MCDA
Muller Consulting & Data Analytics, LLC

September 9, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CY2022 Solicited PFS Policy around Software as a Medical Device (SaMD)

Dear Administrator Brooks-LaSure:

Muller Consulting & Data Analytics, LLC (MCDA) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) CY 2022 Physician Fee Schedule (PFS) Notice of Proposed Rule Making (Proposed Rule) published in the July 23, 2021 *Federal Register (Vol. 86, No. 159 FR, pp. 39104-39907)*. We are writing to comment on the Proposed Rule's general solicitation of input into the treatment of Artificial Intelligence (AI) and more broadly Software as a Medical Device (SaMD) in the PFS.

MCDA specializes in U.S. healthcare policy and data research, including 13 years of experience replicating and modeling the PFS Practice Expense (PE) rate-setting methodology and related policies. In response to the impending need to tackle the expansive and complex payment and coverage policy issues around PFS reimbursement of SaMD, we have produced the attached report entitled "*Reimbursing Software as a Medical Device (SaMD) Costs under the Physician Fee Schedule: Perspectives for a policy framework for CMS and the MACs.*"

In the spirit of CMS's broad solicitations of input on SaMD and related PFS rate-setting issue, MCDA has produced the attached report to hopefully contribute to the policy debate in such a way that CMS can help patients, providers, manufacturers, investors, innovators, itself, and the Trust Fund by evolving CMS policy around SaMD.

Following are our summary recommendations around the broad topic of PFS reimbursement of SaMD products and our responses to CMS's structured specific questions on SaMD policy, both excerpted verbatim from our report.

MCDA is available for questions and comments by CMS and other stakeholders as needed via james.muller@MCDAintel.com.

Sincerely,

James Muller
Muller Consulting & Data Analytics, LLC
Washington, DC

Main Recommendations

Recommendation 1: CMS should aim to describe their concerns and thinking around PFS SaMD reimbursement in as much detail as possible, as CMS's past minimal descriptions of their concerns and analysis of the issues underlying those concerns has inhibited detailed analysis oriented towards solutions. We commend CMS for significantly expanding their exposition around their concerns in the PFS 2022 proposed rule (allowing, for example, us to produce our report), however we note that the expanded exposition is still relatively brief and high-level given the complex and important SaMD policy territory, and additionally note that we are left suspecting that there are additional concerns CMS has not articulated in the rule text (which could be analyzed if they were described).

R**ecommendation 2:** CMS should classify and think about SaMD as a medical device rather than a software add-on to physical supplies or equipment. CMS should move away from thinking about software as a subordinate tool that is not its own legitimate class of medical devices.

Recommendation 3: Include Software as a Medical Device (SaMD) costs as PFS direct inputs under four specific cases:

1. If the AMA's CPT Editorial Panel created a specific CPT® code inextricably built upon a specific SaMD input, implicitly accepting the efficacy of the code's service, then allow the SaMD input to be included.
2. If a SaMD direct input was previously included in the PFS, grandfather that direct input in. If in the future the RUC reviews the code and changes its specification, then consider revising accordingly.
3. If the SaMD product accompanies and is required by a specific physical direct equipment input in the service as typically performed, then include it as a direct input. This is the case where a software input could equally have been packaged into a physical equipment input's purchase price, however the software happened to be unpackaged from the physical equipment input.
4. Otherwise, include the SaMD product as a direct input if both:
    a. The RUC recommends the SaMD input is integral and essential under the "typical procedure" vignette for a CPT® code created by the AMA or HCPCS code created by CMS to describe a clinically valid healthcare service; and
    b. The input conforms to the current FDA definition of SaMD, regardless of whether the SaMD input is or will be marketed for direct sale in the U.S..

The current statutory definition of SaMD for FDA purposes is presented in Section 2.1 of the report.

Recommendation 4: If CMS wishes to establish additional guardrails around which SaMD products may be included as direct inputs, then CMS could:

1. Require the SaMD input is actually FDA-cleared (beyond being consistent with the FDA SaMD definition). In general, SaMD products will only be FDA cleared if the manufacturer seeks FDA clearance in order to market and sell the product in the US.
2. Only cover the SaMD input's CPT® code when the code is ordered by a physician that is at arms-length of the provider of the SaMD input's CPT® code. Analogous to "physician self-referral" or "Stark Law" rules, this adjustment to the CPT® code's national coverage decision (NCD) or local coverage decision (LCD) would be to prevent SaMD providers from referring patients to their own services.

