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Advancing Health in America

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The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

CMS-1748-P: Medicare Inpatient Rehabilitation Facility Prospective Payment System for Inpatient Rehabilitation Facilities for Federal Fiscal Year 2022

Dear Administrator Brooks-LaSure:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including approximately 900 inpatient rehabilitation facilities (IRF), and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) fiscal year (FY) 2022 proposed rule on the IRF prospective payment system (PPS).

The AHA appreciates CMS' streamlined proposed rule, which allows IRFs and their partners to continue to focus on local COVID-19 responses. In addition, we continue to appreciate the IRF-related waivers implemented by CMS to optimize the field's contribution to the national response, both in those communities still experiencing surges, as well as for higher-acuity patients recovering from the virus who require both hospital-level care and intensive rehabilitation to address longer-term clinical after effects. This letter addresses several issues, including the use of claims for active and recovering COVID-19 cases in the annual payment update and several proposed changes related to quality reporting. In addition, this letter responds to the agency's requests for information related to digital quality reporting and health equity.

IRFs and COVID-19
In response to COVID-19's strains on the health care delivery system, inpatient rehabilitation units and freestanding hospitals stepped forward in multiples ways. Specifically, they:

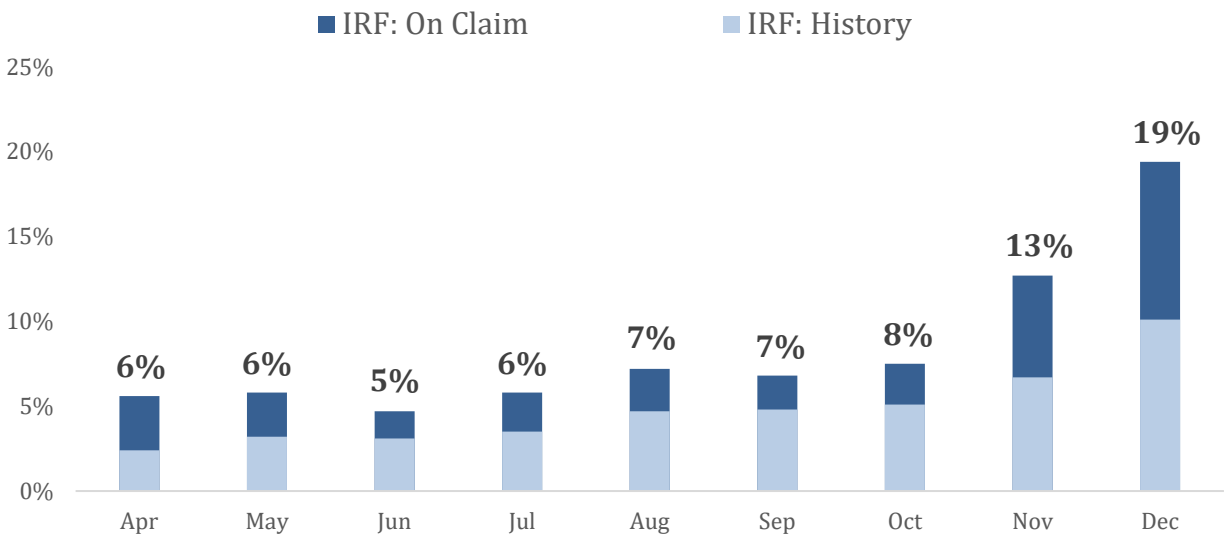
- treated patients with active virus;
- treated patients transferred from overwhelmed general acute-care hospitals;
- treated patients relocated from other overwrought settings; and
- most recently, are treating patients with long-term clinical COVID-19-related needs that align with IRF core strengths.

IRFs' specialization in treating clinically-complex patients who require hospital-level care in combination with intensive rehabilitation is well suited to the needs of patients recovering from COVID-19 who continue to have relatively high case-mix levels. In particular, IRFs are providing valuable care for those post-COVID-19 patients who need assistance recovering from after effects associated with "long-haul COVID-19," such as recovery from cognitive deterioration, respiratory-related limitations, and other forms of debilitation. As we are learning, this population of patients includes those with material and persistent deficiencies weeks and even months following the abatement of an active virus.

