Providing Leadership in Health Policy and Advocacy

October 5, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 314-G
Washington, D.C. 20201

SUBJECT: CMS-1736-P; Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician Owned Hospitals; Proposed Rule, Federal Register (Vol. 85, No.156), August 12, 2020

Dear Administrator Verma:

On behalf of our more than 400 member hospitals and health systems, the California Hospital Association (CHA) is pleased to submit comments on the calendar year (CY) 2021 outpatient prospective payment system (OPPS) proposed rule.

California's hospitals — like hospitals across the nation — continue to be challenged by the unprecedented response to the COVID-19 public health emergency (PHE). Though the full extent and duration of the pandemic are unknown, hospitals expect to be operating in this challenged environment well into 2021. Hospitals across California — including those in communities that have not emerged as hot spots — continue to dedicate significant resources to obtaining personal protective equipment (PPE), readying their facilities to surge patient capacity as needed, and ensuring that front-line health care workers are prepared to meet the community's needs.

CHA greatly appreciates the many flexibilities the Centers for Medicare & Medicaid Services (CMS) has granted to allow hospitals to respond to this crisis in innovative ways. We are pleased to see that as part of its 2021 rulemaking cycle, CMS proposed to maintain a number of these flexibilities permanently. However, we are concerned that many proposals may further challenge hospitals that are laser focused on delivering the acute care services that only they can provide to the patients who depend on them.

In summary, CHA:

- Opposes CMS' existing and proposed payment methodology for 340B purchased drugs and respectfully requests that CMS restore payment for separately payable drugs acquired through the 340B program at average sales price (ASP) plus 6%.
- Urges CMS not to finalize its proposal to eliminate the inpatient only (IPO) list over three years.
- Continues to oppose CMS' unnecessarily redistributive policy that decreases payments to all hospitals to offset an increase in the area wage index (AWI) for the hospitals in the lowest AWI quartile.

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- Strongly opposes CMS' ongoing policy to reduce payment for clinic visits furnished in excepted provider-based departments (PBDs) at 40% of outpatient payment rates.
- Opposes CMS' proposal to expand its prior authorization program to include two additional service categories.
- Generally supports CMS' proposed changes to the hospital overall star ratings methodology to simplify and improve stability in the star ratings.

OPPS Payment Methodology for 340B Purchased Drugs

In the CY 2018 OPPS final rule, CMS adopted a policy to pay for separately payable drugs acquired through the 340B program at ASP minus 22.5%, instead of ASP plus 6%. In 2019, CMS continued this policy and expanded it to apply to off-campus provider-based departments (PBDs) that are subject to section 603 of the Bipartisan Budget Act of 2015 and paid under the Physician Fee Schedule (PFS)-equivalent rate equal to 40% of the OPPS payment amount. The 340B payment policy does not apply to rural sole community hospitals, children's hospitals, or PPS-exempt cancer hospitals.

For CY 2021, CMS proposes to modify its payment policy and pay for separately payable drugs acquired through the 340B program at ASP minus 34.7%, plus an add-on of 6% of the product's ASP, for a net payment rate of ASP minus 28.7%. **CHA strongly opposes CMS' proposed payment methodology for 340B purchased drugs and respectfully requests that CMS restore payment for separately payable drugs acquired through the 340B program at ASP plus 6%. As it stands, CMS' current and proposed payment rates fundamentally undermine the program's intent and goals and will have devastating impacts on patients served by 340B hospitals and clinics.**

Congress established the 340B Drug Pricing Program more than 25 years ago to provide safety-net hospitals financial relief from high prescription drug costs with the intent for the savings from the 340B program to help participating entities *"stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."* Specifically, section 340B of the Public Health Service Act requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to health care organizations that care for many uninsured and low-income patients. These organizations include community health centers, children's hospitals, hemophilia treatment centers, critical access hospitals, sole community hospitals, rural referral centers, and public and nonprofit disproportionate share hospitals that serve low-income and indigent populations. **In California, 175 hospitals across more than 1,800 sites participate in the 340B program. These hospitals rely on 340B savings to not only reduce the price of lifesaving pharmaceuticals for vulnerable patients, but also expand additional health services throughout the community. In fact, a recent analysis by the American Hospital Association found that in 2017 – the most recent year for which this information is available – tax-exempt hospitals participating in the 340B program provided $64.3 billion in total benefits to their communities.**

