REIMBURSING SOFTWARE AS A MEDICAL DEVICE (SaMD) COSTS UNDER THE PHYSICIAN FEE SCHEDULE

Perspectives for a policy framework for CMS and the MACs

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Summary of Recommendations

This section summarizes the recommendations and suggestions presented through the report. Ultimately, the goal of these recommendations is to establish PFS SaMD policy in sustainable and valid way to support the needs of patients, providers, manufacturers, innovators, investors, CMS, and the Trust Fund in the long-run; and not to establish SaMD policy in a way that will be gamed and exploited in a way that will undermine this valuable technology and innovation over the coming years and decades. Following our main recommendations below, we also repeat verbatim our responses to CMS's broad solicitation of input into SaMD policy.

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.

Executive Summary

SaMD: The maturation of software to becoming a category of medical devices

Sophisticated clinical software systems employed in specific healthcare services have matured to the point that they are now classified as medical devices for the purpose of FDA regulation. They are formally called Software as a Medical Device, or SaMD. In response to 21st Century Cures Act and the broader reality that this class of software is most appropriately treated and thought about as medical devices, the FDA has established regulation clarifying which types of software are and are not SaMD, excluding generic operations, data storage, lifestyle management, and other non-service-specific software functions, but including diagnostic tools and potentially other service-specific software systems that ostensibly serve functions that would otherwise be performed by either human labor or physical medical devices.

As well as the definition of SaMD being refined by the Cures Act and FDA's regulations, the FDA and others have and continue to work intensively on developing policy frameworks to address unique characteristics of this new class of medical devices. For example, where physical medical devices have well-known policies regarding the clearance of new products and the treatment of modified products, SaMD (as with all software) is subject to ongoing refinement, and in particular, Artificial Intelligence (AI) systems evolve as more and different data become available – resulting in changes in how input data (e.g., an ophthalmic image) would translate into results (e.g., a diagnosis). The FDA and others are actively researching and developing policy to adapt their policy frameworks to account for these realities to protect patient safety and to provide a clear structure that innovators can expect when investing in new SaMD products.

SaMD in the Physician Fee Schedule – Current Treatment

While CMS has included SaMD direct inputs in the PFS, historically, most of the inputs they included were inextricably linked to physical direct equipment items used in the same codes. This historical treatment made sense while SaMD was fully subordinate to those physical medical devices, providing the functions of operating systems (e.g., the "flight control system" of an advanced radiological imaging device) or being necessary supportive tools used in conjunction with the physical device.

With the acknowledgment of both US law and FDA regulations that SaMD has matured into something more, CMS is now receiving the first trickle of what will become a growing flow of requests to reimburse PFS services for which SaMD is the defining feature of the codes, for which the primary function of the codes is performed by the SaMD product, and for which the costs incurred by physician practices and other providers are significantly comprised of those SaMD inputs.

Currently, CMS is soliciting input into how it should treat SaMD in the PFS. The primary question is whether to consider SaMD products to be "direct inputs" or "indirect costs." For the types of codes currently at consideration in the PFS – technical component codes – considering SaMD to be an indirect cost is fully equivalent to CMS refusing to reimburse any costs for SaMD. Where CMS had previously held a staunch position that SaMD costs were indirect, in the 2022 proposed rule, CMS has softened its position

and is actively researching the topic with the goal of establishing global policy around how SaMD is treated in the PFS.

In the interim, CMS has adopted an informal solution to reimburse SaMD inputs – crosswalking the PFS payment rates for the SaMD-inclusive code in question to a different service whole rate is close to what CMS would have paid if the SaMD product had been included as a direct input. While this is obviously an awkward long-term (or even medium-term) workaround, it is a reasonable second-best approach while CMS comes to a well thought policy position on SaMD.

CMS's Ethical Duty to Establish Viable and Well Developed PFS Payment Policy for SaMD

As stewards of the PFS program and protectors of both Medicare beneficiary access to care and exposure to ineffective services, CMS has an ethical duty to expeditiously develop and establish clear policy around SaMD that safeguards both Medicare's program integrity and beneficiaries, while simultaneously providing access to care and establishing a clear economic structure that allows innovators to confidently invest time and capital to operate in.

Just as software that traditionally provided a supporting role in healthcare services has matured into being a category of medical devices in its own right, performing the primary function on certain types of services, we can safely assume that SaMD will continue to mature in sophistication, capacity and independence in the provision of healthcare over time. For example, one of the codes under current consideration is termed an "autonomous AI" that fully replaces physician interpretation of ophthalmic imagery to detect diabetic retinopathy. It is easy to imagine plausible near-future extensions to this type of "autonomous AI" such as directly reviewing a patient suffering a complex disease to prescribe a full treatment regimen and heuristically adapting that regimen based on the patients' responses to treatment.

While such science fiction possibilities are both frightening and realistic, CMS can trust that the AMA, the FDA, the FTC, and others are working intensively on establishing frameworks to evaluate safety around SaMD now and in the future. Of particular importance is the American Medical Association's (AMA) special role in creating the CPT® codes, for devices determined to be safe by regulatory agencies, through which PFS services are reimbursed. The AMA's CPT® Editorial Panel is responsible for the creation and maintenance of CPT® codes, and effectively serves as a gatekeeper between services that have no place in healthcare and Medicare's obligation to pay for them. That is, the system has existing guardrails in place, and refinements and additions to those guardrails are being researched and developed in real time.

In the meantime, if CMS declines to recognize SaMD costs in the PFS, that will not just slow innovative activity but potentially divert portions of the underlying skill base to other sectors. Facilitating reasonable, sustainable, and not exorbitant reimbursement for SaMD will, over time, grow a pipeline of healthcare technology innovators who would otherwise specialize in fields other than healthcare.

A Potential Framework for When to include SaMD as Direct Inputs in the PFS

The specific FDA definition of SaMD is that the software fits within the FDA definition of a medical device but whose primary function is not record-keeping, data storage, operational flow, or lifestyle improvement, but which may include diagnostic and certain other service-specific functions. We believe the FDA SaMD definition provides an excellent starting point for CMS's consideration in when a proposed SaMD input should and should not be considered a direct input in the PFS.

Specifically, if a SaMD product being proposed as a PFS direct input fits within the FDA definition of SaMD, then we believe CMS should treat the SaMD product just as it would any other service-specific medical device. If CMS is concerned about the safety of SaMD inputs, then CMS might defer some of the risk of adverse consequences to the FDA's evaluation of clinical efficacy and safety by additionally requiring that the SaMD product has received clearance from the FDA. This potential expansion may be necessary for SaMD products that providers theoretically could request be cleared by the FDA, but because the product is not directly sold or marketed (e.g., being an input into a larger service provided by a vertically integrated provider), it lacks FDA clearance.

While we believe CMS should adopt a framework similar to the FDA's SaMD definition for when to include software direct inputs in the PFS, we also believe CMS should allow the policy to evolve as new data and realities are understood. In the PFS 2022 proposed rule, CMS solicited input into a range of structured questions designed to understand strengths, weaknesses, opportunities, and threats of SaMD with respect to payment, costs, efficacy, and risks of abuse. In some of these questions, the realities are that we will know in time, but with SaMD being such a nascent component of the current physician practices, and with so few products in active use, attempting to anticipate all possibilities is unrealistic. We will know the impacts of SaMD on physician practices in time, but currently we can only guess. And therefore, allowing the policy to evolve through reiteration of the policy in each annual rulemaking and soliciting comments on the policy – at least for the first few years as the PFS SaMD market matures – would be sensible.

How Practice Costs are Paid in the PFS

Frequently in debates over the reimbursement of individual codes, stakeholders raise the concern about "payment adequacy" for their services. Under the Social Security Act, CMS has one primary job with respect to the PFS: setting relative payment rates between services to reflect relative resources incurred. Beyond this, CMS has no power to increase the overall payment levels for a given service, and because the PFS is a budget neutral ("zero sum") payment system, doing so would benefit one particular service at the cost of all other services in the PFS .

While statutorily irrelevant under CMS's instructions from the Social Security Act, it is perfectly understandable that stakeholders would be concerned about payment adequacy for their services. Both their ability to serve their patients and to operate viable businesses depends on overall reimbursement adequacy. In response, it is also common to see stakeholders essentially scramble over each other to ensure that their service will receive the most favorable treatment, which in turn exacerbates CMS's challenges in obtaining accurate data with which to fulfill its obligation to set relative payments based on relative resources.

According to CMS's own data used to determine 2021 final rule Practice Expense (PE) Relative Value Units (RVUs), each $100.00 of (direct and indirect) practice expense costs translates to approximately $57.15 in PFS payment. While there is certainly inaccuracy in CMS's data and likely some amount of bias in those data that exaggerate this relationship, it also seems improbable that the PFS covers anywhere close to 100% of practice expenses on average. If Congress wished to equalize overall payment with overall costs (at least according to CMS's data), doing so would require increasing the practice expense portion of the PFS by around 75%, or $33.6 billion.

Indeed, at the overall practice or specialty level, it appears likely that private insurers make up for negative profitability under Medicare by paying, as estimated by the Kaiser Family Foundation, 143% of what Medicare pays for the same physician services.

Given this stark reality, CMS has little option but to simply do what it can under the law – set relative payments based on relative costs. We ask in Section 3.1, however, whether there might be a place for a broader discussion of increasing the overall PFS budget by, say, 25%, in exchange for improved data from physicians that could potentially benefit providers, Medicare beneficiaries and in the long run the Medicare Trust Fund.

What Happens when Medical Devices are Excluded from Being PFS Direct Inputs?

While the PFS pays below cost according to CMS's own data, excluding a SaMD input from being reimbursed as a direct input (instead classifying it as an indirect cost) fully excludes it from any form of reimbursement – direct or indirect. Because the SaMD products in current consideration are "technical component" services, the PFS methodology has no mechanism to account for the missing SaMD input's costs.

In Section 3.2, we analyze the PE rate effect of excluding the (SaMD) AI analysis fee recommended by the RUC from diabetic retinopathy analysis code 92229's direct inputs. In the 2021 proposed rule, this is what CMS had proposed to do, and after significant public comment arguing that it should be included, CMS has softened their language around staunchly considering the AI analysis fee to be an indirect cost. Ultimately, we conclude from our analysis that including the AI analysis fee results in reasonable payment rate relativities between 92229 and related services, and excluding it results in strikingly wrong rate relativities between 92229 and related services.

In lieu of CMS including the AI analysis fee in the 2022 proposed rule, CMS proposed to crosswalk 92229's PE RVU to a different ophthalmology code. This proxy code's PE RVU is almost exactly the midpoint between what 92229 would have received under two versions of the direct cost per service of the AI analysis fee, making the proxy rate both appropriate (as validated by the reasonableness of the relativities when the analysis fee is included), and evidently a way for CMS to maintain some distance between what they believe is the correct reimbursement level (CMS explicitly stated that they believed the proxy code correctly reflected the resources used in the service) and establishing a SaMD direct input policy before they are ready.

How Do Medical Device Costs translate into PFS Rates?

Under the PFS 2022 proposed rule methodology and data, on average one incremental $100.00 of direct supply or equipment cost translates into $88.80 in PFS payment, with this ratio varying by specialty. Under the 2021 final rule, this ratio was $115.24 per $100 of direct supply or equipment costs. As currently designed, the PFS has an unwritten, unintentional, de-facto, approximate device offset policy built into it. This artefact of the methodology may explain why the PFS is viable for many advanced medical devices despite evidently paying below cost on average. Essentially, if a code involves a high cost medical device, then on average the PFS will pay a significant portion of the cost of that medical device.

Equally, this property of the methodology underlines the importance that CMS cautiously approach any new technology such as SaMD whose economics and business models are evolving, and design guardrails around policy to cover costs of that technology to protect Medicare's program integrity.

Should SaMD Attract Indirect Allocations?

CMS mentioned that one reason for their reticence to include SaMD products as direct inputs was the potential over-allocation of indirect PE RVUs under the methodology. CMS justified this by observing that SaMD products (92229's AI analysis fee in the particular case being discussed) were different to traditional medical devices because they had a low physical footprint and did not require administrative staff to maintain them. While reasonable on the surface, this ignores that no other direct input is subject to that requirement – including direct supply inputs that are predominantly small (minimal physical footprint) and do not require any maintenance. Additionally, under the current methodology, maintenance of medical equipment items is explicitly accounted for as *direct* costs, and is not considered an indirect practice expense.