The public health emergency (PHE) flexibilities that CMS implemented during FY 2020, which continue in FY 2021, greatly helped IRF patient care by allowing providers to concentrate their time, personnel and other resources on both the traditional types of patients and the influx of pandemic-affected patients. We also appreciate the permanent change for FY 2021 and beyond that permanently eliminated the post-admission physician valuation (PAPE) requirement required for each discharge. This change streamlined the plan of care as well as made actual care delivery more efficient for both patients and IRF clinical teams.

The data below show the IRF field's significant concentration on treating active-COVID-19 and post-COVID-19 patients. The active-COVID-19 rates are based on IRF claims, and the COVID-19-affected rates are based on claims from all settings, both of which grew between April 2020 and December 2020. In December 2020, these groups of patients accounted for about one out of five IRF patients.

COVID-19 IRF Cases: April 2020 through Dec. 2020
Percent of all IRF Cases; COVID Status from Both Prior Services and IRF Claims



Sources: Medicare fee-for-service claims, Centers for Medicare & Medicaid Services, Chronic Conditions Data Warehouse, https://www2.ccwdata.org/web/guest/home.

In addition, the data below show the change in volume, case-mix index and average length of stay from the 12-month period preceding the PHE to the first 12 months of the PHE for patients discharged from referring hospitals to post-acute care settings, including IRFs. COVID-19 materially changed these factors, inducing a substantial drop in patient volume, as well as increases in average acuity and average length of stay (ALOS), for patients discharged to PAC. These data, as well, indicate that COVID-19 continues to affect the IRF patient population, and underscore the need for waivers to continue through the PHE.

Percent Change from Pre-PHE to PHE Period, by IPPS Discharge Destination[1]

Inpatient Hospital Discharge Destination	Case Volume	Case-mix Index	Average Length of Stay
All Inpatient PPS Discharges	-17.6%	6.3%	8.2%
HH	-6.1%	4.6%	8.7%
SNF	-30.2%	2.7%	8.3%
IRF	**-11.7%**	**3.2%**	**7.9%**
LTCH	-12.9%	7.1%	12.4%

[1] A comparison of the PHE period of Jan. 27, 2020 to Jan 26, 2021 versus the pre-PHE period of Jan. 27, 2019 through Jan 26, 2020.

Source: Medicare fee-for-service claims, Centers for Medicare & Medicaid Services, Chronic Conditions Data Warehouse, https://www2.ccwdata.org/web/guest/home.

Proposed Use of PHE Data in the Calculation of the FY 2022 Payment Update

Unlike its approach in other FY 2022 proposed rules, such as the proposed annual payment updates for the inpatient and long-term care hospital PPSs, CMS proposes to use IRF PPS claims data from FY 2020 in its update calculations to use the most recently available data. **The AHA is concerned by both the agency's inconsistent proposals regarding the use of FY 2020 data across the different payment systems.**

Proposed Update to Relative Weights. To update the IRF PPS case-mix group (CMG) relative weights and related average length of stay values for FY 2022, CMS proposes to use the FY 2020 IRF claims and FY 2019 IRF cost report data. The rule explains that, thus far, these are the most current and complete data available to CMS. The rule also notes that the values in the final rule will be updated to reflect any more recent data that becomes available after the publication of the proposed rule. **AHA notes the rule's limited discussion of the impact of COVID-related claims on these updates, and asks CMS to expand on such impact in the final rule to enable the field to more fully understand this relationship.**

Proposed High-Cost Outlier (HCO) Update. To set the HCO threshold for FY 2022, CMS proposes to use FY 2020 claims data in combination with the standard methodology used since the implementation of the PPS. CMS stated that without an adjustment to the HCO threshold, IRF PPS HCO payments in FY 2022, as a percentage of total estimated payments, would be 3.3%. Thus, in order to maintain a 3% outlier pool, CMS proposes to raise the threshold to allow fewer cases to qualify for an outlier payment. Specifically, CMS proposes to raise the FY 2021 threshold of $7,906 to $9,192 in FY 2022.

