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Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore MD 21244-8016
Attention: CMS-4203-NC
P.O. Box 8013

Re: Medicare Program; Request for Information on Medicare

Dear Administrator Brooks-LaSure:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on your Request for Information (RFI) on Medicare, CMS-4203-NC, published in the Federal Register on August 1, 2022. We applaud the agency's effort to continue to improve and strengthen Medicare Advantage (MA) and ensure alignment with the Vision for Medicare and the CMS Strategic Pillars, released in April, that prioritize health equity to inure to the benefit of MA beneficiaries.

Consistent with our mission, PhRMA believes that diversity, equity, and inclusion are essential to the discovery of new medicines and people of all ethnic, racial, socioeconomic, gender, and other identities should have equitable access to treatment.[i] We support policies that will enable a more just, equitable health care system, including improving clinical trial diversity and building a diverse workforce, investing in data infrastructure to assess disparities, and promoting best practices to improve equity in health care screening, diagnosis, and treatment.

The COVID-19 pandemic continues to have a disproportionate impact on seniors and communities of color due to a myriad of factors, including historic, systemic racism, glaring gaps in access to health care, and the racial wealth gap.[ii] The pandemic has shown us that the time to fix inequities in our health care system is now, and we look forward to supporting CMS in these efforts.

Our comments are focused on sections A: Advance Health Equity and B: Expand Access and Care. Our comments will expand upon addressing affordability and access barriers, addressing social determinants of health that affect access to quality care, and improving collection and use of health equity data.

Our detailed comments follow below.

* * *

A. Advance Health Equity

1. Addressing Affordability and Access Barriers

Many patients in the U.S., including those with insurance coverage, face exorbitant out-of-pocket costs for their medicines. In many communities of color, and certainly for seniors, the eroding value of health insurance can exacerbate delays in diagnosis and access to medicine, further widening disparities in health outcomes. Due in part to systemic racism, the racial wealth gap persists in the United States; therefore, Black and Brown families are less likely to have available resources to pay for out-of-pocket medication-related expenses.[iii] Medication affordability challenges also hit hardest on lower-income communities that are disproportionately non-white.[iv, v] A disproportionate share of adults who identify as lesbian, gay, bisexual, transgender, or queer often delay or do not fill prescribed medicines, partly, due to lack of insurance coverage.[vi]

Nearly 94% of Medicare beneficiaries have one or more chronic diseases.[vii] Improving adherence to medicines for patients with chronic conditions would improve health outcomes and reduce Medicare spending on inpatient and outpatient hospitalizations and provider visits. For example, it is estimated that preventable hospitalizations are 40% higher among Medicare beneficiaries living with chronic diseases in rural areas versus their counterparts in urban areas.[viii] Improving patient access to medicines and rates of adherence would keep Medicare beneficiaries healthier and out of the hospital and could help reduce disparities in chronic disease. Estimates show that Medicare could save $5.6 billion annually if the 23% of beneficiaries who are non-adherent to heart failure medicines were adherent.[ix] In addition, adherence to chronic obstructive pulmonary disease (COPD) medicines is associated with more than $3,500 in lower annual Medicare spending.[x]

By helping to protect patients from out-of-pocket costs that hinder their ability to access and adhere to important treatments, adequate insurance coverage for prescription drugs plays a crucial role in patients' ability to take their medicines as prescribed.

Promote policy solutions to improve affordability and equitable access to medicines.

While there is no one-size-fits all solution to improving health equity in access to medicines, reducing insurance and patient cost barriers for medicines is a clear solution that can have wide-reaching impacts on health equity.

Millions of beneficiaries face higher out-of-pocket costs when plan sponsors do not pass on rebates at the point-of-sale, even when savings from lower premiums are factored in. This is especially true for beneficiaries with deductibles or coinsurance, whose prescription drug cost-sharing is based on an undiscounted price that does not take rebate savings for their medicine into account. According to one actuarial firm, the failure of plan sponsors to pass along even a portion of the manufacturer rebate at the point-of-sale has led to a system of "reverse insurance," whereby plan sponsors require patients with high drug expenditures to pay more out-of-pocket, while rebate savings are spread out among all beneficiaries in the form of lower premiums.[xi] In

effect, chronically ill Medicare patients with high drug costs end up subsidizing premiums for healthier enrollees, which is contrary to how health insurance is supposed to work.

