substantial funding from pharmaceutical companies -- be conditioned upon means testing, or be specifically targeted to individuals or families with low income. Such a change would ensure that assistance is going to those financially in need – and not being used as subterfuge to increase the use of expensive branded products (and prevent migration or steerage to affordable generic alternatives).

5. Take Affirmative Steps to Address International Freeriding

Previous work by the Brookings Institution has found that Americans carry an undue amount of the burden for funding the pharmaceutical innovation pipeline. For example, from "*The global burden of medical innovation*," January 30th, 2018 (*Dana Goldman and Darius Lakdawalla*):

"U.S. consumers spend roughly three times as much on drugs as their European counterparts.^{4,5} Even after accounting for higher U.S. incomes, Americans spend 90 percent more as a share of income.⁶ Indeed, North American consumers spend about 3.5 times the price per dose of medicine taken, including generics, compared to their European counterparts, even though their income is only 60 percent higher.⁷ Prior research suggests that a substantial share of this gap is due to greater use of newer and higher-strength medicines in the U.S.^{8,9} The rest is due to lower prices for the identical drug overseas.

A back-of-the-envelope calculation suggests that U.S. consumers account for about 64 to 78 percent of total pharmaceutical profits, despite accounting for only 27 percent of global income."

ERIC members believe it is appropriate for Congress to take affirmative steps to address the critical issue of international freeriding by other wealthy, industrialized nations. Doing so should not reduce development of, or access to, life-saving treatments. However, it is critical that the burden of developing these treatments be shared more equitably among the billions of people who will benefit from them.

ERIC member companies understand the difficulties inherent in taking on this challenge, and applaud the Administration's work toward addressing the issue within the Medicare Part B program. However, what works in Medicare may not be a viable approach in the private sector, and other solutions will need to be considered. One

⁴ QuintilesIMS Institute. (2016). Outlook for Global Medicines through 2021. Retrieved from <u>https://morningconsult.com/wp</u> content/uploads/2016/12/QuintilesIMS-Institute-Global-Outlook FINAL.pdf

⁵ U.S. consumers are compared to consumers in the five largest European markets: France, Germany, Italy, Spain, and the United Kingdom. Pharmaceutical spending data are from QuintilesIMS Institute (2016), "Outlook for Global Medicines through 2021," December 2016. Population and income (gross domestic product) data are from the World Bank. ⁶ Authors' calculations based on IMS and World Bank data.

⁷ IMS Institute for Healthcare Informatics. (2015). Global Medicines Use in 2020: Outlook and Implications. Retrieved from https://morningconsult.com/wp-content/uploads/2016/04/IMS Institute-US-Drug-Spending-2015.pdf

⁸ While some have argued that new drugs are approved faster in Europe than in the U.S., Europe imposes stronger restrictions on the use of new medicines. (Sood, N., De Vries, H., Gutierrez, I., Lakdawalla, D. N., & Goldman, D. P. (2009). The effect of regulation on pharmaceutical revenues: experience in nineteen countries. Health Affairs, 28(1), w125-w137.) The net result is greater use of newer medications in the U.S.

⁹ Danzon, P. M., & Furukawa, M. F. (2008). International Prices And Availability Of Pharmaceuticals In 2005. Health Affairs, 27(1), 221-233.

option that has been proposed is reimportation, in which an individual or plan could purchase prescription drugs from pharmacies in other nations. Opponents have long argued that due to superior supply chain management and security in the U.S., reimportation is dangerous and poses a serious threat of diversion. We believe these concerns have merit.

As such, we are interested in learning more about proposals such as the *Safe and Affordable Drugs from Canada Act* of 2019 (S. 61). This bill seeks to address supply chain security concerns by subjecting foreign pharmacies to FDA inspection and approval, limiting reimportation to drugs likely to be practicably sent in a safe manner, and focusing on Canada rather than risking overseas pharmacies more likely to be infiltrated by third-world knockoffs. ERIC is interested to learn how this legislation would apply to beneficiaries of ERIC members' self-insured plans; for instance, could plan sponsors build provisions into a plan that would allow for reimbursement to individuals who purchase imported drugs? Would those reimbursements be allowable plan expenses and subject to the same tax treatment as other plan costs? **Regardless, we encourage Congress to examine this and other ways of spreading the cost of new drug development to other wealthy, industrialized nations.**