The agency's rationale for proposing to use FY 2020 data for the FY 2022 update is based the agency's finding that the use of both FY 2019 and FY 2020 claims would produce similar, positive impacts in FY 2022 of $200 million versus $160 million, respectively. Ultimately, CMS chose the FY 2020-claims based calculation because it believes that it "is appropriate to…ensure that IRF PPS payments continue to reflect as accurately as possible the current costs of care in IRFs." **We ask CMS to use the final rule to further expand upon the relationship between COVID-19-related claims in these calculations, to enable stakeholders to better understand CMS's take on the ongoing impact of PHE claims, from both the prior and current FYs, on FY 2022 payments and beyond.**

IRF Quality Reporting Program (QRP)
The Affordable Care Act mandated that reporting of quality measures for IRFs begin no later than FY 2014. Failure to comply with IRF QRP requirements will result in a 2.0 percentage point reduction to the IRF's annual market-basket update. For FY 2020, CMS requires the reporting of 17 quality measures by IRFs.

CMS proposes to adopt one measure and adjust the denominator of another for the FY 2023 IRF QRP. In addition, CMS proposes updates on publicly reported data in light of the COVID-19 public health emergency (PHE) and seeks feedback on several requests for information (RFIs).

While the AHA appreciates that the proposed measure on COVID-19 vaccination among health care personnel is intended to address an urgently important topic, we do not believe that the measure should be adopted for the FY 2023 IRF QRP. If CMS is intent on implementing the COVID-19 vaccination measure, we would urge the agency to either make the measure voluntary for the FY 2023 program, or delay implementation by at least one year.

FY 2023 Measurement Proposals
Adoption of COVID-19 Vaccination among Health Care Personnel (HCP) Measure. This measure would calculate the percentage of HCP eligible to work in the facility for at least one day during the reporting period who received a complete vaccination course. The measure would exclude persons with medical contraindications to the COVID-19 vaccination as described by the Centers for Disease Control and Prevention (CDC), but otherwise all facility personnel — including licensed independent practitioners affiliated with but not directly employed by the facility and students, trainees and volunteers — are included in the denominator, regardless of clinical responsibility or patient contact. The measure would be reported using CDC's National Healthcare Safety Network (NHSN) Healthcare Personnel Safety Component submission framework.

The AHA strongly supports COVID-19 vaccinations of both HCPs and the communities they serve. We have worked closely with our members and the federal government to encourage vaccination to help protect both patients and our health care workforce from this crippling disease. Health care facilities have made remarkable progress in vaccinating large proportions of their teams in a short timeframe, and are working hard to close any remaining gaps. Notwithstanding the remarkable scientific achievement of having three available and highly effective COVID-19 vaccines, we are barely six months into deploying them. The underlying scientific evidence about how to implement the vaccines continues to evolve, and there remain important unanswered questions that would affect both the design and feasibility of any HCP vaccination measure. To list just a few, for how long do the vaccines confer immunity? How frequently might booster shots be required? Should one receive the same type of booster shot as the original shot? Will vaccine supply remain sufficient across the nation to ensure all HCP can receive it?

None of these questions detract from the importance of encouraging COVID-19 vaccinations. However, the answers to all of these questions are of foundational importance to building a meaningful, accurate and fair performance measure whose results would be shared publicly. The AHA is concerned that a premature mandate to report this measure would lead to unpredictable shifts in reporting requirements that would prove disruptive to hospitals, and result in data that are unhelpful to policymakers, the public and health care providers.

Due to the unique nature of the COVID-19 pandemic and the limited experience the nation has with the vaccine products currently available, we do not recommend implementing this measure for mandatory reporting this year, as its use could have negative unintended consequences and might not be the most useful tool to promote vaccination. Instead, the AHA recommends that CMS either delay adoption of the measure for at least one year (i.e., until Oct. 1, 2022), or adopt the measure for voluntary reporting for at least the first year to allow time for the issue described below to be addressed. Any voluntarily reported data should not be publicly reported.