A recent analysis found that 92% of Part D beneficiaries' out-of-pocket spending is based on the list price rather than the discounted price their insurer gets. Charging higher cost sharing for sick patients taking brand medicines and using the rebate savings to lower premiums for healthier enrollees is not how insurance is supposed to work.[xii] Analysis by Milliman suggests that taking into account behavioral changes, a concerted effort on rebate pass through policy could generate net savings for the federal government of up to $73 billion over 10 years.[xiii] Implementing rebate pass through would allow for more predictability in costs and help bridge health disparity gaps by enabling better access to prescribed medicines known to be effective at preventing or treating chronic illness. A recent study found that sharing rebates directly with patients in commercial health plans taking brand oral antidiabetic drugs could reduce overall healthcare spending by $8 billion over 10 years, with the greatest relative impact on affected Black and Hispanic populations.[xiv] CMS should ensure these savings are passed on to patients at the pharmacy counter.

PhRMA strongly believes that beneficiaries should directly benefit at the point of sale from the rebates, discounts, and other price concessions that come from the significant price negotiations taking place in the Part D market today. The current Part D rules regarding the treatment of manufacturer price concessions may not always provide plan sponsors and pharmacy benefit managers (PBMs) with strong incentives to prefer the lowest-net-cost treatment options for beneficiaries or the Medicare program. This hurts patients and increases costs. Requiring that plans pass through a portion of manufacturer rebates at the point of sale is the most important step CMS can take to ensure that beneficiaries directly benefit from the significant price negotiations taking place in the Part D market. This policy change would immediately and visibly lower out-of-pocket costs for millions of Part D beneficiaries, lower government low-income cost-sharing subsidies and reinsurance payments and realign stakeholder incentives by reducing plans' potential incentive to prefer medicines with high rebates to alternatives with a lower net cost but lower rebates.

In 2022, MA plans received an average rebate from CMS of $164 per-member per-month (PMPM) to use toward supplemental benefits or lowering beneficiary out-of-pocket costs, a record high. Plans are predicted to use 43% of this funding to reduce cost sharing in 2022, a decrease from 46% in 2021 and 49% in 2020.[xv,xvi] While reduced cost sharing provides a direct benefit to enrollees, the impact of supplemental benefits is less clear. CMS should consider collecting more data on who is accessing supplemental benefits and these benefits' impact on health outcomes compared to the use of rebate dollars to lower OOP costs. Just this year, CMS took the first step at re-balancing the Part D program by redefining negotiated price and requiring plans to pass through pharmacy price concessions to patients in CMS-4192-F. We urge the agency to require that Part D plan sponsors pass through manufacturer rebates and other price concessions to further reduce negotiated price.

2. Addressing Social Determinants of Health

We commend CMS for working to ensure that MA beneficiaries from different backgrounds have access to the care they need, and for recognizing that social determinants of health (SDOH)—including where we live, work, play (indeed our zip codes)—have enormous bearing on health outcomes. Research clearly shows that SDOH impact life-long health care outcomes across all communities, and especially in marginalized communities.[xvii] PhRMA recognizes that creating sustainable policies to address SDOH is critical for the advancement of health equity, particularly for communities of color. Addressing health inequities not only requires reducing insurance barriers and other policy changes, but also identifying barriers to care that are specific to a given community, which requires connecting with and learning from communities that are experiencing inequities, especially in areas where disparities have been exacerbated by COVID-19.[xviii] Recognizing the importance of community-led efforts to understand and impact inequities, PhRMA and its member companies have been actively working to build partnerships in underserved communities to improve access to COVID-19 testing, vaccinations, and treatments to end the pandemic.[xix,xx]

Last year, PhRMA conducted focus groups to understand the overarching factors inhibiting health equity. Focus group members expressed that addressing systemic racism, discrimination, and bias are challenges to reducing disparities. Recent research among a nationally representative cohort of Americans found that 32% of Black Americans, 20% of Latino Americans, and 23% of Native Americans stated they had been discriminated against when seeking health care because of their race or ethnicity.[xxi] Also, 14.1% of patients living with HIV experienced discrimination, of whom 82.2% attributed the discrimination to HIV.[xxii] Multiple studies have revealed that discrimination is associated with increased incidence of mental health disorders,[xxiii ,xxiv] hypertension,[xxv] and all-cause mortality.[xxvi] This evidence and the expressed challenges faced by focus group members demonstrate the harms of discrimination, a key social determinant, on health and health outcomes.