CMS's indirect allocator methodology is a standard cost accounting methodology with policy features. Indirect allocations at the specialty level are based on practice survey data – the AMA's Physician Practice Information Survey. CMS imputes the indirect allocations for individual services using cost bases, specifically, direct clinical labor, direct medical supplies and direct equipment costs, and using physician work RVUs. The service level direct cost bases are further refined by applying an estimated ratio between direct and indirect practices expenses from the PPIS data based on the specialties that bill the service. Nowhere under the current methodology does the indirect allocation consider other factors such as physical footprint or maintenance needs of devices.

Additionally, under the current methodology and data, it can be shown that 57.2% of indirect PE RVUs are driven by the physician work basis, 25.4% are driven by the direct clinical labor cost basis, 11.1% are driven by the direct medical supplies basis, and 6.3% are driven by the direct medical equipment basis. That is, medical supplies, the preponderance of which have almost no physical footprint and none of which require maintenance, explain roughly twice as much of indirect PE allocations as medical equipment.

A Potential Approach to Mitigating PFS Reimbursement Strategy Abuse Risks

CMS's caution over its treatment of SaMD in the PFS is warranted. Indeed, this is true for any new technology whose economics and market are evolving and whose implications for payment, patients and clinical practice are yet to be understood. For example, the artefact of the methodology that, on the margin, the PFS pays medical devices close to cost ($100 of direct supply or equipment costs attract $88.80 in PFS payment rate on average -- $115.24 in 2021) means that CMS should be guarded against SaMD manufacturers effectively naming their own price in the PFS. While this risk is true of any innovative technology whose market necessarily begins as a monopoly, the unfamiliar nature of SaMD does seem to warrant caution.

Simultaneously, CMS must also not harm the development of a valuable new technological modality by, effectively, refusing to pay for it at all. As discussed above and through the report, not including SaMD products as direct inputs in technical component services (who lack physician work with which to allocate indirect PE RVUs) is equivalent to entirely excluding their costs from the PFS. There is no other mechanism with which to allocate indirect costs for SaMD if SaMD is not included.

Additionally, it appears that the methodological artefact leading the PFS to pay medical devices close to cost may explain why, despite the PFS paying significantly below cost overall, advanced medical devices

are viable for PFS services. As with all other advanced medical device, CMS should allow the methodology to inadvertently allow those devices to remain viable under the PFS.

Given these trade-offs between program integrity risks and both the viability of SaMD companies and patients' access to their products, CMS might consider a middle ground between not paying SaMD and over-paying it. Specifically, CMS might consider capping the amount of SaMD direct costs that can be used to allocate indirect PE RVUs for SaMD services. Under our policy idea, direct PE RVUs would continue to be paid under the usual approach without any such cap.

In Section 5, we argue that such a cap should intentionally be set high – well over the 99th percentile of medical supply and equipment input costs per service – to establish a constraint that would not be binding for all SaMD services being considered for immediate PFS reimbursement, which would allow increased PFS reimbursement beyond the cap ("the SaMD indirect allocator direct cost cap"), albeit at a diminished marginal rate. We suggest that CMS might set such a cap might be set at 3.0 standard deviations above the geometric mean, mirroring CMS methodology for identifying statistical outliers in other payment systems. Under the 2022 proposed rule methodology and data, this would result in a cap of $102.07.

If CMS were to establish such a guardrail, we recommend that CMS should closely monitor the policy and adjust it if CMS observes SaMD direct costs cluster around the cap (suggesting SaMD manufacturers are setting their prices to go up to the cap) or if genuine SaMD products above the cap are being existentially harmed by the policy (and they can prove it).

Specifying SaMD Direct Inputs

If CMS allows SaMD products to be reimbursed in the PFS via specification as direct inputs, CMS must then specify those direct inputs. This task has a technical aspect and a strategic aspect.

For every SaMD case except locally installed computer programs that are used in at most one service at one time, the most rational approach is to cost the SaMD product as a direct supply input. For supply inputs, CMS's data collection task is simply to obtain invoices or other cost data whose invoice prices are consistent with a count of services furnished over the invoice period. This may be decentralized invoice data collected from physician practices; centralized invoice data obtained from SaMD providers; or when the SaMD provider directly bills Medicare, cost data detailed enough to isolate direct and indirect costs for the specific service in question.

Only for locally installed computer programs with an upfront payment, for which a useful life that can be estimated and for which are only used in one service at one time, does the CMS equipment amortization formula work without modification. While theoretically, CMS could modify the equipment amortization formula to accommodate a broader group of cases, this would add significant complexity to the data CMS must collect to specify the input and introduce significant additional problems in the data acquisition game. CMS should avoid any situation where it must essentially request and use volume forecasts supplied by SaMD providers.

The strategic reality of stakeholders negotiating with CMS over the specification of direct inputs is defined by an information asymmetry in which CMS needs the data (but does not have it) and providers have the data (but are not required to share them). This periodically results in impasses between CMS and providers when they are reluctant to share detailed cost data in the form CMS needs for valid and

reliable specification of direct inputs. Periodically, these impasses are resolved by CMS simply making a best-available-information guess at the direct costs per service; in other cases, CMS has deferred payment to the Medicare Administrative Carriers (MACs) for local payment determinations, which may either result in a useful outsourcing of research into a code's costs or result in MACs facing the exact same barriers CMS faced in attempting to reimburse the code.

Ultimately, these impasses between stakeholders and CMS result in delayed payment decisions and potentially inaccurate payment relativities, undermining CMS's charge under the Social Security Act to set PFS payment relativities based on cost relativities.

CMS holds significant power in this negotiation process. CMS could significantly simplify the calculus of stakeholders in the negotiation process by setting clear rules and consequences when stakeholders are not willing to share necessary and reasonable data that CMS requires to fulfil its statutory obligation. Specifically, CMS could create an explicit policy that if a provider withholds necessary and reasonable data required to specify a direct input, then the code will be reimbursed at the rate of another code (unlikely to cost more than the code of interest) in the same modality of substantially the same service until the data are shared, or if no such code exists, to set the direct input at question to have a zero price; as is current practice, CMS should continue to honor stakeholder privacy for the underlying data used to derive the publicly available direct inputs database. Such a policy would certainly vex stakeholders whose reimbursement strategists are tuned to exploit the CMS-stakeholder information asymmetry, but would also eliminate a large portion of wasted effort and inaccurate and delayed payment proposals resulting from the dynamic.

If CMS were to establish such "house rules" for stakeholders in their negotiations over direct inputs, CMS should also be reasonable. The purpose of such a policy would be to provide actions-have-consequences framework, not to be inflexible when legitimate extenuating circumstances arise. If the stakeholder is bound by legal or contractual constraints, or the data simply do not exist or the conceptual framework CMS is asking for is inconsistent with the realities within the provider, CMS should defer payments to MACs while it works with the providers to resolve the issues. Such a policy would be existentially undermined if it were applied in a cruel manner lacking nuance or exception.

CMS's General Solicitation of Input on PFS SaMD Policy

In the PFS 2022 proposed rule, CMS solicited public comments on a list of structured questions on strengths, weaknesses, threats, and opportunities with regard to SaMD (including AI) payment and coverage policy, as well as the general nature of SaMD technology. These questions spanned payment issues, cost accounting issues, ethical issues, and the technology's effect on physician practices and patient outcomes.

Central to answering questions is the rapidly evolving SaMD marketplace. Just as clinical software products have matured to become medical devices in their own right, we can expect SaMD to continue rapidly maturing and evolving in ways that would appear alien to us now. Obviously, this means that PFS SaMD policy will need to evolve as the products do, and that policy inferences drawn based on the SaMD market in 2021 will likely be noticeably different to those based on the SaMD market, say, in 2022.

Additionally, the SaMD market in physician practices is currently quite small. There are Just two AI-based technologies currently reimbursed in the PFS, and two more being under current discussion in the 2022

proposed rule. From a sample size perspective, this is not a representative sample of the universe of possibilities CMS's policy will affect over the next few years.

Nonetheless, in Section 7, we present answers to each of CMS's questions where appropriate, and highlight questions whose answers will likely be interesting but have limited usefulness for informing policy because of the nascency of SaMD in the PFS.

Implications for Other Services under Consideration

Beyond the AI-based diabetic retinopathy code 92229, around which CMS organized much of their discussion of the general topic of reimbursing SaMD in the PFS, CMS is currently grappling with three other SaMD services.

First, Trabecular bone score (TBS) dual X-ray absorptiometry (DXA) analysis codes 77X01 and 77X03. This service's PFS situation is analogous to 92229, as the RUC has recommended direct inputs and the final decision point in the reimbursement debate is whether to include its SaMD analysis fee as a direct input. As with 92229, CMS has proposed to crosswalk the service's PE RVU to another code, 71101; and as with 92229, the PE rates resulting from this crosswalk are close to what CMS would have arrived at CMS had adopted the RUC recommendations as they were proposed, i.e., inclusive of the SaMD direct input; that is, we can validate the proxy PE RVU level because it is close to what would have resulted from application of the standard methodology inclusive of the SaMD input. Finally, CMS was careful to adopt a proxy code within the same broad clinical modality – diagnostic imaging services – and which is consequently subject to the same policy characteristics as 77X01 and 77X03, namely the OPPS cap on PFS technical diagnostic imaging payment rates. When selecting proxy codes, we agree that CMS should both choose a proxy that is at least a somewhat close clinical cousin of the code being valued, with roughly the same specialty mix, and which shares the same policies applicable to the code being valued.

Second, estimation of fractional flow reserve (FFR) using advanced analysis software, codes 0501T and 0503T. Technical component code 0503T is currently paid under the OPPS at a rate of $950.50 per service; and with an estimated geometric mean cost to the hospital of $804.35 per service. In the PFS, 0501T and 0503T are carrier priced, but the prevailing payment rates are so low ($76.49 for 0501T and $38.22 for 0503T) that an estimated 740 units of 0501T were billed in the two year period 2019-2020, and fewer than 220 units of 0503T were billed in the same period. CMS noted in their discussion that they have been attempting to identify useable 0501T and 0503T cost data with which to value the services, however evidently not to the point of obtaining data CMS feels comfortable presenting in a formal direct input specification. While it is unclear what the hold-up is, there is at least enough publicly known information about the work-flow of 0501T-0503T to frame a draft set of data points and questions for the main provider – HeartFlow. While the option always exists to continue, effectively, not reimbursing the service under the PFS (in effect, applying the zero-payment rule we suggest above to short circuit impasses between providers), it would strike us as in both HeartFlow's and CMS's mutual interest to confidentially share and review data to ensure this clearly valuable service is reimbursed under the PFS. Last, we should note that the FFR service may well be one that could trigger the "SaMD indirect allocator direct cost cap" suggested above, although it is unclear to what extent. Noting that hospitals incur roughly $804.35 in cost when using HeartFlow's service, it may well be that PFS reimbursement when HeartFlow bills the service would be in this ballpark.

Third, extended external ECG monitoring and reporting, codes 93243 and 93247. These codes remain carrier priced at a prevailing MAC rate of $114.57 for the 15-day service and $103.44 for the 7-day service in Houston, Texas. In the 2022 proposed rule, CMS reiterated its standing solicitation for invoice and other cost data with which to specify the direct inputs. Of central importance in this debate is how the SaMD costs underlying their service are reflected in the codes' direct inputs specification. In MCDA's two 2020 reports on extended external ECG reimbursement in the PFS, we formed two primary recommendations around reimbursing the service, both of which resulted in substantively equivalent payment rates. First, using iRhythm's own cost data reported to the SEC, we excluded the portion of total costs that were unambiguously indirect costs from the original direct inputs specification, and simulated PE rates. Second, we developed a full direct inputs specification based on hardware and software purchased from the second dominant provider. Included in this latter specification was a locally installable software license consistent with the requirements for costing the input as equipment. Depending on the specific assumptions made about the software – which performs the whole AI function of the service – the SaMD direct input costed at between $3.95-9.95 per service. When incorporated into the broader direct inputs specification, this resulted in total PE rates that were essentially the same as using the dominant provider's – iRhythm's – cost data. That is, it appears CMS has all the data needed to appropriately value the service under the PFS when they settle on a broad policy for reimbursing SaMD services.

