March 31, 2021

Dear Director Fowler:

Congratulations on your recent appointment as the new Director of the Center for Medicare and Medicaid Innovation (CMMI). We appreciate the significant experience that you bring to this role, look forward to your leadership, and welcome the opportunity to work with you on critical issues facing the healthcare community.

We support Congress and the Biden administration's decision to delay the onset of the Radiation Oncology Alternative Payment Model (RO APM) and assess its full impact, and as leading clinicians treating cancer across the country, we respectfully request that you specifically review the treatment of proton beam therapy under the model. For the reasons outlined below, we strongly believe that proton beam therapy should be excluded from the payment episode, which will have very significant unintended consequences on critical cancer treatments for patients. We applaud the President's commitment to prioritize cancer for the 1.7 million Americans diagnosed each year, and we appreciate his clear recognition that "proton beams can be used and not do as much damage" to critical normal tissues compared with conventional x-ray radiation therapy.[1]

During the previous consideration of the RO APM, we raised a number of important concerns and were disappointed to see that the final model did not adequately address those concerns. (*See* **Attachment 1**). A number of our esteemed colleagues from Emory, Mayo Clinic, MD Anderson, The University of Pennsylvania and Washington University expressed this same view in a leading cancer publication just a few weeks ago.[2]

Proton therapy is an emerging radiation treatment modality that has the proven ability to reduce side effects for patients by limiting the amount of normal tissue exposed to radiation. Unlike conventional x-ray radiation, which has both entrance and exit doses, proton therapy delivers radiation to the target, with little to no radiation extending beyond the target. In addition, there is new evidence that proton therapy may have an enhanced biologic effect on tumors over conventional x-ray therapy. Although proton therapy can improve disease outcomes, reduce radiation toxicity, and improve quality of life for patients with cancer, it is now under significant financial constraints due to the decision by the prior administration to include proton therapy in the RO APM.

Under the previous analysis of hospital radiation oncology claims to determine the proposed bundled payment rate, the reviewed claims included very few proton treatments, as proton therapy accounted for < 1% of the total sample analyzed. Given the rarity of proton therapy in the data, the rate-setting methodology described in the proposed rule would not produce national payment rates for the disease sites treated by proton beam therapy in a manner that would appropriately reimburse providers for their costs. Currently, proton therapy as an emerging technology is a more costly treatment due, in part, to the higher cost of the capital equipment required to deliver it, the higher

[1] http://transcripts.cnn.com/TRANSCRIPTS/2002/05/se.01.html

[2] Baumann BC, Metz JM, Frank SJ, Mahajan A, Bradley JM. Stifling Innovation: Proton Therapy Should Be Excluded From the New Radiation Oncology Alternative Payment Model. ASCO Daily News, https://dailynews.ascopubs.org/do/10.1200/ADN.21.200441/full/.

cost of maintaining a proton center, and the greater complexity of proton therapy treatment planning and delivery.

Data recently compiled by the National Association for Proton Therapy from proton centers mandated to participate in the Model show cuts in year 1 of the RO APM ranging from 24.8% to 45.9%. (*See* **Attachment 2**) Such a massive financial loss incurred in year 1 alone (of a 5-year model) would place proton centers in significant and immediate financial jeopardy. Although pediatric patients are excluded from the RO APM, they will nonetheless be affected, as fewer proton centers will be able to continue operations, limiting children's access to proton therapy, which is considered the optimal delivery method of radiation and clear standard of care for most pediatric malignancies. We must not forget the 9.1 million Americans under 65 years with disabilities covered under Medicare (16% of the total Medicare population) who would greatly benefit from treatments that could avoid long-term side effects and secondary malignancies.

Proton therapy is a high-value treatment for appropriately selected pediatric and adult patients; however, the Center for Medicare & Medicaid Innovation has postulated that the therapy as a whole is "low-value" without acknowledging the most recent published data over the last 4 years. Specifically, as proton therapy is a relatively new treatment modality, most multi-center and National Institutes of Health-funded data on proton therapy have just emerged in the past few years, and high-quality comparative effectiveness data are now available that clearly contradict the claim that proton therapy is "low-value." Moreover, **Attachment 3** illustrates how this clinical research directly applies to the Medicare beneficiaries fighting certain cancers. Coverage policies are rapidly evolving in favor of proton therapy. Proton therapy should be excluded from the RO APM to provide proton centers time to gather the necessary additional data on comparative effectiveness and to complete numerous ongoing randomized trials to further clarify proton therapy's value for patients with cancer. Many of the trials are funded by the National Cancer Institute who has committed tens of millions of dollars in these trials to definitely demonstrate that proton therapy improves survival and reduces toxicities for cancer patients across multiple cancer sites and patient populations.