Further, financial insecurity during the pandemic has affected lower-income workers' ability to pay for necessities, with 44% stating that they have used money from savings/retirement to pay bills, and 35% stating that they have received food from a food bank/organization since the start of the pandemic.[xxvii]

As CMS considers effective approaches in MA for screening, documenting, and furnishing health care informed by SDOH, we offer the following:

Empower community-based organizations and leaders to be partners to engage the community and develop/implement SDOH programs.

PhRMA's outreach with various focus groups found that communities of color value authentic engagement as critical to solving health inequities, as well as addressing discrimination and racism in health care. To effectively address SDOH that influence health outcomes at a national level, PhRMA proposes that CMS take a multi-faceted community-based approach with organizations that are integrated with and understand the specific needs of the communities. These organizations can recommend approaches most likely to resonate with their

seniors and their families. Community-based organizations understand how to effectively reach rural, Tribal, and/or underserved communities and are in the best position to assist with outreach and data collection regarding implementation of SDOH programs.

PhRMA is taking steps to drive action with urgency. In April 2019 PhRMA created the Collaborative Actions to Reach Equity (CAREs) grant program, which has since awarded nearly $500,000 to community organizations, institutions, and individuals who are working to advance health equity. The PhRMA CAREs grant program aims to address health inequities through partnership with community-led organizations to support local and national activities and research. With funding assistance provided through the PhRMA CAREs grant program, grantees nationwide are driving meaningful change on-the-ground by addressing pressing social determinants of health issues, such as maternal mortality, access to COVID-19 treatments and vaccines, disparities in medication use/access, and bias in seeking health care.

For example, Bridge-Pamoja, one CAREs grant recipient, is a network of faith-based leaders and culturally specific organizations dedicated to addressing unique needs of African and African American communities in the Portland, Oregon area through grassroots and community-based efforts. To combat the COVID-19 pandemic, Bridge-Pamoja aims to break down barriers to the uptake of COVID-19 vaccines within local African and African American communities using a three-pronged approach: 1) partnering with state officials to track how many Africans and African Americans successfully complete doses of COVID-19 vaccines; 2) monitoring how the state government partners with Black-led organizations (including houses of worship) to perform outreach to the African and African American communities regarding COVID-19 vaccination; and 3) hosting virtual forums with Black community and faith leaders to address the successes and challenges of the state's COVID-19 vaccination outreach process.[xxviii] Through these efforts, Bridge-Pamoja has helped to create an environment that fosters relationships of trust through reliable messengers.

This is just one example of the type of impact on-the-ground organizations can have to improve health equity—and how PhRMA aims to support that work. We would welcome an opportunity to provide CMS and staff with additional information about our CAREs grant program and its impressive group of community-based recipients.

Measure progress on health equity.

As CMS continues to pursue the goal of advancing equity throughout the Federal government, as specified in the January 2021 Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,[xxix] it should ensure that progress is appropriately measured. We propose that CMS focus on SDOH and measure progress through equity evaluations, specifically process and outcomes evaluations. Process evaluations may include conducting surveys and other qualitative research within rural, Tribal, and underserved communities to gain feedback on the execution of activities to address SDOH in local communities.

We also suggest that CMS and related Federal agencies conduct outcomes evaluations, which focus on progress on critical areas, such as reducing disparities in mortality, under-

treatment, and disease; increased partnerships with diverse community-based organizations to address SDOH and inequities; and advancing the inclusion of patient perspectives within planned activities and programs. We recommend that plans for equity assessments be included in MA SDOH initiatives to ensure that funds and future efforts are put toward programs and initiatives that will have the greatest impact on improving health for underserved communities. In addition, CMS should provide clear, concise guidance to all beneficiaries about the potential differences in benefits between traditional Medicare FFS and MA plans that operate in their geographic areas. CMS should conduct equity assessments to examine differences in affordability of MA and Medicare FFS plans across population subgroups, such as: persons with different races/ethnicities, socioeconomic backgrounds, sexual orientations and gender identities, and cultures.