In continuing these cuts, CMS not only runs contrary to congressional intent of the 340B program, but also the district court's ruling on the CY 2018 and 2019 final rules where they said the U.S. Department of Health and Human Services (HHS) was "plainly wrong" to assert existing legal authority to make these cuts. While we acknowledge these are open issues currently proceeding through the courts, hospitals continue to be concerned these proposed payment reductions will directly threaten access to care, especially in rural and other vulnerable communities. Furthermore, due to budget neutrality requirements, and as stated in Judge Cornelia Pillard's partial dissent to the U.S. Court of Appeals for the District of Columbia Circuit decision, "(t)he net effect of HHS' 2018 and 2019 OPPS rules is to

redistribute funds from financially strapped, public and nonprofit safety-net hospitals serving vulnerable populations – including patients without any insurance at all – to facilities and individuals who are relatively better off."

CMS' proposed cuts to the 340B program come at a time when the entire health care system is facing unprecedented challenges**.** Beginning in late February, California's more than 400 hospitals quickly recognized and reacted to the gravity of a global pandemic that continues to threaten millions of lives around the world. To flatten the curve and prepare for a potential COVID-19 surge, hospitals canceled non-emergency surgeries and elective procedures, bought large quantities of PPE, and in some cases retrofitted facilities. All this preparation came at great expense. At the same time, many non-COVID-19 patients were avoiding the hospitals, leading to a 35% decline in discharge volumes and 62% decline in emergency room visits in April 2020, according to Kaufman Hall data. This has resulted in a financial shock that will have ramifications for hospitals and the communities they serve for years to come. **California hospitals are now facing a likely $14.6 billion net loss in revenues through the end of 2020, according to the Kaufman Hall report. Continued and deepening cuts to the 340B program further threaten hospitals serving our most vulnerable populations at a time when those populations have been disproportionately impacted by COVID-19.**

For CY 2021, CMS states its proposed payment rate is based on the results of its Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Outpatient Drugs (SCODs), which was issued in the spring of 2020. CMS administered the survey to 340B OPPS hospitals between April 24, 2020, and May 15, 2020 – collecting data for certain quarters within CY 2018 and 2019 – and surveyed all hospitals that participate in the 340B program. **While CMS cannot control when a global pandemic occurs, the timing of this survey and the requested response time could not have come at a more challenging time, as hospitals – particularly those in California – were focused and dedicating all available resources to the response to the COVID-19 PHE. Both CMS and HHS were aware of the significant challenges providers faced during this time, as HHS prioritized the release of over $40 billion in Provider Relief Funds between April 24 and May 15.**

Though CMS provided hospitals a choice in how to respond to the survey during the three-week period — a detailed survey or a quick survey — CMS notes that only 7% of 340B hospitals responded to the detailed survey, and 38% did not respond at all. While CHA generally supports rulemaking efforts that are based on actual data, we have serious concerns with basing these proposed changes on a survey that was conducted during the peak of a global pandemic and one that received less than a significant response rate with actual detailed data. In addition, we are concerned that CMS' survey fails to generate a statistically significant estimate of the average hospital acquisition cost for each SCOD in violation of the Medicare statute, as detailed in comments by the American Hospital Association.

Updates to the Inpatient-Only List

The inpatient-only (IPO) list specifies services and procedures that Medicare will pay for only when provided in an inpatient setting. Currently, the IPO list includes approximately 1,740 services. CMS now believes that the difference between the need for inpatient care and the appropriateness of outpatient care have become less distinct for many services, and that rather than placing services on the IPO list, the physician's clinical judgment — together with consideration of the beneficiary's specific needs — should suffice to select an inpatient or outpatient setting for care. In the proposed rule, CMS proposes to eliminate the IPO list over a three-year period, from 2021 through 2024. CMS proposes to begin

phasing in the elimination of the list by removing 266 musculoskeletal services from the IPO list for CY 2021.