In 2020 alone, several key studies demonstrated the promise of proton therapy in making significant and clinically meaningful reductions in acute toxicity in our patients. The study by Baumann et al published in *JAMA Oncology* found that in a cohort of 1,483 patients with solid malignancies treated with definitive chemoradiotherapy for nonmetastatic disease, proton therapy was associated with a statistically significant two-thirds reduction in acute grade ≥ 3 adverse events on propensity weighted analysis (RR 0.31, 95% CI [0.15, 0.66]; $p = 0.002$) and a significant reduction in the rate of Eastern Cooperative Oncology Group (ECOG) performance status decline from the start to the end of treatment (RR 0.51, 95% CI [0.37, 0.71]; $p < 0.001$) compared with the photon group.[3] Disease-free survival and overall survival were comparable between the two cohorts. Although the study was retrospective, the data on adverse events and survival were gathered prospectively, and 90% of the patients on the photon arm received the most advanced form of photon radiotherapy: IMRT. The cost-effectiveness was not reported in that study, but a two-thirds reduction in serious adverse events associated with hospitalizations would be expected to more than offset the higher upfront cost of proton therapy, as has been demonstrated for several disease sites. Additionally, this report suggests the intriguing opportunity to intensify treatments with proton therapy, which could,

[3] Baumann BC, Mitra N, Harton JG, et al. Comparative effectiveness of proton vs photon therapy as part of concurrent chemoradiotherapy for locally advanced cancer. *JAMA Oncol.* 2020;6:237-246

in turn, improve oncologic outcomes for patients who receive chemoradiotherapy. With fewer patients experiencing a drop in their ECOG performance status during proton chemoradiotherapy, there could be cost savings to society, as more patients would be able to work during treatment and/or handle their own self-care, freeing up their families and caretakers to remain at their jobs. In 2020, we also saw the publication of a randomized prospective trial of proton compared with photon chemoradiotherapy for esophageal cancer by Lin et al in the *Journal of Clinical Oncology*.[4] Similar to the *JAMA Oncology* study, this trial found comparable oncologic outcomes but a statistically significant reduction in the primary endpoint of total toxicity burden in favor of the proton arm. Proton beam therapy was associated with 2.3-times lower total toxicity burden than photon therapy, as well patients having an average of 5 fewer days needed in the hospital for protons compared with photons to recover from their cancer treatment.

While the Lin et al and Baumann et al studies reported a benefit for proton therapy in reducing the risk of severe acute side effects, there is also excitement about the potential of proton therapy to limit late side effects of radiation, occurring months to years after treatment has completed. The study by Xiang et al also published in 2020 in the American Cancer Society's journal *Cancer* reported pooled data on second malignancies from the National Cancer Database on patients with a wide range of solid malignancies treated with definitive radiotherapy (450,373 patients). They found that proton therapy was associated with a statistically significant two-thirds reduction in the rate of second malignancies compared with photon therapy, including in the head-to-head analysis comparing proton therapy with IMRT. There is also recent data on long-term intelligence outcomes for proton compared with photon cranial radiation. In a study also published in 2020 by Kahalley et al in the *Journal of Clinical Oncology*, children treated with proton therapy for medulloblastoma exhibited superior long-term outcomes in global IQ, perceptual reasoning, and working memory compared with the photon-treated cohort ($p < 0.05$ for all).[5]

In addition to these acute and late toxicity benefits of proton therapy over conventional radiation therapy, proton beam therapy has been shown across multiple disease sites to improve overall survival, either by reducing life-threating toxicities, being more biologically potent at tumor killing, or allowing for more targeted and escalated doses of irradiation to be delivered directly to the tumor. In 2020, more literature was published supporting the survival benefit of proton therapy for select tumors, including the report by Cheng et al in the journal *Radiation Oncology* showing on a propensity-matched series a significant survival benefit to proton therapy over photon therapy ($p=0.032$), for hepatocellular cancer while also cutting the rate of radiation-induced liver disease by over two thirds (11.8% vs. 36%, $p=0.004$).[6]

There are many reasons to be excited about the promise of proton therapy and a compelling argument to be made that it is in the public's best interest to nurture proton therapy as a critical technology of the future that is part of the President's solution of ending cancer as we know it and thus exclude proton therapy from the RO APM.