In its rationale and explanation of the measure's design, CMS relies heavily on the specifications and experience with the Influenza Vaccination among Healthcare Personnel measure (NQF #0431). However, the circumstances around use of the COVID-19 vaccine are not entirely comparable to those of the influenza vaccine, as COVID-19 and the vaccines have had a short and at times, unpredictable implementation. The three vaccine products on the market — from Moderna, Pfizer, and Johnson and Johnson — are currently only available under the Food and Drug Administration (FDA)'s emergency use authorization. While we are confident in the safety and efficacy of these products and at least one is likely to receive full FDA approval imminently, we find it to be incongruous to adopt a measure into federal quality reporting programs that assesses the use of a product that has not yet received full federal approval.

Another important distinction between the measure proposed in this rule and the influenza measure already in use is that the COVID-19 vaccination measure has not gone through the rigorous testing and NQF endorsement review process to which other measures adopted in CMS quality reporting programs are subject. The measure was presented to the NQF's Measure Applications Partnership (MAP) as a concept rather than as a measure ready for implementation; CMS leadership explained during the MAP meetings that the agency was bringing forward a measure that wasn't "fully fleshed out" in anticipation of incorporating it into rule-writing in 2022 at the earliest.

While the measure is designed nearly identically to the flu vaccine measure in terms of its calculation and reporting structures, many questions about the specifics of the COVID-19 measure remain (questions that might be answered during the testing and NQF endorsement processes). For example, what are the long-term plans for use of this measure in terms of its reporting period? The flu vaccine measure assesses

vaccinations during “flu season,” which is defined as October through March; will there be a similar “COVID-19 season,” and how will reporting interact with that of the flu measure? Is this measure in alignment with other COVID-19 vaccination measures under consideration, such as the Merit-based Incentive Payment System measure that was reviewed by the MAP which assessed patients who received at least one dose (as opposed to a complete course)?

Considering the magnitude of changes in the circumstances regarding COVID-19 vaccinations in 2021 alone, additional questions concerning the logistics of this measure may arise. The availability of doses played a major role in vaccination status earlier this year; for example, safety violations at a single plant resulted in millions of unusable doses of the Johnson and Johnson vaccine. If the supply chain were disrupted again, health care facilities could be unable to ensure the vaccination status of their employees through no fault of their own. The nation has not yet completed the first wave of complete vaccinations — as of this writing, less than 40% of Americans were fully vaccinated — and thus we have not yet begun to address needs or logistics for “booster” shots. Because of the rapidly changing circumstances in which the COVID-19 vaccines are being deployed, we believe it is unwise to permanently adopt this measure into federal quality reporting programs at this time.

In addition to these logistical concerns, CMS also should consider the potential unintended consequences of the use of this measure. The reporting burden associated with this measure may be high depending on how it interacts with other COVID-19 data reporting requirements. Certain health care settings (including skilled nursing facilities (SNFs) as well as inpatient psychiatric facilities) do not currently use the National Healthcare Safety Network (NHSN) to report data for quality reporting programs, so the introduction of this measure would require adjustments in workflow for which CMS would need to provide significant technical support. In addition, use of this measure may cause providers to amend other employee-facing policies, which take time to implement.

Moreover, while the measure does not directly compel facilities to ensure that their employees are vaccinated, publicly reporting performance on this measure might incent facilities to adopt mandatory vaccination policies for their personnel. Clearly, a vaccination mandate could be beneficial to measure performance. Yet, the decision about whether to implement a mandate is complex, and in some cases, the decision may be beyond the control of health care facilities. Already, multiple states have introduced or passed legislation prohibiting discrimination based on COVID-19 vaccination status; other existing state laws might also run afoul of mandatory vaccine policies. In practical terms, this could mean that facilities that are unable to mandate the vaccine could be at a systematic performance disadvantage on the measure. We also urge CMS to be mindful of other complex issues that could shape any mandatory vaccination approach. For example, the measure only excludes patients who do not get the vaccine due to medical contraindications. According to the Equal Employment Opportunity Commission, employers must provide a reasonable accommodation if an

employee's sincerely held religious belief, practice or observance prevents them from receiving the vaccination; this policy seems to conflict with the specifications of the proposed measure. A mandatory vaccine policy — with suitable exceptions and employee protections — might be appropriate, but until we have more than eight months of data on the vaccine's safety and side effects, we are unsure whether indirectly encouraging through the mandatory public reporting of COVID-19 vaccination rates is judicious.