CHA has significant clinical and policy concerns with CMS' proposal, and we urge the agency not to finalize its proposal to eliminate the IPO list over an arbitrary three-year period. Services on the IPO list require inpatient care because of the invasive nature of the procedures, the need for at least 24 hours of postoperative recovery time, or the underlying physical condition of the patient requiring surgery. Through its annual review of the services on the IPO list, CMS has already established the appropriate process and criteria to evaluate procedures for potential removal on a case-by-case basis.

Though CMS notes that removal from the IPO list does not mean a procedure cannot take place in the inpatient setting, there are many procedures – such as invasive heart surgeries, organ transplants, or amputations – where we do not believe the outpatient setting is clinically appropriate. In these cases, the IPO list reduces administrative burden while allowing the clinician's judgment to determine the patient's length of stay. Under the two-midnight rule, CMS has maintained that IPO procedures are appropriately excluded from the two-midnight benchmark, and one-day stay inpatient procedures will continue to be performed in the inpatient setting. Should the IPO list be eliminated, a clinician's determination that an inpatient procedure can require less than a two-midnight stay could be challenged on a case-by-case basis, greatly increasing the level of documentation required for these cases.

CHA is also concerned that the agency does not have the claims data necessary to appropriately determine how to place new outpatient covered services into existing ambulatory payment codes (APCs) or create new APCs. While the proposed rule includes proposed APC assignments for 266 musculoskeletal-related services, CMS fails to provide any data or rationale for the proposed assignments. Further, given the breadth and timing of CMS' proposal to eliminate the IPO list over three years, determining appropriate payment for the volume of services would be a massive undertaking for the agency.

Proposal to Exempt Services Removed from the IPO List from Certain Medical Review for Two Years

As stated previously, CHA is concerned that the elimination of the IPO list will increase documentation burden for clinicians and hospitals to ensure that their clinical judgment in determining the appropriate care setting is not challenged in medical review. **While CHA strongly supports CMS' policy to exempt services removed from the IPO list from certain medical review activities, should CMS finalize its proposal to eliminate the IPO list over the course of three years, procedures should be able to remain on the exemption list for more than two years.**

Specifically, for 2021 and subsequent years, CMS proposes to continue its existing two-year exemption from site-of-service claim denials under Medicare Part A, eligibility for Beneficiary and Family-Centered Care Quality Improvement Organizations referrals to recovery audit contractors (RACs) for non-compliance with the two-midnight rule, and RAC reviews for patient status for procedures that are removed from the IPO list. **CHA believes this policy is appropriate when services are removed from the IPO list on a case-by-case basis under the current criteria for removal. However, the elimination of the IPO list would require a significant re-thinking of the overall medical review process.**

For example, the agency could consider an approach in which procedures removed from the IPO list remain on the medical review exemption list indefinitely, until there is ample evidence that the

procedure is being performed safely in numerous hospitals on an outpatient basis, similar to the existing criteria for removing a procedure from the IPO list. CMS must also allow appropriate time to ensure that contractors have developed and are aligned on specific medical review guidance on the appropriate care setting for these newly outpatient covered services. CHA urges CMS to consider the challenges that have occurred as a result of previous changes to the IPO list and medical review criteria, and afford itself and its contractors sufficient time to develop guidance that can be shared in advance for stakeholder input before finalization of such criteria.

Area Wage Index

CMS proposes to adopt the final fiscal year inpatient prospective payment system (IPPS) post-reclassified wage index as the calendar year wage index for the OPPS. As a result, any adjustments for the federal fiscal year (FFY) 2021 IPPS post-reclassified wage index are to be reflected in the final CY 2021 OPPS wage index beginning on January 1, 2021. CHA submitted comments to CMS in response to the FFY 2021 IPPS rule, which has been finalized since the release of this OPPS proposed rule. **CHA continues to strongly oppose CMS' unnecessarily redistributive policy that decreases payments to all hospitals to offset an increase in the area wage index (AWI) for hospitals in the lowest AWI quartile. We continue to assert that CMS does not have the legal authority to make this reduction under the IPPS or to make any similar reduction under the OPPS and refer the agency to our detailed comments on the FFY 2021 IPPS proposed rule.**