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[4] Lin SH, Hobbs BP, Verma V, et al. Randomized phase iib trial of proton beam therapy versus intensity-modulated radiation therapy for locally advanced esophageal cancer. *J Clin Oncol*. 2020;38:1569-1579.

[5] Kahalley LS, Peterson R, Ris MD, et al. Superior Intellectual Outcomes After Proton Radiotherapy Compared With Photon Radiotherapy for Pediatric Medulloblastoma. *J Clin Oncol*. 2019;38:454-46`.

[6] Cheng JY, Liu CM, Wang YM, et al. Proton versus photon radiotherapy for primary hepatocellular carcinoma: a propensity-matched analysis. Radiat Oncol. 2020;15(1):159.

[PHYSICIAN SIGNATURES, AFFILIATED INSTITUTIONS]

Attachment 1

March 6, 2020 Letter to CMS Administrator from Cancer Care Physicians available at: https://www.proton-therapy.org/wp-content/uploads/2021/02/Physician-letter-to-Administrator-Verma-3.6.20.pdf

Attachment 2

Overview of Analysis

- As currently defined in the RO APM, thirteen proton therapy centers fall under the model
  - Mandated members span 8 different states
  - Centers by institution type:
    - 10 hospital based centers
    - 3 freestanding centers
- Requested center specific metrics by component
  - Case mix factor
  - Historical experience adjustment factor
  - Efficiency factor

Cancer Types

- Anal Cancer
- Bladder Cancer
- Bone Metastases
- Brain Metastases
- Breast Cancer
- Cervical Cancer
- CNS Tumor
- Colorectal Cancer
- Head and Neck Cancer
- Liver Cancer
- Lung Cancer
- Lymphoma
- Pancreatic Cancer
- Prostate Cancer
- Upper GI Cancer
- Uterine Cancer

*Focusing on five of the most common cancer types treated with proton beam therapy based on NAPT annual survey data**

* National Association for Proton Therapy Annual Survey – CY 2019 data

Approach to Analysis

- Recreated the methodology for calculating the payment rates based on the Final Rule
- Assumptions
  - Incorporated a 2% quality withhold
  - Adjusted for the CY 2021 geographic adjustments
  - Modeled the impact of different trend factors
    - Due to lack of clarity on the cancer-specific trend factors, used a trend factor of 1 for each cancer type
- Incorporated the adjustments from the centers
  - To date, there was variability in the type of centers
    - Centers with 3 years experience vs. no experience
    - Centers with predominantly protons vs. centers with service mix

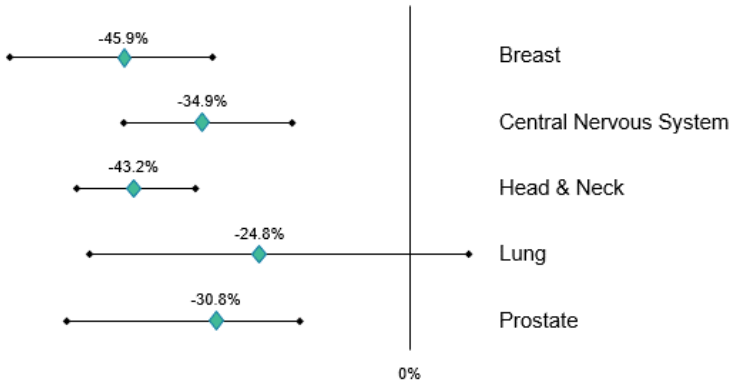
Approach to Analysis

- Compared the technical component rates in **PY 1** to each center's historical reimbursement rates for technical component

$$\%\,\Delta = \frac{\text{(PY 1 TC Rates by Cancer)} - \text{(Historical TC Rates by Cancer)}}{\text{(Historical TC Rates by Cancer)}}$$

Findings

PY 1 RO APM PROVIDER-SPECIFIC RATES VS. AVERAGE HISTORICAL RATES (N=6)