Other Miscellaneous Commonsense Rx Solutions

There is much discussion in Congress about the potential for unintended consequences from policy changes related to prescription drugs. As such we urge Congress to move carefully but importantly to recognize that the current trajectory of health care costs – particularly prescription drug costs – is unsustainable for the employer-based system and the nation. ERIC urges Congress to consider the following commonsense solutions to ensure a functioning, affordable market for prescription drugs:

1. Eradicate Sovereign Immunity Schemes

By now, Capitol Hill stakeholders are well aware of a scheme in which the intellectual property rights of a blockbuster medications were attempted to be sold to a Native American tribe, effectively staving off certain challenges that would be lodged through the U.S. Patent and Trademark Office (USPTO).

The good news is that the plot was unsuccessful. However, the fact that it was even attempted shows a weakness in the current system, and one that could be easily addressed by Congress. We applaud the effort of Senators Cotton, Ernst, and Toomey to prevent this kind of arrangement in the future by introducing the *Preserving Access to Cost Effective Drugs (PACED) Act* (S. 440). Congress should include the PACED Act in any larger bill to address drug costs – or simply pass it, by unanimous consent.

2. Facilitate Meaningful Comparative Effectiveness Research (CER)

Prior to the enactment of the ACA, ERIC member companies asked Congress to help create a public-private partnership or other entity that could conduct meaningful research to compare the effectiveness and value of various treatments and medications. As a result, Congress created the Patient-Centered Outcomes Research Institute (PCORI). However, changes to PCORI, or an alternative entity, are necessary to ensure that meaningful CER is conducted, disseminated, and implemented in plan design, particularly as it pertains to prescription drugs.

In order to ensure that CER speaks to prescription drugs sufficiently and fairly, as it pertains to governmentchartered entities such as PCORI, we suggest Congress consider the following:

- Require cost-effectiveness to be taken into account and included in analyses;
- Redirect funds and research focus to more immediate needs and projects more likely to directly inform plan and formulary design;
- Require pharmaceutical and device companies to donate products for CER trials; and

• Ensure CER entities are governed by a board that includes plan sponsor representation at least equal to that of providers, pharmaceutical companies, and patient groups funded by industry.

As reauthorization for PCORI is debated in Congress this year, ERIC will provide a fuller set of policy proposals. However, at this time, and specifically relating to prescription drug costs, the above four policy changes are the minimum necessary change to ensure that CER is adequately meeting the needs of plan sponsors and their beneficiaries.

3. Encourage Value-Based Contracts for Prescription Drugs and Medical Devices

It is our understanding that many pharmaceutical and medical device manufacturers are interested in delving deeper into the area of value-based contracting, but are hindered by a number of government policies. As you are no doubt aware, plan sponsors are strong supporters of value-based purchasing, and see this as a key element of the movement away from paying for volume and instead paying for value. Among others, we understand that aspects of the following laws, rules, and regulations are getting in the way:

- Medicaid "best price" drug rules
- Stark Law and Anti-Kickback Statute

We believe that making changes to these rules would encourage a greater degree of participation by pharmaceutical and medical device manufacturers in value-based contracting, and that this contracting would accrue to the benefit of plan beneficiaries. While some have proposed mandatory reinsurance for high-cost drugs, or other heavy-handed mandates to reduce patient out-of-pocket costs, value-based contracting can reduce costs throughout the system, rather than simply shift those costs to others.

4. Streamline Substitution by Incentivizing Point-of-Prescribing Tools

ERIC member companies and our service providers work with doctors and hospitals to implement systems that they can use to help patients make informed decisions about prescription drugs. Unfortunately, many providers do not use these systems, in part because government programs like Medicare do not put an emphasis on doing so. While we are agnostic as to what the incentives for providers should look like, we believe <u>Congress should</u> condition some portion of Medicare reimbursement on confirmation that providers have implemented comprehensive tools that allow them to advise patients on drug costs at the point of prescribing.