In addition to the code-specific policy issues around extended external ECG, relevant to the broader SaMD policy discussion is iRhythm's ongoing efforts to return their reimbursement to the levels they had become accustomed to before 2021. Specifically, after its first proposal turned out to have serious cost accounting flaws – via the inclusion of indirect costs in the direct inputs – iRhythm appears now to have turned to policy features in the Clinical Laboratory Fee Schedule (CLFS) to continue its attempts to increase its PFS reimbursement rate. As discussed in Section 8.3, all policy elements we can identify in the CLFS that could help iRhythm in the PFS rate-setting process are wholly inappropriate for transplantation over (except that the PFS already uses crosswalking when no data exist to specify a code's physician work or direct inputs, which is not applicable to extended external ECG, for which those data are known and/or available from the providers), and both CMS and the MACs should be extremely careful in entertaining any attempts to apply CLFS-specific policy (whose economics, payment characteristics, and policy characteristics are completely different to the PFS) to value any PFS services.[1]

While adjustments to the methodology are sometimes appropriate, CMS is wise to approach methodological changes with a high degree of caution and reject any below a high bar. Our own policy sketch presented in Section 5 should be met with no less. The potential ripple effects are simply too vast to do otherwise. If any stakeholder wishes for a methodological override for their particular code or group, and that methodology would be inappropriate if extended to the whole PFS (in extended external ECG's case, technical component services involving SaMD and whose *current* billing providers are primarily vertically integrated), then that methodology is inappropriate for the PFS.

For patients wishing to gain access to PFS services involving SaMD inputs, providers and manufacturers providing the services and inputs (and the societies representing them), investors supporting the SaMD

[1] Importantly, this is not to say that SaMD or AI have no place in the CLFS, nor that the CLFS does not have lessons for the PFS. We are simply concluding that none of the current payment mechanisms of the CLFS are appropriate for transplantation into the PE rate-setting methodology, except for crosswalking, which is already used under the PFS.

companies, innovators developing future SaMD products, CMS, and the Medicare Trust Fund itself, it is critical that CMS establish policy around SaMD in a way that is methodologically integrated into the PFS in a *sustainable way*. That is, as the inevitable expansion of SaMD products plays out, CMS must ensure that the policy is unlikely to create a mess for all that undermines future access to innovations for patients and the work of all of the upstream stakeholders.

Section 1. Introduction

1.1. Background and Policy Context

Over the last decade, an increasing number of companies have developed diagnostic and clinical decision-making tools based on artificial intelligence (AI) and other modern quantitative computational methods. In some cases, these tools are bundled into traditional medical devices (e.g., analytical software is built into a device and that packaged device is what FDA has approved) and in other cases, the solutions are exclusively the software product (e.g., the product is a software tool that takes data from a separate device and then produces summary data for the physician).

In response to this reality, Congress passed the 21st Century Cures Act (Cures Act) to refine the Food & Drug Administration's (FDA) definition of what software the FDA should regulate as a medical device – Software as a Medical Device (SaMD). Before and after this law and the resulting regulations, SaMD products had been approved by the FDA for marketing in the US. The Cures Act excluded four specific categories of software for eligibility for SaMD approval (presented in Section 2, and the remaining software types are specific software that will, generally, be appropriate as direct inputs into single or well contained modalities of PFS services. We believe that this is a reasonable approach, significantly improving the regulatory framework of medical software that impacts specific healthcare services and procedures.

These innovations are now beginning to permeate into the Medicare payment systems, including the Physician Fee Schedule (PFS). CMS is currently tackling the first cases to appear in the PFS, and it is clear that reimbursement policy decisions must be made so that explicit, publicly known ground rules exist for innovators of current and future technologies. The largely sub-regulatory approach currently being used has, from our experience, led to controversies and national reimbursement reversals, deferring what ought to be national payment decisions to local Medicare Administrative Contractors (MACs). CMS's current approach is a reasonable second-best option but adds to the chaotic PFS payment policy dynamics.

In lieu of clear global guidelines for how these technologies should be handled in the PFS, CMS has been facing each case individually, essentially as a payment methodology experimentation effort framed around sub-regulatory discussions and regulatory comment from providers, innovators, investors, and the public. Additionally, in the cases where CMS has deferred initial national PFS rate proposals back to the MACs, CMS has recognized that there are unresolved issues in the cost accounting of new technologies, and that the issues must be studied further. While the PFS regulatory policy process is always chaotic – there are simply too many discrete policy issues at play in the PFS rules – it strikes us that the lack of clear global guidelines around this issue (at least a working draft) is creating uncertainty that simultaneously risks both hesitancy from innovators and overpayment from Medicare.

To illustrate, in the PFS 2021 final rule, CMS discussed their decision to defer payment for the AI-based diabetic retinopathy code 92229 (which is differentiated from two predicate codes 92227 and 92228 primarily by the use of AI rather than human labor for diagnostic evaluation of the images) to the MACs, which followed their initial proposal to exclude the AI cost component of the service from being a direct

input, which in turn resulted in numerous comments arguing that the AI cost should be included as a direct cost. CMS's response to comments and final decision were as follows: [2]

> *As the PE data have aged and AI applications are emerging, we recognize that issues involving the use of AI are complex. While we agree that the costs for AI applications should be accounted for in payment, AI applications are not well accounted for in our PE methodology. In recent years, we have considered other services that use algorithms or artificial intelligence components to render key portions of a service. For example, in the CY 2018 OPPS final rule (82 FR 59284), we discussed the fractional flow reserve computed tomography (FFRCT) service. We noted that that the service, which we considered to be separate and distinct from the original coronary computed tomography angiography service is not an image processing service but rather, the diagnostic output from the FFRCT reports functional flow values that can only be obtained using FFRCT. We found FFRCT to be similar to other technologies that use algorithms, artificial intelligence, or other new forms of analysis to determine a course of treatment, where the analysis portion of the service cannot adequately be reflected under the PFS payment methodology. Accordingly, we established contractor pricing for the service and have continued to gather information from stakeholders on payment that appropriately reflects resource cost for this service under the PFS payment methodology for the codes below. Our recent reviews of the overall cost for the service and specifically for the analysis component of the service related to the analysis services listed below have shown the costs to be similar, to the costs reflected in payment under the CY 2021 OPPS final rule for CPT code 0503T (analysis of fluid dynamics and simulated maximal coronary hyperemia, generation of estimated FFR model).*
>
> *We look forward to continuing to seek out new data sources and ongoing conversations with stakeholders to help in updating the PE methodology and the underlying data to better reflect such services. In the meantime, we are finalizing payment based on contractor pricing for CPT code 92229.*
>
> *After consideration of the comments, we are finalizing the work RVUs and direct PE inputs for CPT codes 92227 and 92228 as proposed and are finalizing contractor pricing for CPT code 92229 as detailed above.*

Next, the current design of the main relevant component of the PFS for SaMD – the Practice Expense (PE) component – contains design elements that we believe should *not* be waived or worked around for *any* service reimbursed under the PFS. In fact, at the extreme, it is possible that waiving or working around these design principles may be in conflict with CMS's statutory authority. In particular, the PFS is a budget neutral system, with payments increasing due to volume growth and a price index (and occasionally statutory overrides), and restricts the reimbursement of indirect practice expense costs for services to be primarily based on the average direct/indirect cost structure of the specialties who bill the services.

From our experience, CMS periodically undergoes reimbursement negotiations with providers who argue for code specifications that would include plainly indirect costs as direct inputs, or pad direct inputs to the extent that a CPT® code's proposed specification implicitly works around PFS's budget neutrality

[2] See the p.64630 of the PFS 2021 final rule available at https://www.govinfo.gov/content/pkg/FR-2020-12-28/pdf/2020-26815.pdf.

rules, unreasonably favoring that service over alternative PFS services.[3] We understand the incentives that lead certain stakeholders to negotiate for such positions, however CMS must continue to disallow stakeholders to accomplish these negotiation goals, which would vastly undermine the integrity of the Medicare program. It strikes us that the PFS AI reimbursement debate is a high risk policy environment for these kinds of problems, with innovators potentially arguing that, for example, billing providers' sales and marketing, corporate overhead, etc. costs to be included as direct inputs in the reimbursement. CMS must proceed very carefully with such entreaties, as the inevitable increasing volume of medical technology providers could generate a reimbursement bias under the PFS that favors those providers over other specialties and service modalities. CMS should be concerned about any approach that could create a new dynamic similar to the primary care vs procedural services imbalance that it has been working to correct for well over a decade.With regard to efficacy of new technologies in the PFS, CMS has at least one major filter supplied by the American Medical Association (AMA) – the creation of CPT® codes through which those technologies will be reviewed. When creating a CPT® code, the AMA reviews the clinical characteristics of the service it represents. It is safe to assume that the AMA's CPT® Editorial Committee is generally averse to creating codes that accomplish no clinical benefit – simply because that would be unprofessional, unethical, and because doing so would risk embarrassing the AMA.

In addition to the AMA's preference for creating clinically valid CPT® codes, CMS has additional filters available to avoid reimbursing ineffective technologies in the future. Triggered by the Cures Act, the FDA and others have been engaged in a significant amount of work to design policies, frameworks and processes around evaluating the efficacy of the SaMD technologies it is responsible for. A common theme through FDA's guidance, discussion, and action plan documents is the need for evaluation of both the initial efficacy (and related issues such as algorithmic bias) in the products they review, and the treatment of medical devices that naturally evolve as more data become available upon which to calibrate the algorithms. Many of the issues being analyzed by the FDA and others overlap with the questions CMS asked around SaMD and AI in the 2022 proposed rule. As they develop and are rolled out (the FDA's and related policy frameworks – including CMS's own – are being actively developed as of the writing of this report), CMS may consider requiring that SaMD direct inputs be covered by the FDA or similar frameworks[4].

Germaine to the broad debate around valuing SaMD in the PFS is the sustainability of any policy CMS creates today as a basis for SaMD in the PFS going forward. Bad policy or policy that is so incomplete as to allow nefarious providers to abuse the PFS for their own goals – potentially with no benefit to patients – threatens the goals of every other stakeholder in the system: patients, providers, manufacturers, inventers, investors, CMS and the Trust Fund. It is relevant that jury selection in the Elizabeth Holmes fraud trail began today, the date we are publishing this report, with Sunny Balwani's severed fraud trial to follow in January 2022.[5] The damage their alleged behavior caused to the medical innovation space cannot be understated. In talking with medical device innovators, one theme is that companies such as CVS and Walgreens still ask innovators whether they are "another Theranos," reflecting a high degree of risk

[3] Note that many such attempts to maximize reimbursement are entirely ethical from the provider's perspective, with providers simply wishing to remain viable as businesses so that they may serve their patients.

[4] For example, in January 2021 the FDA published "Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan that builds up previous work internally and with stakeholders to further develop their policies. See https://www.fda.gov/media/145022/download. See also https://www.fda.gov/media/100714/download for the FDA's guidance on SaMD clinical evaluations as at late 2017.

[5] See https://www.justice.gov/usao-ndca/us-v-elizabeth-holmes-et-al.

aversion created by a single (alleged) bad actor, and certainly resulting in cases where valuable medical technologies are hobbled in the market. Now, the FDA, FTC, AMA (through the creation of CPT® codes), and CMS all – unfortunately – inherit responsibility to prevent future such fiascos before they occur. For this reason, in our report, we acknowledge and agree with CMS's cautiousness around integrating novel technologies into the PFS, and present draft guardrail policies that we hope will be useful to CMS in *safely* but *expeditiously* reimbursing SaMD in the PFS. Again, a bad policy that collapsed under abuse and controversy would be the worst possible outcome for every single stakeholder in the SaMD market.

Ultimately, how CMS approaches these issues in the short-to-medium term has implications for the future of reimbursement and incentives to innovate new technologies. If CMS sets up a clear and explicit regulatory approach (which it also makes clear will be refined over time through proposal and public comment), and it reimburses services according to its existing and well-designed cost accounting principles with any necessary modifications to safeguard against future risks, then we believe it is possible to both incentivize ongoing technical innovation and maintain Medicare's program integrity as these technologies proliferate.

1.2. CMS's Ethical Obligation to Develop Policy around Difficult Issues

This report argues that CMS should develop and publish explicit policy around this issue, presents recommendations for where CMS might start, suggests a process for evolving an inevitably-imperfect policy framework, lists some of the likely problems that will occur as CMS tackles the policy issues under this approach, and suggests guiderails that CMS might choose to mitigate harm to the PFS as those problems arise. Implicit in this framework is CMS's ethical obligation – beyond its statutory obligation – as skilled policy stewards of national payment policy to tackle these issues in the first place.