All centers facing substantial cuts vis-à-vis historical reimbursement rates

Key Observations

- On average, for PY 1, the percent change from historical proton rates to center specific rates under RO APM was **-36.0%**
  - Historical reimbursement based on a mix of fractionation protocol and technology schemes
  - Depending on the clinically appropriate protocol for the patient given their cancer, cuts in PY 1 may be even greater
  - Inefficient and efficient practices are facing comparable cuts in payment rates, creating disincentive for efficiency
- Difference in rates may be exacerbated or mitigated based on the trend factors
- Effects of the adjustment factors inconsistent with expectations established based on the Final Rule
  - Not a muted glidepath to the national base rates
- Uncertainty and significant concern as to the impact in PY 2 – PY 5 given the estimated impact in PY 1

Attachment 3

Research Article	Median Age	Date Published
Lin SH, Hobbs BP, Verma V, et al. (2020). Randomized Phase IIB Trial of Proton Beam Therapy Versus Intensity-Modulated Radiation Therapy for Locally Advanced Esophageal Cancer. *J Clin Oncol*, 38(14), 1569–1579. https://doi.org/10.1200/JCO.19.02503	67	August 2020
Xiang M, Chang DT, Pollom EL. Second cancer risk after primary cancer treatment with three-dimensional conformal, intensity-modulated, or proton beam radiation therapy. *Cancer*. 2020;126(15):3560-3568.	63	May 2020
Baumann BC, Mitra N, Harton JG, et al. (2020). Comparative Effectiveness of Proton vs Photon Therapy as Part of Concurrent Chemoradiotherapy for Locally Advanced Cancer. *JAMA Oncol*, 6(2), 237–246. https://doi.org/10.1001/jamaoncol.2019.4889	62 (66 for proton cohort)	December 2019
Van Rossum P, Deng W, Routman DM, et al. (2020). Prediction of Severe Lymphopenia During Chemoradiation Therapy for Esophageal Cancer: Development and Validation of a Pretreatment Nomogram. *Pract Radiat Oncol*, 10(1), e16–e26. https://doi.org/10.1016/j.prro.2019.07.010	63.1 +/- 10.7 years (Entire cohort)	July 2019
Rice SR, Li YR, Busch TM, et al (2019). A Novel Prospective Study Assessing the Combination of Photodynamic Therapy and Proton Radiation Therapy: Safety and Outcomes When Treating Malignant Pleural Mesothelioma. *Photochem Photobiol*, 95(1), 411–418. https://doi.org/10.1111/php.13065	69	December 2018
Routman DM, Garant A, Lester SC, et al. (2019). A Comparison of Grade 4 Lymphopenia With Proton Versus Photon Radiation Therapy for Esophageal Cancer. *Adv Radiat Oncol*, 4(1), 63–69. https://doi.org/10.1016/j.adro.2018.09.004	66	September 2018
Vyfhuis M, Rice S, Remick J, et al. (2018). Reirradiation for locoregionally recurrent non-small cell lung cancer. *J Thorac Dis*, 10(Suppl 21), S2522–S2536. https://doi.org/10.21037/jtd.2017.12.50	n/a	August 2018
Verma V, Lin L, Simone CB, 2nd (2018). Proton Beam Therapy for Bronchogenic Adenoid Cystic Carcinoma: Dosimetry, Toxicities, and Outcomes. *Int J Part Ther*, 4(4), 1–9. https://doi.org/10.14338/IJPT-17-00014.1	67	July 2018
Liao Z, Lee JJ, Komaki R, et al. (2018). Bayesian Adaptive Randomization Trial of Passive Scattering Proton Therapy and Intensity-Modulated Photon Radiotherapy for Locally Advanced Non-Small-Cell Lung Cancer. *J Clin Oncol*, 36(18), 1813–1822. https://doi.org/10.1200/JCO.2017.74.0720	67	January 2018
Chang JY, Verma V, Li M, et al (2017). Proton Beam Radiotherapy and Concurrent Chemotherapy for Unresectable Stage III Non-Small Cell Lung Cancer: Final Results of a Phase 2 Study. *JAMA Oncol*, 3(8), e172032. https://doi.org/10.1001/jamaoncol.2017.2032	70	August 2017