Other Areas of Potential Bipartisan Cooperation on Health Care Costs

Besides those "Top Three" issues outlined above, ERIC believes there are numerous other aspects of the health care system that are ripe to be addressed by Congress. In particular, we believe that a number of issues which are well-suited to be considered in the current environment could potentially help to lower costs, improve quality, and improve the health care system. A brief synopsis of each follows:

(1) Provide Relief for Patients with High-Deductible Health Plans (HDHPs) and Health Savings Accounts (HSAs)

Since HSAs were first created alongside the Medicare Modernization Act in 2003, plan sponsors have learned a lot about what is necessary to incentivize smart shopping while also driving value and controlling costs in health care. Unfortunately, the laws and regulations governing HSAs, and more importantly, the HDHPs that go with these accounts, have not kept pace. Importantly, as of April 2018, there were more than 22 million beneficiaries with HDHPs paired with HSAs.¹⁰ Many large employers offer only HDHP options and generously fund employee HSAs. This is not an experiment or one that is used by a select few.

Last year, ERIC worked with a number of stakeholders to advance legislation through the U.S. House of Representatives that would have represented a major step forward had it been signed into law. Dubbed the *Restoring Access to Medication and Modernizing Health Savings Accounts Act of 2018* (H.R. 6199), the bill passed the House by a vote of 277 to 142, including 46 Democrats voting in favor of the legislation – a significant bipartisan achievement.

The core of the bill was based on the *Bipartisan HSA Improvement Act* (H.R. 5138), by Representatives Mike Kelly (R-PA) and Earl Blumenauer (D-OR). The bill contained 7 provisions, each bipartisan in its own right, including:

- Ensure excepted benefits such as telehealth do not jeopardize HSA contribution eligibility;
- Allow plan sponsors to coordinate onsite and retail clinic benefits with HSAs and HDHPs;
- Fix a quirk in the Internal Revenue Code related to two spouses: one with an HSA and one with an FSA;
- Allow "adult children" on their parents' HDHP to use HSA funds;
- Streamline rollovers from HRAs and FSAs into HSAs;
- Expand the definition of preventive services to allow plan sponsors to provide first-dollar coverage of treatment for chronic conditions; and
- Allow HSA beneficiaries to use the funds to pay for certain physical activities.

The broader bill (H.R. 6199) also included several other bipartisan or noncontroversial provisions:

- Allow coordination of Direct Primary Care (DPC) benefits with HSAs and HDHPs, and ensure DPC payments are allowable HSA expenses;
- Restore ability to use health accounts such as FSAs, HSAs, etc., to purchase over-the-counter medications without a prescription.

Additionally, ERIC supports several other HSA and HDHP improvements that should be able to pass bipartisan muster, such as:

- Designate a more appropriate name for HDHPs, such as "HSA-Qualified Health Plans";
- Allow an HSA and HDHP to coordinate with TRICARE benefits for veterans;

¹⁰ <u>https://www.ahip.org/more-americans-choose-a-health-savings-account/</u>

• Ensure that eligibility for other government programs (such as Medicare or the Indian Health Service) does not exclude individuals from being able to establish and fund an HSA.

ERIC urges Congress to avoid HSA improvements that do not widely benefit those with HDHPs, such as doubling the contribution limits, or measures without strong bipartisan support.

Instead, the bipartisan reforms and improvements laid out above focus on improving the quality of coverage and care available to those who already have an HSA – whether it was their top choice for health coverage, or they work for an employer who has done a full shift to HDHPs, or they are in an ACA exchange and found the HDHP to be the plan with the most affordable premium. Further, these reforms level the playing field for various segments of the population who right now may be unfairly excluded, or may be overly financially burdened due to the current rules. As such, we believe both sides of the aisle could agree to move forward some of these limited reforms, and we urge Congress to take up HSA legislation.

(2) Leverage Data to Benefit Patients and Plan Sponsors

ERIC members appreciate the goal of leveraging data to drive competition and quality, as well as to forecast trends, analyze spending and utilization, and empower beneficiaries to make the best choices. However, we face two serious problems when attempting to engage:

First, there continues to be some degree of disagreement between plan sponsors and our service providers, including third-party administrators (TPAs), PBMs, insurers, and more. It is ERIC's position that the plan sponsor owns the plan data, in total. However, often times it has been incredibly difficult simply to obtain the data from service providers, much less to put that data to use. Therefore, <u>ERIC recommends that Congress clarify that</u> <u>plan data is owned by plan sponsors</u>, thus allowing them to leverage that data to use for the benefit of plan beneficiaries.

Second, ERIC members for the most part operate large, national plans that have beneficiaries all over the country. We value the administrative simplification inherent in reporting to the federal government via the Department of Labor (DOL) Employee Benefits Security Administration (EBSA). It would be completely impractical to run a national plan that was subject to the whims and demands of 50 states and the various districts and territories. But the states and territories want the same thing plan sponsors want: to be able to look at the totality of their health claims data.