Site-Neutral Payment Policy for Off-Campus Provider-Based Departments

As required by Section 603 of the Bipartisan Budget Act of 2015, CMS restricts OPPS payments for services provided by certain off-campus provider-based departments (PBDs) that opened after November 2, 2015, with limited exceptions. In CY 2019, CMS expanded the Medicare physician fee schedule (PFS) payment methodology to excepted off-campus provider-based departments (PBDs) for hospital outpatient clinic visits (HCPCS code G0463), with a two-year phase-in of 70% of the OPPS rate for CY 2019, and fully reduced at 40% of the OPPS rate for CYs 2020 and beyond. For CY 2021, CMS proposes to continue to identify the PFS as the applicable payment system for non-excepted services and will set payment for most non-excepted services at 40% of the OPPS rate. CMS also proposed to continue its policy to pay for the hospital outpatient clinic visit services in excepted PBDs at 40% of the OPPS payment amount. **CHA continues to strongly oppose CMS' policy to reduce payment for clinic visits furnished in excepted PBDs. As stated in previous comments, CHA believes this payment cut for hospital outpatient clinic visits threatens to impede access to care, especially in rural and other vulnerable communities — and that CMS, by continuing the cut, has undermined clear congressional intent and exceeded its legal authority.**

Proposed Prior Authorization Requirements for Additional Outpatient Services

In the CY 2020 final rule, citing "unnecessary increases in the volume" of certain covered outpatient department services, CMS finalized a prior authorization requirement for five categories of services: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation. This policy was intended to help ensure these services, which are often cosmetic, are billed only when medically necessary. The 2020 prior authorization program was implemented for dates of service beginning on or after July 1, 2020.

For CY 2021, CMS proposes requiring prior authorization for two new service categories – cervical fusion with disc removal and implanted spinal neurostimulators – to be implemented July 1, 2021. CMS again

cites higher than expected volume increases for the two proposed service categories and believes that the increase in volume of these services is unnecessary because the data show the utilization far exceeds what would be expected in light of average rate-of-increase in the number of Medicare beneficiaries, concluding that increases are due to financial motives. However, CMS has failed to consider additional clinical explanations for the increase in these services. Specifically, the increase in Implanted spinal neurostimulators services can be attributed to national efforts to address the opioid crisis, as these services are commonly performed as a non-pharmacological treatment for pain management. In addition, in 2012 and 2016 respectively, CMS removed both cervical fusion with disc removal codes (22551 and 22552) from the IPO list, which can explain the increase in outpatient utilization of these services. **CHA urges CMS to revisit its analysis of the increased utilization of these services and not to finalize its inclusion in the prior authorization program.**

Furthermore, we are concerned that CMS is moving too quickly in expanding its newly implemented prior authorization policy. As stated in CHA's comments on the CY 2020 proposed rule, we welcome opportunities for stakeholder engagement and meaningful dialogue about the challenges and opportunities a prior authorization process presents, such as the possibility to reduce post-payment reviews of claims. However, with a previously finalized process implemented just three months before the comment deadline, it is too early to provide the agency with meaningful input on the challenges hospitals are facing with implementation or process improvements that could be made. **CHA urges CMS not to finalize its proposal to expand the prior authorization to additional service categories.**

Finally, CHA continues to be perplexed as to why the agency has not focused prior authorization processes directly on Part B physician claims for these services. Patients consult with their doctors in determining their course of treatment, and CMS has not provided evidence that the unnecessary utilization is occurring in greater instances in hospital outpatient departments than in the physician office setting. Unlike most states, hospitals in California are generally unable to employ their doctors and, as such, must endeavor to navigate a complex regulatory framework in which to fully integrate. Policies like these – when applied to a hospital outpatient department setting but not the physician office setting – create misalignment, clinician frustration, and beneficiary confusion. CMS should reconsider its continued approach of putting hospital administrators in the middle of that patient relationship with their clinician under a prior authorization process.