In addition, we recommend that CMS follows the ongoing work by the FDA to develop guidelines and regulations around evaluating SaMD products for its purposes, and also to follow work by the Federal Trade Commission (FTC) who regulates products not cleared by the FDA. As this policy environment is being created in real time, it is likely that work by the FDA, FTC and others will be informative to CMS about appropriately including (and excluding) SaMD inputs from the PFS.

Recommendation 5: Until CMS reaches a comfort level with the inclusion of SaMD direct inputs, CMS should continue to use the "proxy PE RVU" approach that CMS has been using recently. Specifically, CMS may continue calculating what the PE RVU would have been if the SaMD input were included but then crosswalk the SaMD service's PE RVU to another code's PE RVU, where the proxy code is in the same broad clinical modality (e.g., ophthalmology to ophthalmology), likely has a similar specialty mix, and is subject to the same PFS policies (e.g., crosswalk an imaging code to a code also subject to the OPPS cap).

Recommendation 6: CMS should work expeditiously but carefully on developing a formal policy around SaMD so that the proxy approach is only used in the short term: one or two years at most. If CMS is able to propose a full policy in the PFS 2023 proposed rule for implementation in CY2023, that would be ideal. When CMS does develop SaMD policy, we recommend CMS explicitly states that it will surveil the policy and adjust it accordingly as the PFS SaMD market matures. We additionally recommend that CMS publishes the SaMD direct input inclusion policy in each year's rule and, at least for the first few years of the policy, annually solicit public input on the policy and its consequences.

Recommendation 7: CMS should specify most SaMD direct inputs as supply inputs, and only specify SaMD direct inputs as equipment inputs if the SaMD product is a locally installed computer package usable in at most one PFS service at one time.

Recommendation 8: When the SaMD input's CPT® code is billed by a physician who purchases the SaMD service from a vendor, then CMS or the RUC may survey traditional competitive-market invoice data from physician practices or collect the same centrally from the SaMD manufacturers. In either case, per-service supply item costs should be calculated as the total invoice price divided by the number of services furnished. The denominator – services furnished – should not be data transactions but should be actual services (i.e., units of the CPT® code presented to Medicare and other insurers) furnished.

Recommendation 9: When the SaMD input's CPT® code is billed solely by the SaMD provider, with no traditional invoices in a competitive environment, then CMS must obtain adequately detailed internal cost information from the (billing) SaMD providers to specify the SaMD direct input exclusive of other direct inputs and all of the SaMD provider's indirect costs. CMS must be strict that no corporate overhead, sales and marketing, etc., are included in the SaMD direct input's cost per service.

Recommendation 10: When the SaMD input is both billed directly by SaMD providers and under the traditional model by physicians, then CMS may choose whether to collect the SaMD input's invoice data from the physicians or from vertically integrated (billing) SaMD providers. Generally, we recommend CMS use traditional invoice data from physicians any time that they are available (even if that is a minority of the volume for the service), as doing so side-steps significant reimbursement strategy complications that may well introduce inaccuracies in the direct input specification and which may be problematic to update over time.

Recommendation 11: if there are no invoices , and CMS is unable to get required cost data from SaMD providers to specify a SaMD input, then CMS should define a strict policy to default the SaMD direct input's cost per service to either a code with similar or lower resource intensity in the same group of services (i.e., if there is a related input with lower similar or lower resource intensity, crosswalk the SaMD input to the alternate input's cost per service) or to set the SaMD direct input's cost per service to zero until CMS is able to get the required data. Additionally, if there are legitimate extenuating circumstances for why the SaMD provider is unable to share the needed cost data such as contractual or legal reasons, then CMS should work with the SaMD provider to find a way to obtain the needed data. The purpose of this recommendation is to short-circuit provider reimbursement strategies aimed at exploiting the information asymmetry between CMS (who needs the cost data) and providers (who have the cost data but are not required to share them) to inflate reimbursement, but is not to penalize or be cruel to providers who have legitimate reasons that they cannot share the data in the form CMS is requesting.

Recommendation 12: To guard against over-allocation of indirect PE RVUs resulting from SaMD products, we optionally recommend that CMS integrate SaMD direct inputs into the PE calculation with an indirect PE RVU allocator cap as follows. First, include the SaMD direct input in the usual way in the direct PE RVU allocation. Second, cap the SaMD direct costs used to allocate indirect PE RVUs to 3.0 standard deviations above the geometric mean of direct supply and input costs per service. That is, while SaMD direct PE RVUs would remain uncapped, the associated indirect PE RVU allocations would only increase up to the cap, and then would remain flat as the SaMD direct cost increased. Our recommended cap of 3.0 standard deviations above the geometric mean (which we recommend should be updated annually) would result in a cap higher than the majority of SaMD inputs under current consideration, but which would provide a guardrail around providers of this relatively new technology essentially naming their own price under the PFS. If CMS does not believe that such a cap is needed – or if it later turns out to not be warranted as the PFS SaMD market matures – then we recommend CMS not apply the cap. This policy recommendation is detailed in depth in Section 5.