This has led various states to attempt to mandate claims reporting by ERISA plans in a number of creative, thorny, and ultimately illegal (preempted by ERISA) ways, which was made clear by the Supreme Court in *Gobeille v. Liberty Mutual* (2016). While we support states in their desire to leverage data, ERISA plans cannot be expected to report to them – even if those states subjected themselves to a streamlined process, format, and other requirements.

Instead, <u>ERIC believes Congress should establish a national all-payer claims database (APCD)</u>. A national APCD would provide one single entity for plan sponsors and our service providers to deal with, and that entity would presumably be well-versed in self-funded plan administration, and thus would have expertise that would facilitate a low administrative burden to submitting claims. That national APCD could then provide state-level data directly to state authorities at their request, without causing disruption or increased costs to plan sponsors. We believe this would provide states with the data they want, as well as plan sponsors with the guarantees and protections that we need.

It should be noted that the sharing of data must be a two-way street; if plan sponsors are expected to submit data, they should likewise be able to see their data pooled with that of other plans, government programs, etc., in order to get a full picture of the market and engage in comprehensive analysis.

(3) Provide Clarity on Employee Wellness Programs

As part of the ACA, Congress included provisions that allowed employers to vary health insurance pursuant to a beneficiary's participation in an employer-sponsored wellness program. Prior to the ACA, the Health Insurance Portability and Accountability Act (HIPAA) allowed plans to vary premiums up to 20%. The ACA provisions increased that to 30% and gave the Administration authority to increase that up to 50%. However, as the HELP Committee is well aware, the Administration produced a complicated rule from HHS, DOL, and Treasury, and the waters were muddied even further by an even more complicated and draconian pair of conflicting rules from the Equal Employment Opportunity Commission (EEOC).

To make matters worse, a lawsuit has caused the previous EEOC rules to be withdrawn, and plan sponsors are now in legal limbo until EEOC acts – and EEOC cannot meaningfully act due to a lack of Senate-confirmed commissioners.

We applaud the Committee's effort to confirm nominees to the EEOC, and <u>urge the full Senate to confirm</u> Janet Dhillon as EEOC chair, as well as additional commissioners such that EEOC can return to full operation and address the wellness issue.

Congress could also act proactively to fix the situation without relying on administrative agencies to develop rules that may or may not reflect congressional intent. Ultimately, the simplest approach would be to <u>confirm that</u> <u>when a wellness program is in compliance with the original ACA rule, that wellness program is deemed to</u> <u>be in compliance with wellness program requirements that may exist under the Americans with Disabilities</u> <u>Act (ADA) or the Genetic Information Nondisclosure Act (GINA)</u>. Conversely, there are a number of things Congress could do to at least alleviate some of the conflicts between rules, such as:

- Eliminate the cap on participation-based programs, but preserve privacy and employment protections owed to employees under law;
- Clarify that the cap under HIPAA and the cap under GINA & ADA are separately calculated;
- Clarify that incentive limits do not apply to preventative services, chronic care management, or health improvement interventions pursuant to wellness program participation;
- Include an exemption for *de minimis* rewards that coincides with current IRS rules;
- Streamline ADA and GINA rules regarding transfer of medical information to carry out activities related to the wellness program;
- Clarify that a request for genetic or disability-related information will not be imputed to an employer for GINA and ADA purposes, as long as the request will not lead to the employer directly obtaining genetic or disability-related information;
- Allow the use of so-called "gated plans" as an incentive for wellness program participation; and
- Clarify that a plan sponsor may opt for the full 50% premium variation, regardless of tobacco cessation efforts, and without any stipulations limiting plan engagement to beneficiary attestations.

Wellness programs can improve the health of beneficiaries and make health care more affordable for everyone. However, the current system is a mess, created by inefficient government regulation. <u>Congress should take the</u> <u>opportunity to fix wellness programs so that employers can go back to driving value, improving health, and</u> <u>controlling costs</u>.