Proposed Changes in the Level of Supervision of Outpatient Therapeutic Services

For CY 2020, CMS changed the minimum required level of supervision from direct supervision to general supervision for most hospital outpatient therapeutic services provided by hospitals and critical access hospitals. General supervision means that the procedure is furnished under the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure. However, some groups of services — such as non-surgical extended duration therapeutic services (NSEDTS) and pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation — were not subject to the change in the required supervision level and continued to have a minimum default level of supervision that is higher than general supervision.

On March 31, 2020, CMS issued an interim final rule with comment period (IFC) to provide flexibilities to allow providers to respond effectively to the COVID-19 pandemic. In the IFC, CMS adopted a policy to reduce the level of supervision for NSEDTS to general supervision for the entire service – including the initiation portion of the service – for which CMS had previously required direct supervision for the duration of the PHE. The agency also finalized that, during the COVID-19 PHE, the requirement for direct

physician supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services allows for the virtual presence of the physician through real-time audio/video communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider. In this proposed rule, CMS proposes to adopt these policies on a permanent basis beginning with CY 2021.

CHA appreciates the increased flexibilities provided during the COVID-19 PHE and strongly supports CMS' proposal to permanently establish general supervision as the minimum required supervision level for all NSEDTS that are furnished on or after January 1, 2021. CHA also supports the proposal to allow the virtual presence of the physician through real-time audio/video communications technology to meet direct supervision requirements for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services. However, we are concerned that CMS' clarification that states "virtual presence" would not be limited to mere availability – but rather real-time presence via interactive audio and video technology throughout the performance of the procedure – is more stringent than existing direct supervision requirements, which require the "immediate availability" of the supervising physician, and we urge CMS to remove this statement.

Hospital Overall Star Ratings

Under the hospital overall star ratings methodology, CMS summarizes hospital quality performance by assigning a rating of one to five stars for posting on the Hospital Compare website. In response to comments from CHA and other stakeholders that have sought a more streamlined and predictable system, CMS proposes to modify the overall star rating methodology used for publication beginning in 2021.

While we continue to have concerns with the proliferation and usefulness of overall hospital star rating systems in general, we are pleased that the agency has proposed certain changes previously requested by hospitals, such as the elimination of the latent variable model. CHA supports the detailed comments from our colleagues at the American Hospital Association and offers additional specific comments on the following proposals.

Proposed Elimination of Latent Variable Modeling

CMS proposes to reorganize the star rating measure groups and simplify the calculation of measure group scores by taking a simple average, which would eliminate the use of latent variable modeling. CHA is pleased that CMS has responded to stakeholders and proposed steps to simplify its star rating system and supports the elimination of latent variable modeling in favor of a simple average of measure scores. This proposed change has the potential to create a system that is more predictable and stable, allowing for hospitals to better understand and improve their performance. However, we note that due to the unpredictability of the current methodology, we are challenged in modeling the impact of the proposed changes. We encourage CMS to provide hospitals with transparent information about how the modified methodology has impacted their star rating scores should it be finalized.

Proposed Stratification of Hospital Readmissions Measure Group

CMS proposes to calculate hospitals' readmission measure group scores by placing them into one of five peer groups based on their proportion of dual-eligible patients, similar to the approach used for the Hospital Readmissions Reduction Program (HRRP). CHA supports CMS' proposal to align its methodology for the readmissions measure group with the approach of the HRRP, which was mandated by Congress to ensure penalties under the HRRP were adjusted for the hospital's proportion of dually eligible

patients, an important sociodemographic factor that has been shown to impact health care outcomes. However, we urge the agency to take steps to increase risk adjustment for sociodemographic factors – such as housing, food insecurity, social support, and transportation – for the underlying quality measures included in the star rating system to better reflect accurate quality comparisons.