Recommendation 13: For the AI-based diabetic retinopathy detection and monitoring code 92229, we believe that CMS's crosswalk of 92229's PE RVU to 92325's yields an appropriate PE RVU for 92229, and should be left in place until CMS attains comfort with a broader SaMD direct inputs policy. This is because doing so results in a PE RVU roughly equal to what would be obtained from including 92229's "AI fee" as a direct input and calculating its PE RVU in the usual way. Additionally, we agree with Digital Diagnostics and Eyenuk in their comments to the 2021 proposed rule that the appropriate direct supply cost per service should be $34 rather than $25, as they appear to be correct that the RUC's recommended $25 was based on $34 per-service invoices minus a $9 discount due to those physician practices participating with the providers in ongoing research and data use; as this is clearly not the usual contract physicians would have with 92229's SaMD providers, it appears inappropriate to apply that discount to the direct input's specification. When CMS develops policy around including SaMD direct inputs, we recommend CMS replace the 92229 proxy approach with the usual methodology including a $34 supply input for the AI analysis fee.

Recommendation 14: For trabecular bone score (TBS) dual X-ray absorptiometry (DXA) analysis codes 77X01 and 77X03, we believe CMS's proposal to crosswalk 77X01 to 71101 and then deduce 77X03 (the technical component) by subtracting 77X02 and 77X04's PE RVUs yields an appropriate PE RVU for 77X03, and should be left in place until CMS attains comfort with a broader SaMD direct inputs policy. As with 92229, this is because the PE RVUs resulting from the proxy methodology are roughly similar to what

would have resulted if CMS simply included the $25 supply input recommended by the RUC for 77X01 and 77X03 and calculated using the standard methodology. Specifically, where CMS's proxy approach resulted in PE RVUs of 0.97 for 77X01 and 0.81 for 77X03, including the $25 supply input and calculating the PE RVUs in the usual way would have resulted in PE RVUs of approximately 0.87 for 77X01 and 0.75 for 77X03. As with 92229, we recommend CMS replace the proxy method for 77X01 and 77X03 with the usual methodology when CMS reaches a comfort level with including SaMD direct inputs in the PFS.

Recommendation 15: For estimation of fractional flow reserve (FFR) using advanced analysis software codes 0501T and 0503T, we recommend CMS works with HeartFlow to develop a direct input specification for these codes. While HeartFlow's service is currently carrier priced under the PFS, its codes are rarely performed under the PFS and their average PFS technical component rate of 0503T ($38.22) is vastly lower than the OPPS APC rate of $950.50. Noting that the OPPS APC rate is based on hospital charge data converted to costs (for 0503T, the OPPS geometric mean cost per service was $804.35 in the 2021 final rule), it seems likely that the actual costs a physician practice would incur when performing 0503T would be in the ballpark of $804-35-$950.50 per service. We also note our experience under the extended external ECG debate that PFS rates resulting from a careful buildup of the direct inputs resulted were broadly similar to the equivalent OPPS estimated cost per service.

While it is unclear why CMS has not obtained cost data to develop a national direct input specification for 0503T (and 0501T) for the PFS, the absence of a specification appears to us to be mutually suboptimal for PFS beneficiaries, HeartFlow, and CMS; and to suggest a route for HeartFlow and CMS to work together towards the mutual benefit of both and Medicare's beneficiaries.

Responses to CMS's General Solicitation of Input on PFS SaMD Policy

Q1: To what extent are services involving innovative technologies such as software algorithms and/or AI substitutes and/or supplements for physician work? *To what extent do these services involving innovative technology inform, augment, or replace physician work? For example, CPT code 92229 is a PE-only code in which the software algorithm may be substituting for some work of an ophthalmologist to diagnose/detect diabetic retinopathy. CPT code 77X01 is a service in which the trabecular bone score software may be supplementing physician work to predict and detect fracture risk. CPT code 0503T may be both substituting for, and supplementing physician work to detect coronary artery disease.*

A1: While a useful thing to know for broader policy discussions, ultimately whether a prospective SaMD input is a supplement or substitute for another PFS cost is irrelevant to the specification of a code. Once CMS has accepted the existence of a CPT® code created by the AMA's CPT Editorial Panel, including its definition, if a SaMD input is integral to the service in the way it is typically performed, then it does not matter whether the code supplements existing services or supplements for alternative services. As CMS notes, the current codes in question span both situations. Additionally, in the future CMS will likely encounter SaMD inputs that perform functions entirely alien to traditional human labor or physical medical technologies.