(4) Prevent Abusive Steerage of Beneficiaries by Big Dialysis Firms

We understand that the Administration is engaged in reimagining the provision of kidney care in the U.S., and in particular, moving to a more value-based system to pay kidney dialysis providers. We believe that this is not only positive, but absolutely necessary – and not just because kidney disease (end stage renal disease or ESRD) is devouring 20% of Medicare costs, costing the program more than \$116 billion in 2016 alone.¹¹ Due to the nature of the dialysis market in the U.S. (primarily, the entire country is served by two giant dialysis providers with monopoly or duopoly power in their respective markets), we believe Congress also has a critical role in ensuring that patients with kidney disease receive quality care, and the health care system finds a way to control the costs of that care.

One aspect of dialysis that the Administration and Congress should address relates to patient steerage. Financial reports have confirmed that for their own financial gain dialysis providers are steering a high volume of enrollees out of government coverage (such as Medicare and Medicaid), and instead into the individual commercial markets or on to employer plans. This is because private payors such as employers and commercial health insurers have little choice but to pay significantly more than Medicare for the cost of dialysis services. As demonstrated by evidence collected during a rulemaking related to the Exchanges, dialysis providers are paying premiums through a financially interested third party—the American Kidney Fund—for ESRD patients in order to steer them into commercial plans so that they can profit from the higher reimbursement rates paid by these issuers.¹²

One report reveals that steering into the employer market generates \$450 million a year in operating income for a single dialysis provider.¹³ These disclosures show that illegitimate "charitable" third parties are urging individuals to elect COBRA coverage rather than consider other options in order to maintain the more generous provider reimbursements offered by employer plans. These third parties may then either make COBRA premium payments on behalf of the beneficiary or "reimburse" the beneficiary for some portion of the costs of the premiums. This results in increased cost due to skewing of the employer plan's risk pool – ultimately increasing premiums for all plan beneficiaries.

For these reasons, while rules governing third-party payments should enable legitimate organizations who are acting in good faith to provide consumer support, we strongly urge that Congress direct CMS to re-issue its rule on steering in the individual market and prohibit third-party payments made directly or indirectly by a financially-interested party. Policymakers should also consider actions to protect the employer market from inappropriate steering.

There are also a number of policies Congress should consider that would provide relief to kidney dialysis patients, prevent premium spikes for plan beneficiaries, and save significant amounts of money for the private sector and the government – without disrupting care. These include:

- Similar to a recent proposal in California, in the case of a dialysis provider that is engaged in funding a charity that pays or reimburses premiums, that provider must disclose financial interests, must accept Medicare rates, and may not balance bill patients;
- In the case of a dialysis patient who is enrolled in a private plan, after some months of the coordination period, the dialysis provider should be required to accept Medicare reimbursement rates, or be excluded from Medicare for some period of time;

¹¹ J.P. Morgan. North America Equity, "DaVita Healthcare Partners: DVA Commercial Mix at Risk, Sensitivity is Material," August 18, 2016.

¹² The American Kidney Fund is registered as an independent charitable 501(c)(3), even though it generates a 500%-700% rate of return for its primary donor.

¹³ DaVita Provides Disclosures Regarding Charitable Premium Assistance, October 10, 2017.

- Apply a medical loss ratio (MLR) for dialysis providers: Dialysis providers must disclose annually their gross revenue, and detail the amount that went toward direct patient care vs. the amount that went toward administrative and other costs. To the extent that this ratio exceeds 80/20, dialysis provider must proportionately rebate payers;
- In the case of a kidney dialysis provider who chooses not to participate in a given insurer's network, but accepts patients enrolled in that insurer's plans, that provider could be "deemed" to agree to the terms of the plan, and may not balance bill the patient more than a reasonable amount of the difference between what the plan pays and the billed charges;
- Dialysis universal rate-setting: require a Government Accountability Office (GAO) or NAM (formerly IOM) study to determine the amount per-patient per-session that dialysis providers need to be reimbursed in order to make a margin similar to the average primary care practice. Raise Medicare reimbursement to this level, but require any dialysis provider participating in Medicare to accept this reimbursement level from all payers; or
- Dialysis balance billing ban: A dialysis provider may choose whether or not to participate in a given insurer's network. However, an out-of-network dialysis provider may not balance bill a patient if that dialysis provider wishes to treat Medicare patients.