Proposed Assignment of Hospitals to Peer Groups and Critical Access Hospital Participation

CMS proposes to place each hospital into one of three peer groups based on the number of measure groups it reports before determining the final overall star rating. CHA appreciates that CMS has proposed a policy intended to address stakeholder concerns that the current star ratings system compares all hospitals regardless of differences in hospital characteristics, such as patient demographics, teaching or safety-net status, number of beds, or range of services provided. However, it is not clear that the proposed approach will adequately group hospitals of similar characteristics. Should CMS move forward with its peer grouping approach, we urge the agency to provide transparent information on the common characteristics of hospitals in each peer group, and continue to consider improvements to the more direct risk adjustment approaches that may obviate the need for peer grouping in the future.

We are also concerned that CMS' proposed approach does not address geographic differences in patient populations and the availability of services. This is of particular concern given the impact of the COVID-19 PHE on many regions across the country, including reductions in scheduled admissions and a higher proportion of urgent or emergent procedures. **We recommend that CMS consider strategies to address these factors for regions of the country with high proportions of hospitalizations and COVID-19 positivity rates in their communities.**

CMS notes that this proposal is contingent on the inclusion of critical access hospitals (CAHs) because they comprise half of the hospitals that report three measure groups. Currently, CMS includes CAHs that voluntarily submit and publicly report measure data in the star ratings, if the CAHs meet measure and group reporting thresholds. CMS proposes to continue this policy. However, CMS also proposes an opt-out policy allowing CAHs to withhold the public reporting of their star ratings from display on Hospital Compare and from the public input file that is posted to help hospitals and others replicate the calculation of star ratings. To opt out, CAHs would need to make the request by midnight of the final day of the star ratings preview period. **CHA supports CMS' proposals to include CAHs that voluntarily report quality information into the overall star ratings, as well as the accompanying proposal that would allow CAHs to "opt out" and have their star rating withheld from public reporting as part of the star ratings review process.**

Physician-Owned Hospitals

The physician self-referral (Stark) law prohibits physicians or their immediate family from referring patients to hospitals where the physician or an immediate family member has an ownership or investment interest, subject to certain exemptions. The Affordable Care Act (ACA) limited the use of some of these exemptions by imposing a ban on self-referral to new physician-owned hospitals. Specifically, the ACA allows existing physician-owned hospitals (POHs) to continue operating subject to several conditions and apply to CMS to expand if they meet certain requirements, but the law prohibited any new POHs from billing Medicare or Medicaid as of December 31, 2010.

CMS proposes to remove certain restrictions on the expansion of POHs that qualify as "high Medicaid facilities." Specifically, CMS proposes to allow high Medicaid facilities to request an exception to the

prohibition on expansion of POHs more frequently than once every two years, remove the restriction that expansion of POHs may not result in the number of operating rooms, procedure rooms and beds for which the hospital is licensed exceeding 200% of the hospital's baseline number of operating rooms, procedure rooms and beds, and remove the limitation that expansion may occur only in facilities on the POH's main campus. CMS further proposes to revise the definition of "baseline number of operating rooms, procedure rooms, and beds" to clarify that a bed is included in this baseline number if it is considered licensed for purposes of state licensure, regardless of the specific number of beds identified on the physical license issued to the hospital. CMS also seeks comment on eliminating the existing community input in the review process for expansion of high Medicaid facilities.

CHA strongly opposes proposals to remove existing restrictions on the expansion of POHs. Entities, including the Congressional Budget Office and the Medicare Payment Advisory Commission (MedPAC), have demonstrated that physician self-referral leads to greater utilization of services and higher costs for the Medicare program. Specifically, the Government Accountability Office, CMS, and MedPAC have all found that patients at POHs tend to be healthier than patients with the same diagnoses at general hospitals. This trend creates a destabilizing environment that leaves sicker and less-affluent patients to community hospitals. It places full-service hospitals at a disadvantage because they depend on a balance of services and patients to support the broader needs of the community. CHA believes that current law is clear, and existing regulation provides the appropriate level of balance between protecting access to care in community hospitals with a limited exceptions process for POHs that can demonstrate a need for growth.

CHA appreciates the opportunity to comment on the CY 2021 OPPS proposed rule. If you have any questions, please do not hesitate to contact me at mhoward@calhospital.org or (202) 488-3742.

Sincerely,
/s/
Megan Howard
Vice President, Federal Policy