Q2: How has innovative technology such as software algorithms and/or AI affected physician work time and intensity of furnishing services involving the use of such technology to Medicare beneficiaries? *For example, if a new software algorithm or AI technology for a diagnostic test results in a reduction in the amount of time that a practitioner spends reviewing and interpreting the results of a diagnostic*

test that previously did not involve such software algorithm or AI technology, and if the software algorithm or AI could be considered in part a substitute for at least some physician work, it may follow that the intensity of the service decreases. It is also possible that a software algorithm for a diagnostic test that is supplementing other tests to establish a diagnosis or treatment pathway for a particular condition could result in an increase in the amount of time that a practitioner spends explaining the test to a patient and then reviewing the results.

A2: The SaMD market is so nascent that it is unlikely any valid and reliable estimates could be made by any stakeholder of overall SaMD effects on physician time and work. While physician feedback to this question should be collected in the comment period, with so few currently-paid SaMD services under the PFS, CMS should not adjust policy based on any responses. Simply, the confidence bounds around any information render any feedback fully anecdotal and unusable for broader conclusions around such policy.

Q3: How is innovative technology such as software algorithms and/or AI changing cost structures in the physician office setting? *As discussed previously, the PPIS data that underlie the PE methodology were last collected in 2007 and 2008, which was prior to the widespread adoption of electronic health records and services that involve care management, non-face-to- face and/or asynchronous remote care; the need to use electronic clinical quality measure data to support quality improvement, disparity identification and resolution, and value based payment; and the emergence of software algorithms and/or AI and other technologies that use data to inform, augment, or replace physician work in the delivery of health care. Do costs for innovative technology such as software algorithms and/or AI to furnish services to patients involve a one-time investment and/or recurring costs? How should CMS consider costs for software algorithms and/or AI that use patient data that were previously collected as part of another service? As technology adoption grows, do these costs decrease over time?*

A3(a): Regarding the impact of cost structures of physician offices, there are so few SaMD products reimbursed under the PFS and the SaMD market is so nascent that it would be impossible to inform future-focused policy on any current realities.

A3(b): Regarding the *development and maintenance* of SaMD technologies, this is purely a question for SaMD manufacturers or the former staff of SaMD manufacturers.

A3(c): Regarding the case where CMS has reimbursed a data collection function in one service, then it must not reimburse the same data collection in another service, as that would be double-dipping reimbursement for the same cost. If CMS considers allowing some amount of direct costs for a specific service, then CMS must require that only the data collection costs associated with that specific service – and no other service – are included in that cost. However, we observe that for the two immediate SaMD services at question, all data collection occurs as part of the normal workflow of the service; 92229's ophthalmic image data is transmitted to the SaMD vendor each time the AI analysis is performed. If a SaMD product is locally installed and data are not transmitted to the manufacturer of the SaMD application, then any ongoing data collection would require an entirely separate process and would likely constitute R&D activities. Together, while basic accounting principles should be adhered to (i.e., do not reimburse the same costs twice), it appears per-service data collection costs would be either wholly specific to each unit of the service, infinitesimally small (such as when a few hundred gigabytes of data are transmitted over the Internet), or considered R&D costs that should be classified as indirect costs.

A3(d): Regarding whether SaMD costs to SaMD vendors decrease over time as technology is adopted, MCDA's previous research into the extended external ECG situation indicated the answer was yes. Feedback we reviewed from current executive staff of the largest companies in the market and former staff of those companies indicated that, first, the companies may experience decreases in their overall costs over time (as the technology matures and requires less active modification), and second, the relatively fixed overhead costs of developing the underlying algorithms may be spread over a larger pool of individual services as more physicians adopted extended external ECG for remote cardiac monitoring. It is, however, too early to know whether this anecdotal pattern observed in the extended external ECG market applies to other SaMD technologies.