Implementing some or all of these proposals could greatly reduce patient suffering and help control health insurance premiums, while still ensuring that kidney dialysis is a viable business. That being said, it should be noted that attempts to reduce the federal deficit or extend the life of the Medicare Trust Funds by shifting costs to employer-sponsored plans are both inefficient and unfair. We estimate that a recent proposal (a House revenue provision in a mental health bill in the 115th Congress) would have reduced the deficit by \$344 million over a decade¹⁴ – conversely, it would have increased employer costs by more than \$5.5 billion dollars *every year*. **Under no circumstance should employers be required to extend the coordinating period for ESRD, unless during the months added, along with a corresponding number of months an employer is already responsible for, the dialysis provider is required to accept Medicare rates for the patient. ERIC notes that such a policy could potentially lower costs for both Medicare and employers, as the current rates employers must pay are astronomically higher than Medicare rates.**

(5) Implement Value-Driven Employer Innovations in Medicare

ERIC and our partners in the *DRIVE Health Initiative* have been very supportive of a number of Administrative actions aimed at modernizing Medicare, implementing more value-based plan design, and adopting many innovations that employers have developed and implemented in the private sector. We have a full slate of policy proposals on this subject, <u>located here</u>. However, for the purposes of this effort specifically to reduce health care costs and drive quality, ERIC includes two policy proposals here.

First, Congress should adopt legislation to apply the private sector's medical mistakes ("*Never Events*") policies to government programs, starting with Medicare. Medicare currently has a "no pay list" of about 14 conditions that are high cost or volume, cost Medicare money, and could reasonably have been prevented through the application of evidence-based guidelines. Examples include leaving a foreign object in a patient after surgery, certain infections contracted after surgery, and patients given the wrong type of blood. If these adverse events happen, Medicare won't pay the higher bill caused by the adverse event.

¹⁴ https://www.cbo.gov/system/files?file=2018-06/54091-hr6amendedby11578.pdf

Employers expect a lot more from hospitals and demand stronger protections for our plan beneficiaries through policies designed by The Leapfrog Group. And most hospitals have voluntarily agreed and adopted our policies. These include:

- Apologizing to the patient;
- Waiving ALL costs associated with the event, as well as with follow-up care;
- Reporting the incident to an outside agency;
- Conducting a root-cause analysis of how and why the event happened;
- Interviewing patients and family as part of said analysis;
- Informing the patient how future *Never Events* will be prevented;
- Implement a protocol to support the caregivers involved in a *Never Event*;
- Perform an annual compliance review; and
- Publish the *Never Events* policy so it is available to patients upon request.

If a hospital wants to treat Medicare patients, it should agree to these policies. Further, Medicare should align the current medical mistakes on its "no pay list" with the private sector *Never Events* list. These policies should spread from Medicare to other government health programs – including Medicare Advantage plans. When Medicare is up to speed, it should follow the lead of employers and begin conducting claims analysis to detect *Never Events* that may not have been reported or coded properly. Beneficiaries should be able to see where the safest providers and hospitals are, and should be encouraged to see them.

Medicare and other government health programs need to catch up to the safety innovations the private sector began adopting more than a decade ago. Medicare patients deserve these safety improvements, providers and hospitals deserve a consistent approach to patient safety and *Never Events*, and taxpayers deserve the savings that will accrue, which will lengthen the life of the Medicare Trust Fund.

ERIC's second proposal to drive value and align Medicare more with private sector innovations is for the <u>Congress to direct the Center for Medicare and Medicaid Innovation (CMMI) to implement a Centers of</u> <u>Excellence (COE) demonstration project</u>. Employers have demonstrated many times over now that through experiments such as the Employers Centers of Excellence Network (ECEN), significant savings can be realized by driving patients to the highest-performing health systems. ERIC members participating in ECEN have been able to achieve far superior outcomes for patients, thus significantly reducing unnecessary health costs related to readmissions, unnecessary or inappropriate treatments, and the like, while at the same time, they have been able to maximize steerage by offering perks such as no patient copays, free transportation (including air travel) and lodging, and more.

CMMI has in the past been frustrated in efforts to move forward with a COE demo because the Medicare Trust Fund has strict rules about expenditures. However, recent moves by both Congress and the Administration have lessened some of these hurdles. It still remains a question how CMMI can best recognize (and then steer to) COE sites, but Congressional direction would be more than sufficient to provide the needed authority. We urge Congress to provide CMMI with sufficient authority to begin experimenting with COEs in order to improve patient care, incentivize superior performance by providers, and save money for the Trust Fund.