Research Article	Median Age	Date Published
Chao HH, Berman AT, Simone CB, 2nd, et al. (2017). Multi-Institutional Prospective Study of Reirradiation with Proton Beam Radiotherapy for Locoregionally Recurrent Non-Small Cell Lung Cancer. *J Thorac Oncol*, 12(2), 281–292. https://doi.org/10.1016/j.jtho.2016.10.018	65	February 2017
Lester SC, Lin SH, Chuong M, et al. (2017). A Multi-institutional Analysis of Trimodality Therapy for Esophageal Cancer in Elderly Patients. *Int J Radiat Oncol Biol Phys*, 98(4), 820–828. https://doi.org/10.1016/j.ijrobp.2017.02.021	60	February 2017
Remick JS, Schonewolf C, Gabriel P, et al. (2017). First Clinical Report of Proton Beam Therapy for Postoperative Radiotherapy for Non-Small-Cell Lung Cancer. *Clin Lung Cancer*, 18(4), 364–371. https://doi.org/10.1016/j.cllc.2016.12.009	65 (proton), 63 (IMRT)	December 2016
Higgins KA, O'Connell K, Liu Y, et al. (2017). National Cancer Database Analysis of Proton Versus Photon Radiation Therapy in Non-Small Cell Lung Cancer. *Int J Radiat Oncol Biol Phys*, 97(1), 128–137. https://doi.org/10.1016/j.ijrobp.2016.10.001	68	October 2016
McDonald MW, Liu Y, Moore MG, Johnstone PA. (2016). Acute toxicity in comprehensive head and neck radiation for nasopharynx and paranasal sinus cancers: cohort comparison of 3D conformal proton therapy and intensity modulated radiation therapy. *Radiat Oncol* (London, England), 11, 32. https://doi.org/10.1186/s13014-016-0600-3	46.7	February 2016
Cheng JY, Liu CM, Wang YM, et al. Proton versus photon radiotherapy for primary hepatocellular carcinoma: a propensity-matched analysis. Radiat Oncol. 2020;15(1):159.	65.53(Mean)	June 2020
Makita C, Nakamura T, Takada A, et al. (2014). High-dose proton beam therapy for stage I non-small cell lung cancer: Clinical outcomes and prognostic factors. *Acta Oncol* (Stockholm, Sweden), 54(3), 307–314. https://doi.org/10.3109/0284186X.2014.948060	77	July 2014
Patel SH, Wang Z, Wong WW, et al. (2014). Charged particle therapy versus photon therapy for paranasal sinus and nasal cavity malignant diseases: a systematic review and meta-analysis. *Lancet Oncol*, 15(9), 1027–1038. https://doi.org/10.1016/S1470-2045(14)70268-2	57.7	June 2014
Kanemoto A, Okumura T, Ishikawa H, et al. (2014). Outcomes and prognostic factors for recurrence after high-dose proton beam therapy for centrally and peripherally located stage I non--small-cell lung cancer. *Clin Lung Cancer*, 15(2), e7–e12. https://doi.org/10.1016/j.cllc.2013.11.002	75	March 2014
Hoppe BS, Michalski JM, Mendenhall NP, et al. (2014). Comparative effectiveness study of patient-reported outcomes after proton therapy or intensity-modulated radiotherapy for prostate cancer. *Cancer*, 120(7), 1076–1082. https://doi.org/10.1002/cncr.28536	66	December 2013

Research Article	Median Age	Date Published
Bush DA, Cheek G, Zaheer S, et al. (2013). High-dose hypofractionated proton beam radiation therapy is safe and effective for central and peripheral early-stage non-small cell lung cancer: results of a 12-year experience at Loma Linda University Medical Center. *Int J Radiat Oncol Biol Phys*, 86(5), 964–968. https://doi.org/10.1016/j.ijrobp.2013.05.002	73.2	August 2013
Chung CS, Yock TI, Nelson K, et al. (2013). Incidence of second malignancies among patients treated with proton versus photon radiation. *Int J Radiat Oncol Biol Phys*, 87(1), 46–52. https://doi.org/10.1016/j.ijrobp.2013.04.030	59	April 2013

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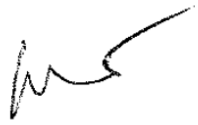

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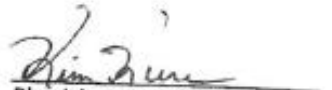

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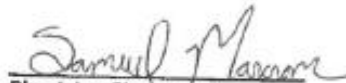

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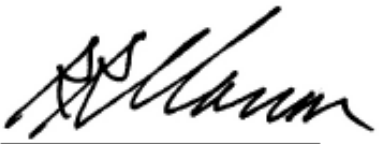

Physician Signature

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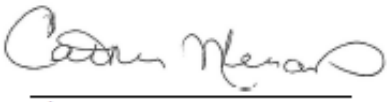