Q4: How is innovative technology affecting beneficiary access to Medicare-covered services? *How are services involving software algorithms and/or AI being furnished to Medicare beneficiaries and what is important for CMS to understand as it considers how to accurately pay for services involving software algorithms and/or AI? For example, it is possible that services that involve software algorithms and/or AI may allow a practitioner to more efficiently furnish care to more Medicare beneficiaries, potentially increasing access to care. Additionally, to what extent have services that involve innovative technology such as software algorithms and/or AI affected access to Medicare-covered services in rural and/or underserved areas, or for beneficiaries that may face barriers (homelessness, lack of access to transportation, lower levels of health literacy, lower rates of internet access, mental illness, having a high number of chronic conditions/frailty, etc.) in obtaining health care?*

A4: Similar to the answers to Q2, any answers to this question will be fully speculative, and are not representative empirical data usable for calibrating future policy. With that said, we can observe that remote diagnostics such as extended external ECG, diabetic retinopathy testing that can be provided in primary care offices, etc., undoubtedly expands access to care for those services, both through improved convenience and binary access to care for those not geographically proximal to a specialist with the needed tools.

Q5: Compared to other services paid under the PFS, are services that are driven by or supported by innovative technology such as software algorithms and/or AI at greater risk of overutilization or more subject to fraud, waste, and abuse? *As we are considering appropriate payment for services enabled by new technologies, there are considerations for program integrity. For example, section 218(b) of the PAMA required that we establish an Appropriate Use Criteria Program to promote appropriate use of advanced diagnostic imaging services provided to Medicare beneficiaries. To what extent do services involving innovative technology require mechanisms such as appropriate use criteria to guard against overutilization, fraud, waste, or abuse?*

A5: It is unclear whether there are greater risks of overutilization, fraud, waste, or abuse in the SaMD market with respect to PFS policy. Generally, the SaMD market is so nascent that CMS should be cognizant of unknown-unknowns. While CMS should not perseverate excessively in developing a SaMD direct inputs policy, CMS is wise to approach the subject cautiously and deliberately. Proposing crosswalks in order to appropriately reimburse codes but delay fixing policy precedent before the policy implications have been thought through is a sensible short-term solution. CMS should strongly prefer establishing regular national policy with adjustable guardrails over crosswalking for more than one or two rulemaking cycles.

Because the AMA's CPT Editorial Panel has decided, so far, to create a small number of fine-grained, highly disease and process specific CPT® codes to reimburse SaMD inputs – all of which have been reviewed and cleared by FDA – CMS's best approach may be to reimburse the SaMD inputs and then monitor future overutilization, fraud, and waste. Specifically, CMS can surveil volume trends and patient outcomes (positive and negative) of the current SaMD codes to evaluate whether any of these concerns is warranted, and then act accordingly if theoretical risks turn out to be real problems.

Q6: Compared to other services paid under the PFS, are services driven by or supported by innovative technology such as software algorithms and/or AI associated with improvements in the quality of care or improvements in health equity? *For example, increased access to services to detect diabetic retinopathy such as the service described by CPT code 92229 could eventually lead to fewer beneficiaries losing their vision. Because CPT code 92229 can be furnished in a primary care practice's office and may not require the specialized services of an ophthalmologist, more beneficiaries could have access to a test, including those who live in areas with fewer ophthalmologists. Additionally, taking into consideration that a software algorithm and/or AI may introduce bias into clinical decision making that could influence outcomes for racial and ethnic minorities and people who are socioeconomically disadvantaged, are there guardrails, such as removing the source of bias in a software algorithm and/or AI, that Medicare should require as part of considering payment amounts for services enabled by software algorithm and/or AI?*

A6: As with Q2 and Q4, the SaMD market is far too nascent and there are too few SaMD products used in the PFS to extrapolate meaningfully into the future. However, as with any new technology, it is certain that some SaMD innovations will be truly excellent, most will be roughly as effective as existing services using skilled physician and clinical labor, and a few will be catastrophically bad. With regard to health equity, the answer is likely very product specific. For example, when priced reasonably, convenient SaMD services such as diabetic retinopathy's 92229 or extended external ECG's 93243 and 93247 appear likely to improve health equity; at the other end of the spectrum, extremely expensive and advanced SaMD services may only be available in similarly advanced practices, implicitly limiting access to those SaMD services to those who have access to those same practices.

Ultimately, it is worth reiterating what SaMD is. SaMD products *are* medical devices. Just as with any other innovative medical device, some will be more accessible and useful to the broad population, and others will only be accessible and useful to a subgroup of the population, at least initially. Simply, CMS should ignore that SaMD is software-based and think about coverage and payment decisions as though it was any other proposed direct input under consideration.