The COVID-19 pandemic is not the last public health emergency this nation is likely to face, but our national response will have long-lasting effects on policy. The AHA is concerned about the precedent of adopting a measure assessing COVID-19 vaccination of HCP under these circumstances, and would thus recommend that CMS reconsider adopting the measure during this rulemaking cycle. **Instead, CMS should either delay adoption of the measure for at least one year or adopt the measure for voluntary reporting only —without publicly reporting performance — for at least the first quarter of the measure's use (beginning Oct. 1 of this year) to allow for time to answer the questions raised above regarding feasibility, validity, and the incidence of any unintended consequences.**

Request for Information on Health Equity. In light of the Administration's efforts to address equity — specifically health equity — the agency requests information on revising several CMS programs to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable for providers and patients. Specifically, the agency seeks recommendations for quality measures or measurement domains that address health equity as well as the collection of other standardized patient assessment data elements (SPADEs) that address gaps in health equity in post-acute care quality reporting programs.

The AHA applauds CMS' focus on addressing disparities in health outcomes by thoughtfully considering how to best leverage data; we agree providing equitable care begins with understanding the unique needs of patients. Data and analytics allow hospitals, health systems, and post-acute care providers to see the challenges and barriers some patients may face when accessing care, and can help pinpoint where resources may be deployed to address gaps in access or quality of care as well as provide deeper insights to instruct and inform intentional actions by leadership and clinical teams. Because of this, the AHA and its Institute for Diversity and Health Equity recently launched the first in a new series of toolkits designed to help hospitals and health systems make progress in advancing their health equity agendas. This toolkit, Data-Driven Care Delivery: Data Collection, Stratification and Use, addresses the importance of segmenting and leveraging patient data to tackle disparate care outcomes and drive improvements. We hope that we can work closely with CMS and the entire Administration to develop best practices based on what our members have told us.

As CMS develops its quality measurement approach to health equity, we encourage the agency to strive for consistency and alignment across all of its provider measurement programs, and with other entities within the federal government. One way to do this is to consider data collection across the continuum of care. In the FY 2020 proposed rules for the IRF, long-term care hospital, SNF and home health prospective payment systems, CMS adopted seven SPADEs addressing social determinants of health (SDOH). In our comments on those rules, we requested clarity from CMS on the potential future uses of these elements and the requirements around data collection for certain elements, such as the frequency with which those SPADEs are collected. In addition, we were unsure that the response options under the race data element were the right ones. It appears that some of the categories are not consistent with those used in other government data collection practices, like the Census or the Office of Management and Budget, and are not consistent with the recommendations made in the 2009 Institute of Medicine report on Standardized Collection of Data on Race, Ethnicity and Language. Considering that health is affected by factors and circumstances not only adjudicated under the Department of Health and Human Services, it is vital that CMS work closely with other agencies and government actors to ensure that we are all collecting the same — and the right — data in the same — and the right —way.

Further, regarding CMS' request for feedback on additional SDOH SPADEs, we would urge the agency to gain more operational experience with these seven newly added elements before adopting additional data fields. These elements have not been in use for an entire year, so the feasibility and usefulness of the information gleaned from their use remains to be seen. As in the rest of its quality measurement enterprise, CMS should strive for a streamlined and parsimonious set of data elements to increase the likelihood of collecting precise information in the most efficient way possible. Indeed, we previously shared our concerns about the rigidity of the data collection process for certain SPADEs in our comments on the FY 2020 IRF PPS proposed rule, and would encourage the agency to consider more flexible timeframes for collecting SDOH SPADEs going forward.

Finally, many of CMS' suggestions, programs and proposals regarding disparities are defined around either race and ethnicity or dual eligibility for Medicare and Medicaid as a proxy for income. While these factors are doubtless vital to assess, the agency — and providers — need to explore other demographic and social risk factors as well. These include, but are not limited to, sexual orientation, gender expression, education and literacy, veteran status, disability status, housing, social isolation, and community resources. These data often rely on patient self-report, and stakeholders are still learning what data elements are the most useful and practical to collect, analyze and use. We would encourage CMS to engage with stakeholders to understand what opportunities there may be to promote greater consistency and standardization of approaches.