Prior to the 2022 proposed rule, CMS had been minimal and terse in listing their concerns to the point that thoughtful policy analysis was almost entirely based on guesswork around CMS's full concerns. Fortunately, in the 2022 proposed rule, CMS significantly expanded the amount of detail they provided around their concerns with valuing SaMD services under the PFS. This is an excellent development for the future of AI reimbursement in the PFS, as CMS's exposition has essentially allowed analyses of the specific concerns CMS raised in their discussion, such in this report. Nonetheless, CMS's description is still relatively brief and minimal given the complex and important issues involved, and we encourage CMS to continue describing – in as much detail as the Federal Register writing guidelines allows – its concerns and thinking around the issues.

Generally, we believe the policy situation with SaMD reimbursement amplifies the national interest in CMS aggressively, robustly, but still cautiously adjusting policy to reflect significant technological developments in the 21st century. Indeed, given that the private insurance sector frequently anchors their coverage and payment policy decisions with CMS decisions, this dynamic within CMS extrapolates itself to coverage and payment decisions in the broader US healthcare sector.

For simple public policy development and ethical reasons, we believe that CMS must continue to face these difficult cost accounting and medical technology coverage issues under the PFS well and expeditiously, but also not circumvent wise thinking about policy designs.

1.3. Structure of the report

The report is structured as follows.

Section 1 Introduces the report and presents the policy context.

Section 2 Discusses the current FDA treatment of SaMD for regulatory purposes, and its relevance for CMS's policy thinking around reimbursing SaMD direct inputs in the PFS. In particular, we present the FDA SaMD definition, discuss where it may have limitations for CMS, and sketch a possible policy CMS could adopt when considering including SaMD products as PFS direct inputs.

Section 3 Examines the topic of payment adequacy for PFS services overall, the effect of omitting true direct costs in technical services on CMS's ability to fulfill its statutory obligation to set PFS rates based on relative costs between services, the interim solution of using proxy codes in lieu of including SaMD direct inputs, and discuss an artefact of the PFS methodology that results in close to at-cost payment for individual medical devices used in PFS services.

Section 4 Discusses the question of whether SaMD inputs should attract indirect PE RVU allocations, including examining CMS's written concerns from the 2022 proposed rule about their reluctance to over-allocate indirect costs for SaMD inputs.

Section 5 Presents a potential PFS payment policy guardrail around including SaMD products as SaMD inputs. Specifically, we present and analyze a draft policy that would limit the indirect allocations SaMD direct inputs could attract, capped at a level that would not be binding for most current SaMD products but which could safeguard CMS in cases where SaMD direct input costs are extremely high.

Section 6 Discusses CMS's task of specifying SaMD direct inputs and collecting the data needed to specify them, including how different types of SaMD business model and product affect whether a SaMD direct input should be a supply or equipment item, and then the challenges with obtaining necessary data from sometimes reluctant providers concerned that they might undermine their reimbursement goals. We conclude with an observation that CMS may be able to resolve certain key problems arising in their stakeholder-CMS reimbursement negotiations with a clear policy of what CMS will do when CMS is unable to obtain the data required to specify a code's direct inputs.

Section 7 Responds to CMS's general solicitation for public input in issues around the reimbursement of SaMD.

Section 8 Presents our analyses of each of the other three SaMD cases in the 2022 proposed rule, covering trabecular bone score (TBS) dual X-ray absorptiometry (DXA) analysis codes 77X01 and 77X03; Estimation of fractional flow reserve (FFR) using advanced analysis software codes 0501T and 0503T, and extended external ECG monitoring codes 93243 and 93247.

Conclusions summarizes and concludes with afterthoughts.

Section 2. FDA Treatment of SaMD as a Policy Predicate for the PFS

Since at least 2012, the FDA has received an increasing number of 510(k), de novo and pre-market approval applications for clinical software products and medical devices with software being the most significant differentiating function of the device. In response, the 21st Century Cures Act (Cures Act), signed in 2016 and implemented in regulations in 2019, clarified the definition of which types of software should and should *not* be regulated by the FDA as medical devices. In our analysis, roughly, the new FDA definition limits to software that either substitutes for or supplements the functions of traditional medical devices or for the clinical labor or physician work that would accompany the specific medical device in a traditional PFS code specification.

In our view, this evolution of policy at the FDA is the most relevant and useful development for CMS's deliberations on when a SaMD product should or should not be included in the PFS as a direct input. Effectively, the FDA now considers much of the software relevant to PFS SaMD reimbursement to be medical devices, because SaMD has matured to the point where its functional equivalence with traditional medical devices must be acknowledged in deciding whether SaMD services may be sold and used in the United States.

In addition to FDA's logical rules about which kinds of software are medical devices, the FDA and others have been working to evolve its policies, processes, and frameworks around assessing safety and efficacy of SaMD products. Distinct to many physical medical devices, SaMD subcategories such as AI and Machine Learning (ML) services inherently evolve over time, including in how input data will translate into output results (e.g., diagnostic evaluations). This is because software products are necessarily maintained in an ongoing way, resulting in revisions to the programming logic, and because AI and ML algorithms are calibrated on databases that typically expand over time, allowing improvements in the ability of the AI/ML methods to "understand" the data.[6]

This maturation of the FDA statute and regulations around SaMD naturally sets the stage for CMS's own treatment of SaMD in the PFS. It first underlines the importance for CMS to evolve PFS policy to recognize SaMD costs. Second, the definition of what is and is not SaMD for the purpose of FDA regulation provides a potentially useful starting point that CMS could adopt for which SaMD inputs it would consider direct costs vs indirect costs.

This section presents:

1. The current FDA definition of SaMD;
2. The current SaMD definition's importance for the PFS;
3. Where the FDA SaMD Definition May Be Inadequate for the PFS;
4. The Regulatory Pipeline of Medical AI SaMD Products; and
5. A Potential First Draft for a Policy to Include SaMD a Direct Input.

[6] For a comprehensive perspectives article on the safety/efficacy and related considerations for AI, see: Abramoff MD, Cunningham B, Patel B, et al. Foundational Considerations for Artificial Intelligence. *Ophthalmology 2021 [in press]*. See https://www.aaojournal.org/article/S0161-6420(21)00643-6/fulltext.

2.1. The current FDA definition of SaMD

The current statutory definition of SaMD for FDA purposes is software that conforms to the definition of a medical device minus certain specific categories excluded by the Cures Act.[7] For convenience, we present the verbatim definitions below.

The definition of a medical device is defined in Section 201(h) of the Food, Drug, and Cosmetic Act (21 U.S.C. 360j):

> An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
>
> 1. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
> 2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
> 3. intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and
>
> which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o).

The *exclusions* of software types from the medical device definition are listed in Section 520(o) of the Food, Drug and Cosmetic Act:

> (o) REGULATION OF MEDICAL AND CERTAIN DECISIONS SUPPORT SOFTWARE.—
>
> (1) The term device, as defined in section 201(h), shall not include a software function that is intended—
>
> (A) for administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow;
>
> (B) for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

[7] Note that the SaMD definition inherits from the International Medical Device Regulators Forum (IMDRF; of which the FDA is a member) definition, however for US regulatory purposes is codified by the law and regulations presented in this Section. See http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf for the 2013 IMDRF definition.

> (C) to serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, so long as—
>
> > (i) such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals;
> >
> > (ii) such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act; and 5 Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-datasystems-medical-image-storage-devices-and-medical-image-communications-devices. Contains Nonbinding Recommendations 3
> >
> > (iii) such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;
>
> (D) for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings.

To interpret thematically, SaMD for the purposes of FDA regulations is now defined as software that fits within the functional definition of a traditional medical device, but is not for administrative or operations flow of the healthcare provider, is not software for general lifestyle purposes (such as fitness or diet trackers), and is not an Electronic Health Records (EHR) system, is not a pure data storage or viewing system, *but, if the software's function is the analysis or interpretation of clinical laboratory test or other device data, results, and findings, the software is SaMD for FDA purposes*.

The two immediate PFS services using SaMD currently paid in the PFS are diabetic retinopathy's 92229 and extended ECG's 93243 and 93247. Two additional services involving SaMD being considered in the 2022 proposed rule are 77X01 and 77X03 for trabecular bone score dual X-ray absorptiometry analysis, and 0501T for estimation of fractional flow reserve using advanced analysis software. In each case, there are unambiguously SaMD inputs involved.

Finally, we note that while this is the statutory and regulatory definition of what the FDA is responsible for regulating as SaMD, not all SaMD products in current use will necessarily have been cleared for sale by the FDA. Particularly for vertically integrated providers whose SaMD inputs are internally developed and maintained, there may be a gray area around those SaMD technologies being cleared for sale and marketing by the FDA. This is discussed further in Section 2.3.

Despite this, the FDA SaMD definition – particularly the spirit of the definition – is unquestionably a central contribution to CMS's thinking about the topic in the PFS.

2.2. The current SaMD definition's importance for the PFS

One way to interpret the current FDA SaMD definition is that it includes and limits the category to software whose function is substantially a substitute for or supplement to either expert analysis by physician or clinical labor, interpretation by a physician, or the function of a traditional physical medical device; and where the software has a complex and service-specific clinical function. In the context of the PFS, this would mean that the SaMD product represents a modern counterpart to what historically would have been reimbursed as physician work, clinical labor, or a physical medical supply or equipment item.

Under this theory, the SaMD product is *substituting* for costs that *counterfactually* would not have been considered indirect practice costs of the billing provider under CMS's long-established PFS rate setting methodology and cost accounting principles. As well as encapsulating cases where the SaMD input substitutes for other resources (in AI nomenclature, "autonomous AI"), when SaMD inputs supplement other resources ("assistive AI"), ultimately that is accomplished by contributing value that would not have been possible without other resources being added as physician work or direct inputs. That is, regardless of whether a prospective SaMD input is considered a supplement or substitute, it is adding clinical value whose value, if not performed through the SaMD input, would have incurred cost through an alternate PFS cost component.

In the case of 92229, this is particularly clear as the SaMD service is "autonomous AI" – replacing physician interpretation of the ophthalmic image, which otherwise must be costed under E&M or interpretation codes accompanying the alternatives. CMS risked causing a significant payment inaccuracy when, in the 2021 proposed rule, CMS proposed to exclude the SaMD direct input from 92229's specification, because doing so was mathematically equivalent to fully excluding those costs from both the individual service's PE RVU and from being accounted for anywhere in the billing specialties. We work through these analyses in Section 3.2.

In the case of extended ECG, MCDA has previously argued that the AI components of these services should be accounted for as direct costs under the PFS methodology. Our view of the SaMD function within extended ECG is that it is clearly SaMD under the FDA definition, being service specific and substituting for analysis (and to a lesser degree interpretation) activities that would otherwise be performed by clinical labor and physicians. Unfortunately, extended ECG's reimbursement saga has been significantly complicated by CMS's difficulty in obtaining detailed cost data for the SaMD component of the services; fortunately, this controversy serves as an excellent case study that informs what CMS might do when SaMD providers who are also the billing providers of their service are unwilling to share data *needed* by CMS to specify direct inputs. We discuss the takeaway lessons from the extended ECG reimbursement saga in Section 6.3, including our recommendation for what CMS should do when providers are unwilling to share needed data with CMS.

While the two immediate cases of SaMD costs discussed above appear to us unambiguously appropriate for inclusion as PFS direct inputs, we recognize two broader limitations in the suggested framework. First, both of these are diagnostic services that are unambiguously included in the FDA SaMD definition; it is entirely possible that other kinds of SaMD may arise in the future, such as, for example, software-driven procedures where human labor has been substituted for robotic, complex algorithmic, or AI-based functions. Second, as medical technology evolves, it sees likely that the current FDA and Cures Act definitions will also evolve. For both limitations, we believe that any regulations CMS proposes outlining its approach to this topic should explicitly be allowed to evolve over time, including annual reiteration of the

framework in the proposed and final rules similar to the broad methodological steps for calculating PE RVUs, but coupled with annual solicitation of public comment on the framework.[8]

2.3. Where the FDA SaMD Definition May Be Inadequate for the PFS

The FDA SaMD definition appears to us to be an excellent starting place for CMS developing an explicit policy for when to include and when to not include software as a direct input under the PFS. However, we also recommend that CMS maintains any such policy each year through reiteration, solicitation of comments, and consideration of refinements – at least during the infancy of such a policy. No PFS SaMD policy is likely to be perfect on first draft – including the status quo of denying PFS reimbursement for all SaMD not subordinate to a physical medical device.