Improve Demographic Data Collection.

PhRMA supports CMS's efforts to expand the collection of demographic data to a minimal set of social, psychological, and behavioral data for the purpose of improving efforts/activities related to quality. PhRMA recommends that CMS continue to work alongside experts and activities aimed at improving the collection of structured, granular demographic data for health care measurement and improvement.

Federal health care programs are uniquely positioned to contribute to the efforts improving the quality and accessibility of demographic data, and PhRMA supports CMS's efforts to do so here. We recommend improvements in data collection and reporting involve strong engagement with experts, community leaders (e.g., historically Black colleges and universities and community health centers), and patients themselves to understand and test which SDOH data are most important to collect and how to collect it. We also encourage efforts to collect and use health data consider the intersection between different social and demographic factors.

Promote collection of robust race/ethnicity and SDOH data in an ethical manner and consistent with legal requirements.

While standards exist for the collection and reporting of race, ethnicity, language, sex, and disability data in all publicly funded national administrative files and health surveys, these standards do not apply to many other reporting entities at the Federal, state, and local levels, including administrative, billing, and medical records. [xxx] Additionally, current Federal standards for race/ethnicity data are not sufficiently granular to reflect diversity—and therefore health disparities—for smaller underrepresented communities within broad categories of race and ethnicity. [xxxi] PhRMA suggests that Federal regulators consider testing, piloting, and facilitating activities to generate standardized, granular data on ethnically diverse populations in Federal health care programs, so that data representing diversity across a broad range of cultures, backgrounds and lived experiences can be synthesized. [xxxii,xxxiii] At the same time, there is limited information on SDOH available in administrative health care claims data. A recent study found that among the 33 million Medicare fee-for-service beneficiaries in 2017, just 1.4% had claims with codes related to SDOH. [xxxiv] The lack of robust data collection on SDOH in Federal, state, and local programs decreases the ability to track health outcomes linked to SDOH.

Although PhRMA strongly supports more robust collection of data, we recognize that increased surveillance and monitoring is not without potential harms to communities. For example, many disadvantaged communities have legitimate fears of sharing personal information due to negative potential consequences.[xxxv] The collection of data should serve to improve health care programs for underserved communities, not provide a means for discrimination for harming individuals. We recommend that CMS consult engagement experts to test and implement safeguarding of data elements, ensuring that personally identifiable information remains protected throughout the process. In addition, we recommend that CMS engage with experts to test and pilot strategies to mitigate against use of patient information that can potentially negatively impact patient access or care. For example, some artificial intelligence algorithms that rely on demographic information to determine treatment regimens could lead to bias in treatment decisions.[xxxvi]

Promote sharing of disparities data.

Federal programs, like MA, that serve seniors and those across varying populations can help to ensure that SDOH data are efficiently shared across Federal programs. PhRMA recommends that Federal agencies test approaches to linking eligibility and enrollment data across programs such as WIC and SNAP. In addition, disparate agencies may be given incentives to build the infrastructure to share SDOH and race/ethnicity data across the WIC and SNAP programs.

B. Expand Access Coverage and Care

1. Step Therapy for Part B Medicines

In 2018, CMS issued a memo to MA plans[xxxvii] that rescinded the September 17, 2012 memo "Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services"[xxxviii] and issued new guidance allowing MA plans to use step therapy for Part B drugs, beginning January 1, 2019.[xxxix] We share the concern raised by many patient and provider organizations about HHS' decision to remove this important patient protection. The potential increased use of step therapy in Medicare Advantage plans prompted letters to CMS from dozens of medical societies and patient advocacy organizations, including the American Medical Association and the American College of Physicians[xl] expressing "serious concerns" regarding the consequences of step therapy both for patients and prescribers.