RFI on Digital Quality Measures (dQMs) and Fast Healthcare Interoperability Resource (FHIR). In this rule, CMS outlines the agency's general considerations for the future development and staged implementation of a cohesive portfolio of dQMs across quality programs, agencies, and private payers, as well as the potential use of FHIR for dQMs within quality programs. The AHA agrees that a digital and interoperable quality enterprise is a laudable goal that could have positive and far-reaching effects of patient outcomes and experience. We also support the potential use of FHIR, as this standard is easier to implement and more fluid than many other available frameworks. **However, we encourage CMS to hone its approach to transforming its quality measurement enterprise by more clearly defining the goals and expectations for providers and considering the specific needs and capabilities of post-acute care providers and their patients.**

The seminal statute for health information technology, the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, resolved to spend $25.9 billion to promote and expand the adoption of health IT; to implement the requirements of the HITECH Act, CMS offered incentives to eligible professionals and hospitals that adopt and demonstrate the meaningful use of electronic health records (EHRs). However, long-term care and post-acute care providers were not eligible for the EHR Incentive Programs (not known as the Promoting Interoperability Programs) under the Act. In its 2019 RFI that accompanied the Interoperability and Patient Access proposed rule, CMS largely attributed the slow rate of EHR adoption in post-acute care settings to the lack of federal incentives available to these providers.

In addition to this lag, the experience with various health IT capabilities in post-acute care is heterogeneous; while some providers have been able to successfully incorporate health IT with higher levels of sophistication, including certified EHR technology (CEHRT), others are using technologies with fewer capabilities for digital exchange. The shortages in HIT professionals and resources dedicated to health IT are particularly dire for post-acute care providers, so any new requirements for attestation to digital capabilities will result in even more competition for vendor attention — both among post-acute care providers and between post-acute and general acute care providers.

Because of these challenges, any approach to digital quality measurement in post-acute care will have to be nuanced and gradual. We encourage CMS to consider developing a "glide path" for post-acute care provider participation in digital quality measurement, one that provides technical assistance for providers who are less advanced in their health IT capabilities as well as more opportunities for achievement for those who are well on their way. **Adoption and implementation of health IT systems like CEHRT is not like flipping a switch; it involves painstaking and thoughtful groundwork to establish an infrastructure — including security and personnel as well as physical investments — that can support highly technical requirements.** A definition of dQMs must be understandable for those providers who do not have as

robust a technology infrastructure so that they can work to someday achieve interoperability rather than abandon hope because the future is daunting and expensive.

We encourage CMS to further hone its definition of dQMs by setting clear and specific parameters for what the agency hopes to achieve and what it expects of participating providers. For example, what would the agency do differently to "transform" its quality measurement enterprise in order for the measures used in various quality reporting programs to meet the definition of dQMs? The definition proffered in the RFI is quite broad, and lists data sources including administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information exchanges (HIEs) or registries, and other sources." Using this definition, it could be argued that SNFs, IRFs, LTCHs, and home health agencies are already reporting dQMs, and thus no "transformation" is necessary. On the other hand, it also could be argued that the agency, in seeking to fully transition to dQMs by 2025, expects providers to be able to interact with all of these data sources and thus take on more than a decade's worth of un-funded work in just a few years. In order to plan for the future of digital quality measurement, CMS should more clearly define what it expects that future to look like for all providers, specifically post-acute care providers, and how those expectations differ from the status quo. The AHA and our members are excited to work with CMS to build their digital quality measurement enterprise, and we would be happy to collaborate on more specific plans for the future.

Thank you for the opportunity to comment on this proposed rule. Please contact me if you have questions or feel free to have a member of your team contact Rochelle Archuleta, AHA's director of policy, at rarchuleta@aha.org, on any payment-related issues, and Caitlin Gillooley, senior associate director of policy, at cgillooley@aha.org, regarding any quality-related questions.

Sincerely,

/s/

Stacey Hughes
Executive Vice President