CMS's concerns will be first including software that probably should not be included as a direct input, and second be excluding software that should ideally be included.

These boundary cases are potentially significant openings for abuse by some stakeholders and disenfranchisement by others, and while we have listed some example scenarios below, the "unknown unknowns" of future medical technological developments amplify the need to formally keep any policy for inclusion or exclusion of software direct inputs a live policy subject to ongoing CMS and public review and refinement.

Example of when software may be included under the strict FDA SaMD definition but likely should be excluded from being a PFS direct input:

- EHR software (including plug-ins or extensions) that perform a diagnostic analysis function over all patients. For example, one speculative market trends article highlights predictive analysis, natural language processing, and prognosis and diagnosis as new features appearing in EHR software.[9] The relevant theme with these particular features is scanning all patients in the EHR for suggestions about diagnoses, treatments, or simply more complete and accurate coding or record-keeping. The diagnostic and treatment recommendations elements of these features, in particular, fall on the boundary of "analysis and interpretation" inclusion and the "operational flow" exclusion for consideration as an FDA-applicable SaMD product.

Example of when software might be excluded under the strict FDA SaMD definition but likely should be included:

- Software integral and exclusive to a specific medical service (or limited group of codes) but which is considered by Cures/FDA to be too generic for consideration of clearance. For example, the current PFS direct equipment input EQ187 ("nutrition therapy software (Nutritionist Pro)") is a clinical-level diet tracking and analysis app. In the 2021 final rule PFS rates, EQ187 is used in a range of nutrition support counseling services, occupational therapy services, and counseling of patients with chronic kidney disease (for which obesity is a "potent risk factor"[10]). In each of these applications of Nutritionist Pro (and equivalents that fit within the generic vignette of the

[8] We recognize that providers and vendors would prefer a clear policy that will not change going forward, however the nascent nature of SaMD will certainly require CMS to allow some amount of flexibility to establish effective policy that can serve providers' and vendors' long-run objectives.
[9] https://www.matellio.com/blog/ai-for-ehr-systems/
[10] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5433675/

code) is clinically valid, the software appears to be integral and specific to the CPT® codes that include EQ187 as a direct input, but this software product appears to be explicitly excluded from FDA's regulatory authority to evaluate it as a medical device.

- Software that is the primary function of its service but which is incidental to or packaged into an FDA-cleared physical device. For example,
    - One current PFS service at debate, extended ECG, is not reflected by a CPT® code whose definition requires AI to be part of the service (if human labor were used to analyze the data, that would apply under the CPT® codes), however iRhythm and all of its significant competitors utilize AI methods as part of the analysis and reporting functions to the codes.

2.4. The Regulatory Pipeline of SaMD Products

Because the current list of FDA-cleared medical devices approximately defines the current universe of products that CMS may encounter via future requests for CMS direct inputs specifications, it is useful to understand what has been cleared.

Unfortunately, there does not appear to be any comprehensive directory of such clearances published by the FDA, and creating such a directory requires searching the FDA's online clearance database. Fortunately, Benjamens et all (2020) published a Nature Digital Medicine article presenting their group's work to collate AI clearances, and they make their living database available online.[11]

In addition to FDA clearances for SaMD products, it is worth listing SaMD products currently included as PFS direct inputs. Table 2.1 presents all equipment inputs (to our knowledge there are no SaMD supply inputs) in the 2022 proposed rule databases that explicitly identify the input as being or including software. As CMS noted in the 2022 proposed rule text, "we have considered most computer software and associated analysis and licensing fees to be indirect costs tied to costs for associated hardware that is considered to be medical equipment." That is, all of the software-plus-hardware equipment items in Table 2.1 are this case, and most software-only equipment items have accompanying hardware in conjunction with which the software is used. However, it is useful to know that PFS software direct inputs are indeed not new to CMS.

In fact, what is new is the modality of the software services. Previously, the software products included were (at least) mostly subordinate to physical equipment inputs – the software could well have been packaged into the physical hardware's purchase prices. Now, as the Cures Act and FDA's regulatory frameworks have had to recognize, software has graduated from being interfaces, operating systems and subordinate tools that support physical medical devices, to being a class of medical devices in its own right.

[11] Benjamens, S., Dhunnoo, P. & Meskó, B. The state of artificial intelligence-based FDA-approved medical devices and algorithms: an online database. npj Digit. Med. 3, 118 (2020). See https://www.nature.com/articles/s41746-020-00324-0 for the article and https://medicalfuturist.com/fda-approved-ai-based-algorithms/ for their living database.

Table 2.1 Software Equipment Inputs in the PFS 2022 Final Rule

CMS Equip-ment Code	Soft-ware Only	Description
ED009		computer and VDT and software
ED020		computer workstation, nuclear pharmacy management (hardware and soft-ware)
ED040	X	genetic counseling, pedigree, software
ED051	X	multimodality software
ED058	X	CAD Software
ED060	X	sheer wave elastography software
ED063	X	Sequence data analytics (alignment/variant calling) and reporting software
EP090	X	IkoniLan Software
EQ008		ECG signal averaging system, w-P-waves and late potentials software
EQ013	X	EEG analysis software
EQ018		EEG, digital, standard testing system (computer hardware & software)
EQ027		Farnsworth-Munsell 100-Hue color vision test w-software
EQ070		barostat system, with hardware & software
EQ075		breast biopsy imaging system, stereotactic (imager, table, software)
EQ087	X	cognitive abilities testing software (Woodcock Johnson)
EQ135		impedance recording workstation w-software
EQ187	X	nutrition therapy software (Nutritionist Pro)
EQ196		pH recording workstation w-software (Bravo)
EQ197		pH recording workstation w-software (Digitrapper)
EQ198		pacemaker follow-up system (incl software and hardware) (Paceart)
EQ212	X	pulse oxymetry recording software (prolonged monitoring)
EQ218		range of motion (spinal) device and software (Myo-Logic)
EQ222		rhinomanometer system (w-transducers and software)
EQ284	X	reader software, CASCADE (Caldwell Labs)
EQ298	X	Coronary CTA Post Process Software
EQ303	X	dermal imaging software
EQ305	X	Diabetes education data tracking software
EQ307	X	Electrophysiology, Pulmonary Vein Processing Software
EQ312		INR analysis and reporting system w-software
EQ315	X	Left Ventricular Function Software
EQ329		ZEPHR impedance / pH reflux monitoring system with data recorder, soft-ware, monitor, workstation and chart
EQ330		EEG, digital, testing system (computer hardware, software & camera)
EQ380	X	flow cytometry analytics software
ER019		densitometry unit, fan beam, DXA (w-computer hardware & software)

CMS Equip-ment Code	Soft-ware Only	Description
ER030	X	film dosimetry equipment-software (RIT)
ER055	X	radiation therapy dosimetry software (Argus QC)
ER070		portal imaging system (w-PC work station and software)
ER077		image-acquisition software and hardware (Brainwave RealTime, PA, Hard-ware)
ER081	X	Calcium Scoring Software
ER112		Software and hardware package for tumor and other distribution Quantita-tion
ES029		video system, capsule endoscopy (software, computer, monitor, printer)
ES049	X	incision programming software

2.5. A Potential First Draft for a Policy to Include SaMD a Direct Input

Here is a potential first draft for a policy for when to include SaMD direct inputs. Note that this simple policy sketch does not address concerns around indirect allocations resulting from the inclusion of SaMD direct inputs; that is discussed in Section 5.

5. If the 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.
6. 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 accord-ingly.
7. If the software direct input accompanies and is required by a specific physical 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.
8. Otherwise, include the SaMD as a direct input if both:
    a. The RUC recommends the SaMD input is integral and essential under the "typical proce-dure" 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..

Regarding the final requirement in the above policy sketch, CMS should consider whether they should apply a strict requirement of FDA clearance to consider the SaMD input to be a PFS direct input (changing point 3.b above to require FDA clearance), or whether that is excessively stringent for CMS's purposes (leaving point 3.b ostensibly as it is).

Specifically, if CMS is concerned about reimbursing ineffective or potentially harmful technologies, the FDA process provides an additional, more stringent clinical efficacy and safety guardrail than if it has not

cleared the product for sale and marketing. (Additionally, the CPT Editorial Panel evaluation of SaMD for a potential CPT® code for the SaMD service constitutes a second guardrail.) While there are certainly valid SaMD products that have not been cleared by the FDA (for example, at the extreme, any physician with the right skills could theoretically build a software algorithm that would aid their clinical activities; if the SaMD device is never marketed, the FDA typically lacks authority to regulate it, though the Federal Trade Commission (FTC) appears to be increasingly interested in reviewing SaMD safety, efficacy and equity considerations[12,13]), and while the FDA does periodically clear products with questionable efficacy (for example, the ferocious debate over the efficacy of Biogen's Alzheimer's drug, Aduhelm™), the FDA's work on evaluating SaMD products is heartening with respect to the clinical value of cleared products.

If CMS were to require FDA clearance of SaMD products before considering them as PFS direct inputs, CMS would also need to establish a process for when FDA retracts its clearances. For example, if a specific SaMD product lost its clearance, there were no alternative SaMD products with which to perform the CPT® code's service, and the CPT® code could not be performed without the SaMD input, then it may be sensible for CMS to consider retracting its coverage decisions. If, on the other hand, a CPT® code could be performed without the SaMD input, then another option is for CMS to exclude the SaMD direct input from the code's PE RVU valuation and publish a revised RVU schedule.

Next, if CMS is concerned about SaMD manufacturers generating their own volume without clinical oversight, one option would be to only cover SaMD-based CPT® codes if they are ordered by a physician without a financial relationship with the provider. While diagnostic services – particularly those relevant to SaMD policy – and other potential future SaMD cases do not appear to fit under any of the Designated Health Services (DHS) categories listed in Section 1877 of the SSA (42 USC 1395nn) (the "physician self-referral law" or "Stark Law"), the spirit of this policy idea would be to prevent ostensibly the same dynamic: A physician with a financial relationship with the SaMD provider could not refer a patient to their SaMD provider.[14]

Finally, regarding additional "filters" that CMS might consider in a SaMD direct input policy, CMS should track any work the Federal Trade Commission (FTC) performs on its treatment of non-FDA cleared SaMD products. Where the FDA has the primary responsible for problems with products the FDA clears, the FTC has the same primary responsibility for problems with products the FDA does not clear. If and when the FTC develops its own policies, frameworks and procedures around SaMD products, that may allow CMS to expand the potential universe of SaMD products it is willing to reimburse in the PFS as direct inputs[15].

[12] For example, the FTC recently published the following blog on safety, efficacy and equity of in-house AI products: https://www.ftc.gov/news-events/blogs/business-blog/2021/04/aiming-truth-fairness-equity-your-companys-use-ai.

[13] Also see: Abramoff MD, Cunningham B, Patel B, et al. Foundational Considerations for Artificial Intelligence. *Ophthalmology 2021 [in press]*, https://www.aaojournal.org/article/S0161-6420(21)00643-6/fulltext.

[14] See https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral.

[15] See https://www.ftc.gov/news-events/blogs/business-blog/2021/04/aiming-truth-fairness-equity-your-companys-use-ai.

Section 3. Payment Adequacy and Ensuring Accurate RVU Relativities

It is important that CMS ensures any policy around reimbursing software inputs preserves the *budget neutrality* constraints around valuing individual PFS services, but that CMS should also consider certain service-specific software (AI) costs to be direct costs. In Section 3, we expand on why each of these factors is important.

A recurring feature in PFS reimbursement debates between CMS and stakeholders seeking reimbursement is whether a specific code or group of services is being paid *adequately* under the PFS. In reality, however, payment adequacy is technically beyond CMS's scope because CMS only has the statutory authority to specify relative value units (RVUs) that reflect the *relative* resource intensity between services. The final translation of RVUs into national payment rates – the conversion factor – is updated via a statutory mechanism that only Congress has the authority to modify. This is important because, if we assume the data CMS uses to calculate RVUs are roughly accurate in aggregate over the whole PFS, then the PFS pays below cost. Payment adequacy arguments are therefore frequent; entirely understandable for stakeholders wishing to serve their patients and run their businesses responsibly; and technically irrelevant to CMS staff under CMS's statutory authority.