(6) Implement Market Stabilization and Employer Mandate Relief

Although the vast majority of ERIC member company beneficiaries are not enrolled in ACA exchange plans, we have a vested interest in seeing an individual market that is stable and functional. As such, we were supportive of efforts last Congress to advance a bipartisan compromise to stabilize the markets by providing reinsurance funds, updating certain rules, and making other changes to encourage stability and help prevent premium spikes.

ERIC believes that Congress should still consider advancing legislation to stabilize the individual and small group markets. Further, we have the following suggestions for provisions that should be included in such a package:

First, Congress should provide clarity on 1332 waivers to ensure that self-funded employer plans are not subjected to mandates, taxes, or compliance burdens preempted by ERISA. As you are aware, states are eager to move forward with various models of reinsurance and other ideas through the use of State Innovation waivers under ACA Section 1332. Many of these proposals have been good ideas that worked well. Others have been poorly developed and may violate other existing laws such as ERISA.

In one example, the state of Oklahoma attempted to obtain a 1332 waiver that would have allowed money to be redistributed from ERISA plans to health insurance companies in the state's individual market¹⁵ – a violation of the requirement that ERISA health plan funds be used only to benefit individuals enrolled in that plan. This application was later withdrawn.

In another example, Maine's waiver, which went into effect on January 1, 2019, includes a "base market assessment" as one of the funding mechanisms for a reinsurance program.¹⁶ The assessment applies to health insurers and TPAs based on the number of insured lives covered by each in the individual, small group, large group, and self-insured markets (excluding state and federal employees), at a rate of up to \$4 per covered person per month. Even a small per-person-per-month assessment can quickly add up to a substantial dollar amount, depending on the number of covered lives a particular plan sponsor has in the state. In order to offset that impact, many employers will need to increase the amount of employees' contributions toward their health insurance premiums. Even a small amount passed on to an employee through increased premiums could have a significant impact on some individuals, and it could cause some current plan beneficiaries to forego coverage or needed care.

The administrative burden assessments like this create also need to be taken into consideration. Insurers and selfinsured employers in Maine will have to submit to the state information on their plan participants in order for the amount of the assessment to be calculated. This will be an additional requirement added to the litany of compliance burdens that plan sponsors already face, and for multi-state employers, will give rise to a patchwork of varying and conflicting state reporting requirements. In the *Gobeille* case mentioned previously, the U.S. Supreme Court found that Vermont's health care claims database law was preempted from imposing reporting requirements on ERISA plans. The reporting requirements pursuant to reinsurance programs such as Maine's will not be merely incidental, but will be a crucial part of planning and running the reinsurance program, and as such will likely be preempted by ERISA.

Another issue with 1332 waivers relates to guidance recently issued by CMS. States can now apply for a waiver without the state legislature passing authorization legislation for the application. If states are no longer required to introduce and pass authorizing legislation to apply for a waiver, impacted stakeholders will have less notice of, and much less opportunity to weigh in on, a state's proposal. While this will have the effect of speeding up waivers, it will also reduce stakeholders' due process, and in the case of a waiver that proposes to unlawfully divert funds from an employee benefit plan into a state individual market, it will serve to raise health insurance costs for plan beneficiaries. In the past, when states introduced authorizing legislation, that acted as a first alert to potentially affected parties that a waiver proposal was being initiated. This provided an opportunity to review the bill, evaluate the proposed waiver, and determine how it would impact stakeholders such as ERIC member companies. Even in cases when the authorizing legislation deferred most details of a proposed waiver up to the state's insurance commissioner, the notice it provided was highly valuable to spur engagement and collaboration

¹⁵ https://www.ok.gov/health2/documents/1332%20State%20Innovation%20Waiver%20Final.pdf

https://www.maine.gov/pfr/insurance/mgara/Complete%20Maine%201332%20Waiver%20Application%20and%20Exhibits.pdf

between stakeholders and legislators. This enabled organizations like ERIC to go on alert that the state was developing a waiver proposal and to better prepare for when the proposal was made available for public comment.

Now that states may no longer need to pass authorizing legislation, stakeholders will be more reliant upon CMS to thoroughly evaluate waiver proposals' impact on all stakeholders. Evaluation for ERISA compliance – and subsequent disapproval of any waiver that is likely to be preempted by ERISA – is extremely important to the employer community, the largest source of health insurance coverage in America.