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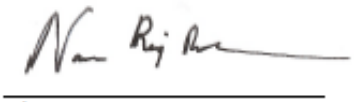

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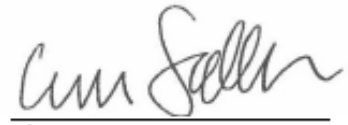

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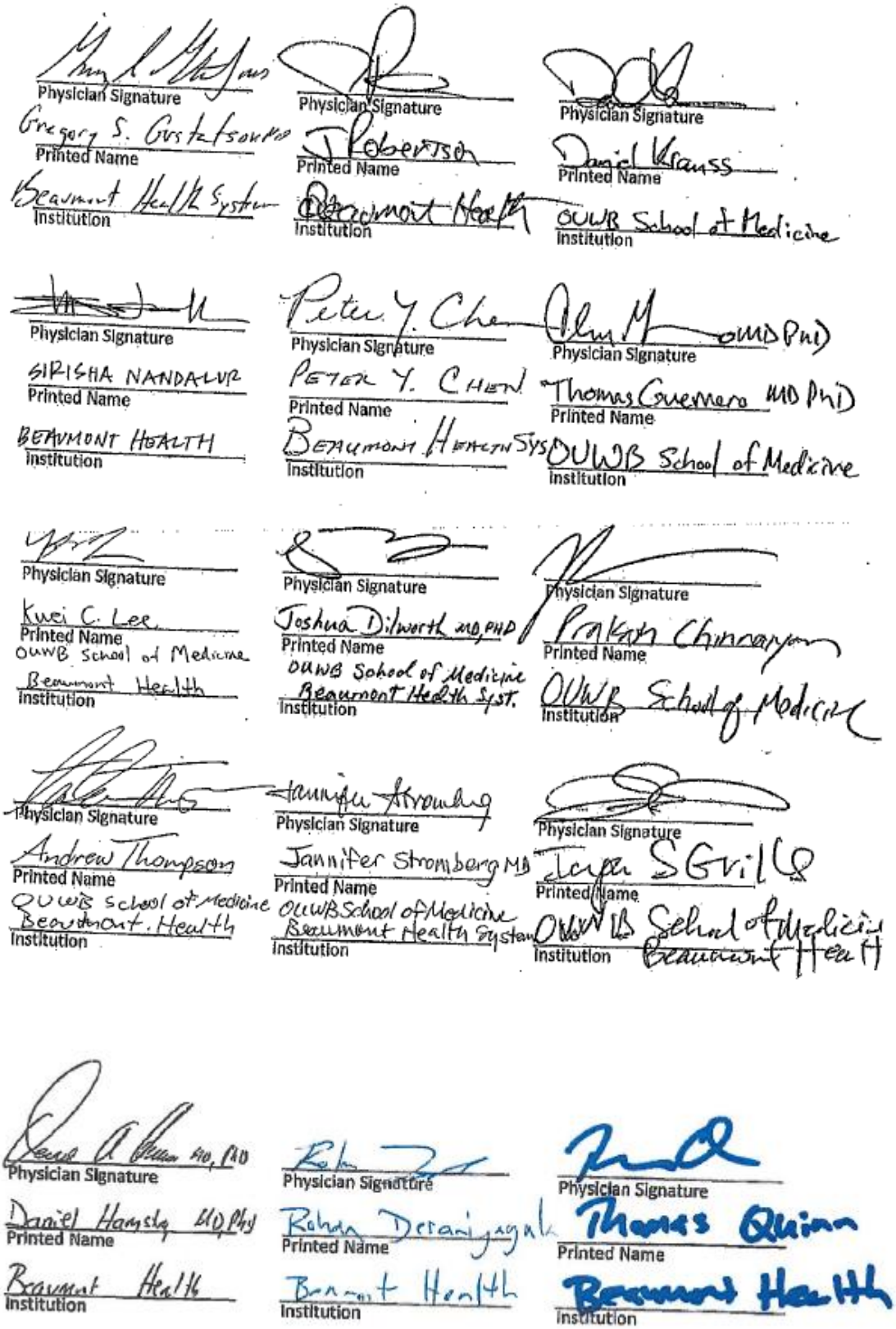
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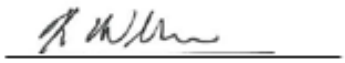

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