In the context of this reality, CMS generally focuses PFS reimbursement negotiations on the data that determine the RVUs: primarily physician time and intensity and the direct inputs used by the practice. Additionally, CMS periodically updates other data (and in the future, potentially methods) that govern the *indirect* practice expense RVUs allocated to individual services, though this rarely enters the debate over specific codes. This report is essentially an analysis of how CMS might adjust their treatment of direct inputs and indirect allocation in light of new technology – SaMD, including AI and other specialized software – employed in PFS services.

Setting aside the relevant but separate topic of indirect allocator methodology and data (discussed in Section 4 and Section 5), this Section 3 examines four questions relevant to the payment adequacy and RVU-setting debate:

1. How much does the PFS pay relative to estimated total service costs?
2. What happens to RVU relativities when true direct costs are prohibited from being direct inputs?
3. Is using a proxy code's PE RVUs a good substitute for specifying direct inputs?
4. What is the incremental contribution to payments as direct costs increase or decrease?

3.1. How much does the PFS pay relative to estimated costs?

According to the data and methodology used to set practice expense (PE) RVUs in the PFS, the PFS pays PE significantly below cost. In fact, using the 2021 PFS data and methodology, each $100 of direct costs translates into $57.15 in direct PE payments, and equally, each $100 of indirect costs translates into

$57.15 in indirect PE payments.[16] Under the 2022 proposed rule, in which CMS has proposed to increase the assumed costs per minute of direct clinical labor (such as nurse time) to account for two decades of wage inflation previous not accounted for, this ratio decreases to $42.85 of direct or indirect PE payments per $100 of direct or indirect cost.

Table 3.1 presents an aggregate summation of total PE RVUs, the direct and indirect portions, the resulting payments according PFS 2021 final rule data, and at the bottom the "unadjusted direct costs" implied by the CMS direct inputs database before being processed through the PE methodology. The Table 3.1 additionally presents the percent of total PE payments (or PE RVUs) that are direct and indirect, and the percent of direct PE payments (or PE RVUs) relative to the direct cost data used to calculate the PE RVUs in the first place. The key data point to observe is that the percent of unadjusted direct costs that are translated into direct PE rates are 57.15%; as noted, this is an estimate of how all practice expense costs (direct and indirect) translate into PE payments.

Table 3.1 The effect of PFS budget neutrality on rates under 2021 final rule methodology and data

	PE RVUs	PE RVU Payments (at National Rates)	% of Total Payments	% of Unadjusted Direct Costs
Total PE RVUs	1,286,195,416	$ 44,879,345,259		
Total Direct PE RVUs	335,750,155	$ 11,715,363,717	26.1%	**57.15%**
Total Indirect PE RVUs	950,445,261	$ 33,163,981,542	73.9%	
Unadjusted Direct Costs		$ 20,498,293,119		

Table 3.2 presents the same analysis under the 2022 proposed rule data and methodology, accounting for the two-decade clinical labor rate inflation update. The total (budget neutral) PE RVUs and payments according to these data are lower for two reasons. First, the 2021 proposed rule had a one-year statutory increase to the conversion factor of 3.5%, which in 2022 is reversed. Second, the volume data in the 2022 proposed rule is from 2020, which is generally lower due to the effect of the COVID-19 pandemic on healthcare utilization.

We also see in Table 3.2 that the ratio of costs to payments is lower, an artefact of CMS's revision to per-minute clinical labor rates . Essentially, because CMS had not updated the clinical labor rates for such a long time, the payment-cost ratio of 57.15% estimated in Table 3.1 was higher than it should have been.

"The state of artificial intelligence-based FDA-approved medical devices and algorithms: an online database". See https://www.nature.com/articles/s41746-020-00324-0 for the article and https://medicalfuturist.com/fda-approved-ai-based-algorithms/ for their living directory.
uch to not exceed the overall indirect bucket.

Table 3.2 The effect of PFS budget neutrality on rates under 2022 proposed rule methodology and data

	PE RVUs	PE RVU Payments (at National Rates)	% of Total Payments	% of Unadjusted Direct Costs
Total PE RVUs	1,102,807,765	$ 37,037,578,216		
Total Direct PE RVUs	291,620,291	$ 9,794,009,150	26.4%	**42.85%**
Total Indirect PE RVUs	811,187,474	$ 27,243,569,066	73.6%	
Unadjusted Direct Costs		$ 22,854,242,258		

When a stakeholder seeks PFS reimbursement for their service's costs, accurate direct cost findings will generally not cover a practice's costs one-for-one. While it is likely that over the whole system the direct costs are biased up by some amount due to information asymmetries between stakeholders and CMS in their reimbursement negotiations (to a large degree, stakeholders choose which data they show CMS, and understandably aim to maximize reimbursement), it seems unlikely that such a bias would result in PE rates being higher than the PE costs incurred by practices and providers.[17]

A natural question, then, is how much Congress would need to expand the PFS to reimburse practice expense costs, on average, fully? If we continue to assume CMS's direct costs and physician survey databases are accurate in the aggregate, Table 3.1 suggests that the PFS PE component would need to expand from $44.9 billion to around $78.5 billion (by $33.6 billion or 75%) to pay 100% of all estimated PE costs.[18] With the Medicare Trust Fund being responsible for 80% of those costs, an additional $26.9 billion would need to be drawn from the Trust Fund each year, which would then be amplified if the proportions of RVUs between work, practice expense and malpractice were held fixed.

In lieu of Congress significantly expanding the PFS's budget, a natural next question is, how *should* CMS treat efforts to attain "payment adequacy" for specific codes or groups of service? Under the budget neutrality constraint of the PFS, increasing any one code's or group of codes' RVUs comes at the cost of decreasing every other code's RVUs. Even if CMS is acutely concerned about access to care for a specific service, giving special favor to it *will* slightly restrict access to care for all other services in the PFS. Simply put, one-off exceptions to CMS's obligation to set RVUs based on relative resources incurred is bad public payment policy with implications that ultimately contradict any motive that CMS might entertain to improve access to care for the PFS's broad slate of over 7,000 valuable services.

Finally, we note the role of Congress in this. Since CMS's own data suggest there may be a system-wide payment inadequacy issue, a natural question is whether Congress should increase the annual PFS budget. MedPAC's July 2021 report concluded that Medicare beneficiaries generally do not have access to care issues under the current PFS, that the supply of clinicians is growing, and that clinician encounters

[17] We note that it is likely that there is some upward bias in the direct costs assigned to services over the PFS, as we can see that physicians and suppliers do indeed perform and bill Medicare for PFS services. However, these are the data that the providers, RUC, and CMS have collected, and represent "best available information" for evaluating the constraints and composition of the PFS PE component.

[18] Note the 2022 proposed rule version of this analysis is not appropriate because the 2020 volume data used to set 2022 rates – which were lower because of the COVID-19 pandemic – would significantly bias the estimate down.

per beneficiary is growing.[19] While this may be true, one hypothesis around the sustainability of Medicare PFS services is that they may be being cross-subsidized by private insurers, who typically pay higher than Medicare for the same services, and higher again than the same Medicaid services. Kaiser Family Foundation (KFF), for example, estimated that private physician rates are 143% of those under Medicare, which we note would significantly offset any underpayment under the PFS.[20] It is therefore still a question of whether PFS's rates actually cover costs. It is also a question of whether any such system-wide PFS underpayment may be complicating the CMS-provider rate-setting dynamic as providers scramble to maximize their rates as aggressively as possible to mitigate such underpayment; and whether the broad PFS program would be better served by increasing the conversion factor by a significant amount.

Noting that arguably the most significant problem with the PFS is obtaining accurate cost data – for specifying direct inputs, allocating indirect practice expense costs, and even designing improvements to the PFS methodology – the idea of increasing the annual PFS budget raises an interesting question. Would physicians, specialty societies, Medicare beneficiaries, the Medicare program's integrity, and even the Medicare Trust Fund's long-term viability all benefit if the PFS budget were increased meaningfully in exchange for CMS being allowed to establish an ongoing, limited, mandatory (tied to Medicare enrollment), and auditable survey program to collect physician practice expense data from practices? Would the improvement in accuracy of the PFS rates and the decreased pressure on stakeholders to attain upwardly biased physician work and direct inputs specifications be worth, for example, a 25% increase in the PFS budget? We do not know the answer to this, however it is an interesting question.

3.2. What happens to PE RVU relativities when true direct costs are prohibited from being direct inputs?

A key question in the debate over service-specific SaMD costs is whether to include them as direct inputs or consider them to be indirect costs (which for technical services, effectively, fully omits the SaMD costs from being recognized anywhere within the PFS).

The AMA created CPT® code 92229 to be similar to the "remote reading" codes 92227 and 92228, with 92229 being primarily differentiated from 92227 and 92228 because it is not remote, its place of service is the physician office rather than remote, it is designed for use in the primary care setting, the diagnostic evaluation and reporting is performed by an AI system rather than using human labor, and because it is a diagnostic evaluation for a specific disease, diabetic retinopathy. [21] In contrast, the two codes 92227 and 92228 are telemedicine codes in which the image is acquired at the physician office (the "acquiring site") and then the diagnostic evaluation is performed remotely by human experts (the "reading site").[22]

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[19] See p.96 of http://www.medpac.gov/docs/default-source/default-document-library/mar21_medpac_report_to_the_congress_secv2.pdf.

[20] See https://www.kff.org/medicare/issue-brief/how-much-more-than-medicare-do-private-insurers-pay-a-review-of-the-literature/#:~:text=The%20difference%20between%20private%20and%20Medicare%20rates%20was,118%25%20to%20179%25%20of%20Medicare%20rates%20across%20studies.

[21] CPT® codes 92227 and 92228 were created in 2011.

[22] Note also that 92227 and 92228 are relatively low volume codes, with an estimated 3,600 services for 92227 and 1,000 services for 92228 (professional/technical component) in 2020, based on the 5% carrier SAF. Note that the

The key factor at debate around 92229 is the "analysis fee" to reflect the charge paid by the physician practice to the AI provider for each service. The RUC had recommended inclusion of a $25 direct supply cost to reimburse the AI service, which CMS's initial 2021 PFS proposed rule disagreed with, arguing that the AI cost was an indirect costs; in the 2021 final rule, CMS then deferred payment to the MACs following significant public comment disagreeing with the initial proposal. [23] Note also that the two main diabetic retinopathy AI vendors whose customers will bill 92229, Digital Diagnostics and Eyenuk, both argued in their comment letters to the proposed rule that primary care physicians actually pay them $34 for the diagnostic evaluation by AI, and supplied customer invoices to support that claim; they pointed out that the RUC's recommended $25.00 was based on a $9.00 "early adopter discount" offered to physicians for "shared data and supported ongoing research. [24]

Table 3.3 presents the direct inputs assumed in 92227 and 92228, 92229's initial proposal[25], and 92229 if the $25 direct supply cost were included, and if the AI supply input were instead costed at $34 per service. PE RVUs and rates for 92229 are simulated based on MCDA's replication of the PFS 2022 proposed rule PE rate-setting methodology. Immediately, we see that 92229 has similar direct inputs to both 92227 and 92228 except for the AI supply input.

utilization data for 92227 and 92228 used for rate-setting purposes appear to have been somehow synthesized as the CMS PFS utilization file contains fractional counts of discrete services, and counts differ significantly from the 2020 claims data (a "count" of 1,790.75 services for 92227 before applying payment adjustors, and a "count" of 698.25 services for 92228 including global and professional components only to avoid double-counting).

[23] In the 2022 proposed rule, CMS has again changed its approach, proposing to directly crosswalk 92229's PE RVU to 92325's PE RVU. Section 3.3 analyzes this new approach in detail.

[24] See https://www.regulations.gov/comment/CMS-2020-0088-15916 and https://www.regulations.gov/comment/CMS-2020-0088-14473.

[25] Note the PFS 2021 final rule direct inputs for 92227 and 92228 were the same as in the 2021 proposed rule.