Certainly, the employer community needs DOL action in the area of 1332 waivers, including administrative findings that the kinds of state activities described above violate ERISA and must be discontinued. DOL should also consult with CMS on 1332 waiver applications and urge modification or rejection of any waiver that seeks to tax or place mandates on self-insured or multi-state plans. However, <u>Congress can also act to prevent bad</u> policies such as these by clarifying that reinsurance (or similar) proposals may not place mandates or levies upon ERISA plans, their service providers, or their stop-loss policies to fund the individual or small group markets.

Further, ACA Section 1332 makes a reference to the employer "shared responsibility" requirements, which could potentially cause confusion and threaten to erode the uniformity of national plan administration, if a state could apply altered requirements to an ERISA plan. <u>Congress should head off this potential issue by cleaning up</u> <u>Section 1332 and removing references to the employer mandate</u>. Further, as Congress addresses the employer mandate in 1332, <u>relief should be considered for employers wrongly assessed penalties under the employer mandate due to the failure of IRS and HHS to adhere to the statutory requirements laid out in the ACA.</u>

(7) Empower States to Address the Air Ambulance Crisis

ERIC believes that, as part of the surprise medical billing crisis, Congress should rein in the egregious practices of the air ambulance industry, which is now highly concentrated in ownership by a few groups. Large employers, plan beneficiaries and other payors are concerned with the escalating and unaffordable costs associated with air ambulance services. Because of current Federal Aviation Administration (FAA) rules, many air ambulance companies have determined the most profitable course of action is to refuse to negotiate and contract with insurers, which has a devastating cost to plan sponsors of both fully-insured plans and self-insured ERISA plans – not to mention the plan beneficiaries who receive massive balance bills. Rural areas of the country are especially hurt by the soaring costs of air ambulance services, as many times ground transportation options are too slow or unfeasible for critically injured patients. However, the air ambulance challenge could potentially be solved in a much simpler fashion than would be necessary to address the entire scope of surprise medical claims. After all, the abusive practices of air ambulance companies have been enabled primarily by a federal law that inappropriately exempts these companies from most regulation on the state level.

Typically, health services are regulated by the states. However, states are limited in what they can do to regulate air ambulance services due to federal law (the Airline Deregulation Act) which preempts state regulation. While ERIC companies prefer to have one national, uniform set of rules to govern our self-funded health insurance benefits, we believe that the national regulation of air ambulances under the Airline Deregulation Act has yielded disastrous results. A federal measure that would permit states to regulate air ambulance services is a much-needed change that would have the effect of lowering air ambulance costs for all payers in each market.

We were encouraged last Congress when the House took steps to remedy the situation with H.R. 4, the FAA Reauthorization Act of 2018. In the version that passed the House, an opening for state regulation of air ambulances was provided. The legislation would have limited federal preemption by excluding from preemption "non-air transportation services," defined as those services provided by air ambulance operators (but not other air carriers). Consequently, this legislation would have enabled states to regulate air ambulance billing. The Senate's version of the FAA Reauthorization Bill did not contain any measures related to air ambulances, and we were

disappointed when such language was dropped in the conferenced version of the reauthorization bill. We urge Congress to consider passing a similar provision in any relevant health care cost legislation to allow states to provide greater clarity and certainty to this increasingly complex and expensive healthcare service.

Additionally, cost-shifting from inadequate reimbursement in Medicare and Medicaid also plays a key role in exorbitant charges for air ambulance services. Employers rightly resist cost-shifting and **government must work to provide fair reimbursement to air ambulance providers**.

Finally, last year's FAA reauthorization did create a new advisory group to study the air ambulance situation and make recommendations to Congress. <u>We urge Congress to ensure adequate payer and plan sponsor</u> representation within that FAA air ambulance advisory group, and to consider allowing states to engage in regulation of air ambulance practices at least insomuch as it relates to their performance as medical providers.

Conclusion

ERIC appreciates the opportunity to work with Congress on this critical project to lower health care costs, incentivize care that improves the health and outcomes for patients, and increase the ability for patients to access information about their care to make informed medical decisions. Our views are comprised from the largest employers in the country, all considering policy proposals in their role as plan sponsors. We hope to provide additional information and technical assistance upon request.

Thank you for considering these comments. Let us know what additional information ERIC can provide, or how we can be helpful in advance a more affordable, value-driven health care system.

Sincerely,

James P. Delfand

James Gelfand Senior Vice President, Health Policy