Step therapy is a tool commonly used by health plans on which patients must fail on one or multiple alternative drugs before the plan will cover the medicine originally prescribed by the patient's health care provider. Since the issuance of the guidance in 2018 MA enrollees have been facing step therapy, as well as other forms of utilization management, for Part B drugs. According to Kaiser Family Foundation, 98 percent of MA enrollees were required to receive prior authorization (PA) for Part B drugs in 2021. An examination of the four largest MA insurers found that 10 of the top 20 Part B drugs were subject to step therapy by at least 1 of those insurers. Additionally, three of the four insurers required step therapy in 2020 for at least one of the drugs.[xli]

The use of step therapy to restrict access to Part B drugs can harm MA enrollees. In forcing patients to take an alternative treatment, step therapy can disrupt the continuity of their care, and could ultimately negatively impact their health outcomes. While the alternative drug might be considered appropriate for the patient's condition, there are often other factors that may necessitate the use of the drug originally prescribed by the patient's provider, such as potential interactions with other medications the patient is taking, patient co-morbidities, or patient preferences. The time delays associated with step therapy can also pose a problem for patients with serious illnesses – as noted by the American Medical Association in its letter -- "For cancer patients, selecting the proper personalized treatment as quickly as possible can be critical to survival. For others, such as those suffering from conditions like autoimmune disorders and progressive blinding eye diseases, delays in getting appropriate treatments can mean prolonged symptomatic periods and irreversible damage, making a 'fail first' approach to treatment inappropriate".[xlii]

Step therapy and other forms of utilization management can also be burdensome to physicians and their staff. For example, physicians sometimes have no ready access to a patient's benefits and formulary information. As has been noted by physicians when discussing the HHS decision, the lack of insight into which treatments might be subject to utilization management can put providers at financial risk for the cost of administered drugs if claims are later denied due to step therapy requirements. If a provider would like to override the step therapy requirement, appeals processes can be complicated and burdensome for physicians and patients alike.

These concerns are similar to the findings from a report from the HHS Office of Inspector General on April 27, 2022,[xliii] which found that MA plans often used PA to deny beneficiaries access to items and services, including physician-administered medicines, that should have been covered under MA rules. While this report did not address step therapy per se, it does underscore the degree to which UM tools in MA specifically can impede patient access to medically appropriate care, and the need for stronger safeguards and oversight.

We appreciate that HHS included limited guardrails when allowing use of step therapy. However, we do not feel these guardrails are sufficient to protect patients, particularly when patient protections are not accompanied by vigorous oversight. We strongly urge CMS to reinstate protections against use of utilization management tools for Part B medicines.

2. MA-Value Based Insurance Design

In the RFI, CMS specifically references the MA-Value Based Insurance Design (VBID) Model. PhRMA has long supported market-based reforms that promote high-value, patient-centered health care. We believe the MA-VBID model can be a productive way to test new benefit and cost sharing designs that achieve this goal. That said, it is also imperative that the Model focus on improving, rather than limiting, access, and drive value as defined by patient and providers, not one-size-fits-all measurements that fail to capture what matters to patients.

PhRMA suggests that CMS consider the following measures to help ensure that VBID can facilitate access to a full range of high-value care:

- VBID should not lead to cost sharing increases for other covered items or services or reductions in the number of medicines on a health plan's formulary
- VBID cost-sharing must be based on an appropriate assessment of value, not price
- VBID should not lead to cost sharing increases for other covered items or services or reductions in the number of medicines on a health plan's formulary
- VBID cost-sharing must be based on an appropriate assessment of clinical value, not price.
- Value assessments should be based on the full body of available evidence, based on a range of study designs
- Value must incorporate relevant clinical quality and patient-centered measures and account for changes in evidence, medical practice, and innovations

CMS also asks for feedback on ways that it can use the MA-VBID Model to drive more equitable health care for enrollees. Currently, VBID plans are permitted to base the allocation of non-uniform benefits on socioeconomic status (SES). But the determination of low SES is limited to one factor: whether the enrollee qualifies for the Part D low-income subsidy. CMS could change this rule and allow plans to take into account additional factors to determine if a person is of low SES and would benefit from additional, targeted supplemental benefits.