Table 3.3 Actual and simulated direct costs, PE RVUs, and PE rates for 92227, 92228 (technical component) and 92229

	92227 Remote imaging for detection of retinal disease with analysis & reporting (technical)	92228 Imaging of retina for detection or monitoring of disease; with remote clinical staff review and report, unilateral or bilateral (technical)	92229 Imaging of retina for detection or monitoring of disease; with remote physician or other qualified health care professional interpretation and report, unilateral or bilateral (technical)		
	Published	Published	Initial CMS proposal - 9225X	Adding $25 AI fee	Adding $34 AI fee
Direct Costs:					
Clinical Labor:					
Minutes of RN/LPN/MTA (@ $0.59/minute)	16	17	18	18	18
Minutes of COMT/COT/RN/CST (@ $0.57/minute)	9	1	-	-	-
Total minutes	25	18	18	18	18
Direct clinical labor cost:	$ 14.57	$ 10.60	$ 10.62	$10.62	$10.62
Medical Supplies:					
AI Analysis Fee	$ -	$ -	$ -	$25.00	$34.00
Total direct medical supplies cost:	$ -	$ -	$ -	$25.00	$34.00
Medical Equipment:					
Minutes of Camera, retinal, for remote imaging (@ ~$0.056/min)	14	14	13	13	13
Minutes of Table, motorized (@ ~$0.002/min)	14	14	13	13	13
Exam lane (opth) (@ ~$0.138/min)	-	-	-	-	-
Direct medical equipment cost:	$ 0.81	$ 0.81	$ 0.76	$ 0.76	$ 0.76
Total direct inputs cost (before budget neutrality scalar is applied):					
Total direct costs	$ 15.38	$ 11.41	$ 11.38	$36.38	$45.38
PE RVUs and Rates					
2022 proposed rule (simulated for 92229):					
PE RVU	0.53	0.43	0.41	1.17	1.44
PE Rate	$ 17.80	$ 14.44	$ 13.89	$39.24	$48.37

Clinical labor for 92229 is slightly higher than 92227 and 92228. Except for the AI supply input in question, none of the codes uses any supply inputs. For equipment, all three use the same equipment inputs – a fundus camera and a motorized table. This means that the question is about the AI fee represented by a direct supply input.

The total direct costs estimated for 92227, 92228 and 92229 (without the AI fee) are $15.38, $11.41, and $11.38, respectively. Simulating the rates using the 2022 proposed rule methodology and data, these result in PE rates of $17.80 for 92227, $14.44 for 92228's technical component, and $13.89 for 92229. That is, under the methodology, excluding the AI analysis fee from the PE rate-setting calculation results in PE RVUs lower than both 92227 and 92228, despite all other direct costs being roughly the same except for an additional $25-34 being incurred by the physician practice each time they perform the service.

Simply, the relativities between 92229's PE RVU and 92227 and 92228's are wrong if 92229's AI fee is excluded.

It is then interesting to examine what happens to the PE RVUs and PE rates when the AI analysis fee is included in 92229's specification. Without the AI analysis fee, 92229's PE RVU is 0.41 and its rate is $13.89. If the AI analysis fee is added at $25 per service, the PE RVU increases to 1.17 and the PE rate to $39.24 (a $25.35 increase). If the AI analysis fee is added at $34 per service, the PE RVU increases to 1.44 and the rate to $48.37 (a $32.54 increase beyond it being excluded). Note that the payment increases more than the total cost of the AI analysis fee simply because of the indirect cost allocation methodology under the PFS, which allocates those specialties' indirect costs to individual services such that their portfolios of billed services cover their indirect costs (subject to the PFS budget neutrality constraints).

Ultimately, the *direct practice expense* costs incurred each time the physician performs 92227 and 92228 are lower than when the physician performs 92229. In the 2021 final rule, CMS responded to public comments arguing that the AI fee should be included as a direct input, writing, "As the PE data have aged and AI applications are emerging, we recognize that issues involving the use of AI are complex. While we agree that the costs for AI applications should be accounted for in payment, AI applications are not well accounted for in our PE methodology"[26]

In order to account for the costs of 92229's AI application, it appears the most valid and least inaccurate approach is to simply include 92229's AI fee as a direct input.

A second best approach if CMS wishes to proceed cautiously with reimbursing SaMD under the PFS is exactly what CMS has proposed in the PFS 2022 proposed rule – crosswalk the SaMD code's PE RVU to one with a similar PE RVU to what would result from simply including the SaMD direct input. This is reviewed in Section 3.3.

3.3. Is using a proxy code's PE RVUs a good substitute for specifying direct inputs?

In the PFS 2022 proposed rule, CMS has solicited comment on potentially crosswalking PE RVUs for services involving AI to other services whose rates they believe are valid and reasonable proxies for the AI service. 92229 is again the code with the most detailed exposition, and serves as a natural theoretical experiment about the effect of omitting what appear to be actual direct costs from inclusion as direct inputs in a code's valuation.

The RUC recommended that CMS include a $25 per service direct supply cost to reimburse the AI service; in the 2021 proposed rule, CMS then omitted the AI fee, arguing that it was an indirect cost. In their comment letters, two of the main manufacturers that provide the AI service, Digital Diagnostics and Eyenuk, argued that not only should the AI fee be included as a direct input, and additionally pointed out that the RUC's $25 recommendation was based on the $34 minus a discount offered to practices working with the manufacturers on data sharing and ongoing research (and therefore the supply input should be priced at $34 rather than $25). CMS then deferred 2021 payment to MACs.

In the 2022 proposed rule, CMS has proposed to crosswalk the PE RVU for 92229 to a different service, 92325 (modification of contact lens), which CMS justified as follows: "*We believe that crosswalking the*

[26] See p.84630 of https://www.govinfo.gov/content/pkg/FR-2020-12-28/pdf/2020-26815.pdf.

RVUs for CPT code 92229 to a code with similar resource costs allows CMS to recognize that practitioners are incurring resource costs for the purchase and ongoing use of the software employed in 92229, which would not typically be considered direct PE under our current methodology." CMS's full proposal to cross-walk 92229 to 92325's PE RVU is as follows:

> *Specifically, we are proposing a crosswalk to CPT code 92325 (Modification of contact lens (separate procedure), with medical supervision of adaptation), a PE-only code used for the eye, as we believe it reflects overall resource costs for CPT code 92229 in the physician office setting. We recognize that the services described by CPT code 92325 are not the same as the services in CPT code 92229; however, we believe that the total resource costs would be similar across these two codes. We believe that crosswalking the RVUs for CPT code 92229 to a code with similar resource costs allows CMS to recognize that practitioners are incurring resource costs for the purchase and ongoing use of the software employed in CPT code 92229, which would not typically be considered direct PE under our current methodology. We are also soliciting comments on our proposal to crosswalk CPT code 92229 to CPT code 92325, and whether other codes would provide a more appropriate crosswalk in terms of resource costs.*

This summary justification follows a lengthy discussion of why CMS believes they should not account for the AI fee as a direct cost:

> *Consistent with our PE methodology and as we have stated in past PFS rulemaking (83 FR 59557), we have considered most computer software and associated analysis and licensing fees to be indirect costs tied to costs for associated hardware that is considered to be medical equipment. In the case of CPT code 92229, the hardware is a retinal camera used for remote imaging. Given that indirect costs are based on physician work, direct costs, and specialty specific indirect percentages that can include high-cost equipment, our concern is that if we were to consider an analysis fee to be a supply cost, as was recommended by the RUC, it is possible that we would inadvertently allocate too many indirect costs for a supply item that may not require additional indirect expenses. Unlike a piece of equipment, such as the retinal camera, an analysis fee for software does not require physical space in an office or administrative staff hours to maintain it.*

That is, CMS is arguing that the analysis fee should not be included as a direct cost because they believe that doing so will over-allocate indirect costs to the service. However, this argument has at least two critical flaws.

First, nothing about the indirect allocator methodology – essentially a standard ratio-based overhead cost accounting methodology with policy modifications – requires that a direct input has a significant physical footprint or incurs maintenance for the indirect allocations to make sense. Indeed, if that were true, most supply inputs should probably be excluded from use in the indirect allocator methodology (which would also not make sense).

Second, even if one believes CMS's argument about over-allocating indirect PE RVUs for this code (which we believe is incorrect), CMS's workaround by using the 92325 proxy does nothing to accomplish that. Table 3.4 presents the actual direct costs, PE RVUs and PE rates for 92227 and 92228 (technical component); simulations of 92229 based on the 2021 proposed rule direct inputs and then adding a $25 or $34 AI fee, and if 92325's direct inputs were used; and the actual 92325 direct inputs, RVUs and rates.

Table 3.4 Actual and simulated direct costs, PE RVUs, and PE rates for 92229 and 92325

	92229 (initial CMS proposal - 9225X)	92229 (adding $25 AI fee)	92229 (adding $34 AI fee)	92325
	Imaging of retina for detection or monitoring of disease; point-of-care automated analysis and report			Modification of contact lens
Direct Costs:				
Clinical Labor:				
Minutes of RN/LPN/MTA (@ $0.59/minute)	18	18	18	-
Minutes of COMT/COT/RN/CST (@ $0.57/minute)	-	-	-	37
Total minutes	18	18	18	37
Direct clinical labor cost:	$ 10.62	$ 10.62	$ 10.62	$ 21.09
Medical Supplies:				
AI Fee	$ -	$ 25.00	$ 34.00	n/a
Total direct medical supplies cost:	$ -	$ 25.00	$ 34.00	$ 14.72
Medical Equipment:				
Minutes of Camera, retinal, for remote imaging	13	13	13	n/a
Minutes of Table, motorized	13	13	13	n/a
Direct medical equipment cost:	$ 0.76	$ 0.76	$ 0.76	$ 5.56
Total direct inputs cost (before budget neutrality scalar is applied):				
Total direct costs	$ 11.38	$ 36.38	$ 45.38	$ 41.37
PE RVUs and Rates				
2022 proposed rule (simulated for 92229):				
PE RVU	0.41	1.17	1.44	1.32
PE Rate (at proposed 2022 CF of $33.5848)	$ 13.89	$ 39.24	$ 48.37	$ 44.33

Using the 2022 proposed rule data and methodology, we simulate 92229's PE rate as it was originally specified in the 2021 proposed rule would be $13.89 – which would be lower than the much lower-direct-cost codes 92227 and 92228(TC). If the AI fee were added at $25, we simulated the PE rate would be $39.24, and if the AI fee were instead $34, the PE rate would be $48.37. By adopting 92325's PE RVU as a proxy, CMS has proposed a PE rate for 92229 of $44.33, almost exactly halfway between what 92229 would have been paid had CMS simply used the $25 or $34 AI fee. Ultimately, CMS's proposal appears to result in a perfectly appropriate PE RVU for 92229, and indeed CMS asserted that "*we believe it reflects overall resource costs for CPT code 92229 in the physician office setting.*" We agree with CMS's statement because CMS's proxy agrees with PE RVUs that would have resulted from including the AI fee as a direct input.

Ultimately, CMS's proposal numerically accomplishes exactly what would have resulted from specifying 92229 in the normal way and inclusive of the AI fee direct supply input, and roughly aligns with what

physicians pay to use the SaMD service. The main consequence of using the proxy code is to distance CMS from setting a policy predicate while CMS analyzes options for developing guardrails in the PE methodology around over-allocating indirect PE RVUs for SaMD inputs. We also encourage CMS to prefer proxies that are roughly within the same clinical modality (e.g., use an ophthalmology proxy for an ophthalmology code), and which are subject to the appropriate policies (e.g., choose an imaging proxy for an imaging code subject to the OPPS cap)[27].

In Section 5, we explore one possible policy guardrail CMS could employ around over-allocating indirect PE RVUs for SaMD inputs if and when CMS includes SaMD direct inputs.

3.4. What is the marginal effect of direct supply and equipment costs on total PE rates?

As currently designed, the PFS has an unwritten, unintentional, de-facto, approximate device offset policy built into it[28]. While overall, the PFS pays overall practice expenses below cost (at least according to CMS's own data), the *effect* of the PE rate-setting calculation is that an incremental $100.00 of direct supply or equipment costs translates on average into $88.80 of PFS reimbursement under the 2022 proposed rule, varying by the specialties billing the specific service. (Note that this is a significant decrease from 2021 and prior, where in 2021 the translation rate was $115.24.) This artefact of the PE cost accounting methodology may explain why many technical physician services are viable despite the overall system apparently paying significantly below cost.

Under the PFS 2022 proposed rule's data and methodology, we can present this pattern for each of the specialties reimbursed under the PFS. Table 3.5 presents how $100 of incremental direct supply or equipment costs translates into increases in PE rates for each specialty recognized in the PFS.[29]

[27] The OPPS cap on imaging services limiting PFS payment for the technical component to be no greater than the same rate under the OPPS.
[28] A device offset policy allows approximate pass-through payment of costs of certain devices.
[29] Note that for individual CPT® codes the incremental effect will be approximately the volume-weighted average incremental effects of the specialties that bill the code. Note as well that these effects are specific to each PFS rule's data and methodology.