3. Value-Based Arrangements

PhRMA and its members strongly support CMS' efforts to facilitate innovative contracts as an important tool to improve care quality and affordability for patients. In the RFI, CMS' discussion of value-based arrangements (VBAs) appears to only focus on agreements between MA plans and providers although VBAs involve others including purchasers, biopharmaceutical, and device manufacturers. Although the RFI scope appears to be limited, PhRMA strongly supports these arrangements, and we encourage CMS to continue their support for innovative solutions. Our input on this section of the RFI consists of several high-level comments; support for innovative contracts,[xliv] specifically VBAs, as an important tool that can be used by MA plans, providers, and manufacturers to improve delivery of high-quality, affordable care; recommending that CMS use clear, consistent terminology to describe these arrangements; underscoring the role of manufacturers in advancing VBAs and value-driven health care.

VBAs may offer an important affordability and accessibility solution for MA plans, providers, and manufacturers.

VBAs between providers and biopharmaceutical manufacturers are important tools for MA plans. MA patients can benefit from an expansion of all types of innovative contracts through broader access, clinically appropriate tailoring of care, and collection of additional real-world evidence. Contracts between MA plans and biopharmaceutical manufactures can provide a mechanism for MA plans to potentially offer lower cost-sharing[xlv] and fewer barriers to access to medicines. Other benefits may include higher adherence rates to

medicines, better health outcomes, increased competition in relevant drug classes,[xlvi] increased evidence generation on the effects of different treatment regimens for different populations,[xlvii] and increased patient access to new medicines – including breakthrough therapies for rare and devastating diseases that previously lacked any effective treatment option.

VBAs between biopharmaceutical companies and pharmacy benefit manager Express Scripts, for example, saved $4.3 billion on medicines in 2019. Patients in these plans with innovative contracting arrangements taking cholesterol-lowering medicines saved nearly $800,000 out of pocket.[xlviii] In 2021, Humana MA enrollees that sought care from a primary care physician enrolled in a Humana VBAs experienced both better medication adherence and lower costs due to the value-based physicians' ability to successfully manage their patients' chronic conditions. As a result, the prescriptions for patients in the VBA plans took more maintenance medications resulting in less reliance on most expensive specialty drugs—including those prescribed to help control diseases such as diabetes, chronic obstructive pulmonary disease (COPD) and rheumatoid arthritis (RA).[xlix]

CMS should promote consistent, clear terminology related to VBAs.

As CMS considers policies to foster more VBAs, the agency should promote consistent and clear terminology when discussing these arrangements. For example, in the RFI CMS refers to these contracts using multiple terms including value-based care, value-based contract, and value-based arrangements. However, in its December 2020 final rule,[l] the agency uses and defines the similar but different term "value-based purchasing arrangement" to describe different types of arrangements that involve payers and manufacturers versus payers and providers. As innovative contracts, including VBAs and alternative financing agreements, involve payers, purchasers, providers, and manufacturers, CMS may want to use a consistent terminology for VBAs as to not inadvertently exclude certain contract type or contracting entity due to unclear language.

CMS should recognize the role of VBAs between manufacturers and health plans as an important solution for access to high quality, affordable care.

Given the substantial benefits that innovative contracts can create, we greatly appreciate CMS' efforts to facilitate and support new innovative contracts. As you know, barriers and uncertainties related to legal requirements (including but not limited to questions related to Medicaid "best price" rules and the Anti-Kickback Statue) can chill expansion of these types of contracts, especially for therapies that require more than one treatment or require contracts that must track more complicated outcomes. We encourage CMS to continue to support all innovative contracts as a valuable tool and help drive the movement of the American health system towards value-based care. We look forward to commenting on future proposals and draft rules and guidance along with continued discussions on the benefits of innovative contracts to help ensure that patients continue to receive the highest quality of care they have come to expect in the U.S.

* * *

Thank you for the opportunity to comment on this important matter. PhRMA looks forward to continuing a dialogue with the Centers for Medicare & Medicaid Services regarding challenges and opportunities related to Medicare Advantage. Please feel free to contact Courtney Christian, Meiti Negari, or Lauren Neves with any questions about this comment letter.

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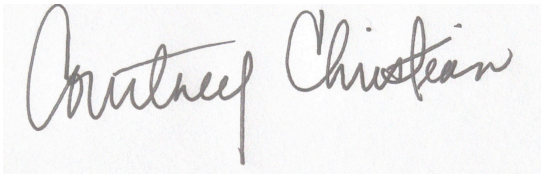
Sincerely,



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