Table 3.5 Incremental PE Rate Effects of Increasing Direct Supply and Equipment Costs

	Specialty	PE Rate Increment		Specialty	PE Rate Increment
00	All Physicians	$ 88.80	41	Optometry	$ 89.76
01	General practice	$ 66.95	42	Certified nurse midwife	$ 81.14
02	General surgery	$ 118.03	44	Infectious disease	$ 121.62
03	Allergy/immunology	$ 78.09	46	Endocrinology	$ 87.54
04	Otolaryngology	$ 100.89	47	Independent Diagnostic Testing Facility (IDTF)	$ 55.47
05	Anesthesiology	$ 78.42	48	Podiatry	$ 85.54
06	Cardiology	$ 70.44	62	Psychologist	$ 157.95
07	Dermatology	$ 99.94	63	Portable X-ray supplier	$ 63.93
08	Family practice	$ 98.43	64	Audiologist	$ 177.28
09	Interventional Pain Management (IPM)	$ 92.80	65	Physical therapist	$ 107.01
10	Gastroenterology	$ 101.21	66	Rheumatology	$ 75.02
11	Internal medicine	$ 102.53	67	Occupational therapist	$ 113.54
12	Osteopathic manipulative therapy	$ 171.90	68	Clinical psychologist	$ 117.26
13	Neurology	$ 182.66	69	Clinical laboratory	$ 47.72
14	Neurosurgery	$ 182.59	70	Multispecialty clinic or group practice	$ 92.04
15	Speech Language Pathology	$ 168.55	71	Registered Dietician/Nutrition Professional	$ 135.39
16	Obstetrics/gynecology	$ 74.99	72	Pain management	$ 85.48
17	Hospice & Palative Care	$ 116.60	76	Peripheral vascular disease	$ 60.08
18	Ophthalmology	$ 104.00	77	Vascular surgery	$ 62.80
19	Oral surgery (dentists only)	$ 76.47	78	Cardiac surgery	$ 101.86
20	Orthopedic surgery	$ 131.51	79	Addiction medicine	$ 145.00
21	Cardiac Electrophysiology	$ 78.62	80	Licensed clinical social worker	$ 220.27
22	Pathology	$ 101.76	81	Critical care (intensivists)	$ 97.78
23	Sports Medicine	$ 88.37	82	Hematology	$ 89.04
24	Plastic and reconstructive surgery	$ 112.43	83	Hematology/oncology	$ 81.94
25	Physical medicine and rehabilitation	$ 163.90	84	Preventive medicine	$ 91.12
26	Psychiatry	$ 154.88	85	Maxillofacial surgery	$ 110.71
27	Geriatric Psychiatry	$ 154.04	86	Neuropsychiatry	$ 139.56
28	Colorectal surgery	$ 108.16	90	Medical oncology	$ 82.70
29	Pulmonary disease	$ 77.73	91	Surgical oncology	$ 91.25
30	Diagnostic radiology	$ 81.42	92	Radiation oncology	$ 72.00
31	Intensive Cardiac Rehab	$ 119.82	93	Emergency medicine	$ 158.16
33	Thoracic surgery	$ 103.76	94	Interventional radiology	$ 76.23
34	Urology	$ 82.10	98	Gynecologist/oncologist	$ 83.72
35	Chiropractic	$ 140.81	99	Unknown physician specialty	$ 88.80
36	Nuclear medicine	$ 67.51	C0	Sleep Medicine	$ 79.13
37	Pediatric medicine	$ 76.83	C6	Hospitalist	$ 240.54
38	Geriatric medicine	$ 79.49	C7	Advanced Heart Failure and Transplant Cardiology	$ 84.57
39	Nephrology	$ 101.80	C8	Medical Toxicology	$ 162.99
40	Hand surgery	$ 121.85	C9	Hematopoietic Cell Transplantation and Cellular Therapy	$ 101.35

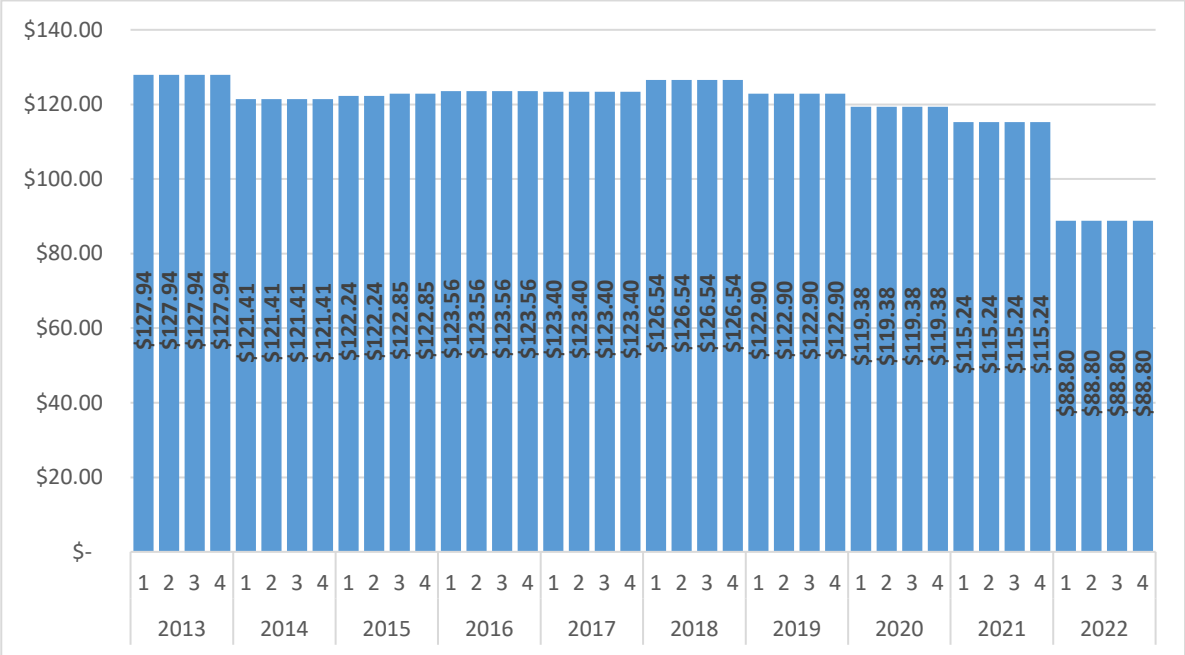
To illustrate, consider the specialty of cardiology (CMS specialty code 06). If a service exclusively billed by cardiologists is specified with $100 of direct supply and equipment costs, then that $100 causes $70.44 in total PE rates under the 2022 proposed PFS. Similarly, if a service is billed by a 50-50 mix of cardiology

and radiology (30), then the incremental PE rate effect of $100 of direct supply and equipment costs is approximately ($70.44 + $81.42)/2 = $75.93.[30]

As direct practice expenses become more dominant in a specialty, this translation ratio decreases. For a specialty with high direct practice expenses such as independent diagnostic testing facilities (IDTFs), the translation rate is $55.47 of PE rate per $100.00 in direct costs. Conversely, for a specialty dominated by indirect practice expenses such as licensed clinical social workers, the translation rate is $220.27 in PE rate per $100.00 of direct supply or equipment costs.

Next, it important to point out that this ratio decreased significantly under the 2022 proposed rule due to the proposed clinical labor rate update. Figure 3.1 presents the overall (all specialties) ratio between direct supply and equipment costs and PFS for 2013-2022 proposed. As mentioned above, the ratio decreased from $115.24 under the 2021 final rule to $88.80 under the 2022 proposed rule, a 23% decrease.[31]

Figure 3.1 Marginal PFS rate effect of direct supply and equipment costs over time



Over the whole PFS, this dynamic is a reality that affects the economics of physicians and vendors, and most importantly for this report, affects the viability of new technologies being reimbursed under the PFS. Without this accidental property of the PE methodology, it appears likely that the PFS would not be viable for most advanced medical devices. Further, in the context of SaMD, it appears treatment of this

[30] Strictly speaking, under the methodology, this relationship is non-linear and this averaging example is a first-order approximation of the true dynamic.

[31] While beyond the scope of this report, the sharp decrease in the marginal PFS payment effect of direct supply and equipment costs due to the clinical labor rate update is of significant policy concern, as it erodes an important accidental dynamic that may explain the viability of medical devices under the PFS. Ultimately, the effect of the clinical labor rate update on medical devices for which charges are not significantly higher than the cost of providing those services may be to make them inviable for specialties for which the "translation ratio" is not high enough for physician practices to cover their costs.

property must be carefully considered in light of the public priority to support new approaches to healthcare such as AI.

Equally, CMS must be diligent to set guardrails in light of this property, as innovative technologies naturally begin with monopolies (the innovator), which naturally lead to situations where CMS may be unable to obtain competitive-market pricing data to specify direct inputs. Under the PE rate-setting negotiation dynamic between stakeholders and CMS, this in turn leads to an environment where CMS must be guarded against vendors setting their own prices that the Medicare program becomes obligated to reimburse.

In Section 4 and Section 5, we discuss the characteristics of the PE indirect allocator with respect to SaMD services.

Section 4. Under the PE methodology, should direct software inputs attract indirect PE RVU allocations?

In the 2022 proposed rule, CMS expressed concern that including software direct inputs for 92229 (and other services involving software) might over-allocate indirect PE RVUs to those services. In the 2022 proposed rule, CMS briefly presented the most detailed explanation to date on why CMS is reluctant to classify AI and other SaMD costs as direct costs. In Section 3.4, we analyzed a key property of the PE methodology that might explain CMS's reticence to classify AI inputs as direct costs: on average, incremental direct supply and equipment costs are paid close to cost. While this property of the methodology is just as true for traditional (physical) supplies and equipment as it is for SaMD inputs, we believe CMS is wise to be cautious in forming PFS payment policy around AI (or any other new) technology.

While CMS's 2022 proposed rule exposition is a major expansion of CMS's publicly known reasoning around this important issue[32], CMS's description is minimal; contains some unclear statements that are somewhat perplexing in the context of the PFS methodology and data; and make a critical assertion around indirect costs that does not seem to be supported by any facts and which, if accepted, would seem to suggest that most direct supply inputs should be omitted from the indirect allocator calculation.

This Section analyzes CMS's presented reasoning, and analyzes the various issues around whether direct software inputs should attract indirect PE RVUs under the methodology. The Section is organized as follows:

1. CMS's described concerns about over-allocating indirect PE RVUs if direct software inputs are included
2. The mechanics of the PE indirect allocation methodology
3. How the cost bases determine PFS indirect PE RVU allocations under the 2022 proposed rule PFS

4.1. CMS's described concerns about over-allocating indirect PE RVUs if direct software inputs are included

CMS's explanation around its concerns about over-allocating indirect PE RVUs if software costs are included as direct inputs appears in one paragraph on pp.39123-39124 of the 2022 proposed rule.

CMS began:

> *Consistent with our PE methodology and as we have stated in past PFS rulemaking (83 FR 59557), we have considered most computer software and associated analysis and licensing fees to be indirect costs tied to costs for associated hardware that is considered to be medical equipment. In the case of CPT code 92229, the hardware is a retinal camera used for remote imaging.*

CMS then continued, explaining their reluctance about including software direct inputs because of potential over-allocation of indirect PE RVUs:

[32] Previously, CMS had tersely asserted that they believe AI costs are indirect costs, that they agree such costs should be accounted for (somehow), and that they looked forward to public and stakeholder input in the topic.

> *Given that indirect costs are based on physician work, direct costs, and specialty-specific indirect percentages that can include high-cost equipment, our concern is that if we were to consider an analysis fee to be a supply cost, as was recommended by the RUC, it is possible that we would inadvertently allocate too many indirect costs for a supply item that may not require additional indirect expenses. Unlike a piece of equipment, such as the retinal camera, an analysis fee for software does not require physical space in an office or administrative staff hours to maintain it.*

CMS's argument appears to be that 92229's AI service (represented by the AI fee, and as a metaphor for future SaMD service costs) incurs either no indirect practice expenses or very little. CMS appears to suggest that unless a prospective input incurs a significant physical footprint or administrative hours to maintain the input, then it does not incur a significant indirect cost. There are several significant problems with this logic:

- First, service-specific indirect allocation in the PFS does *not* use the physical footprint or maintenance demands of direct inputs as its cost accounting basis – the indirect allocator uses physician work and direct costs incurred by the service as its cost accounting basis.
    - For example, most direct medical supply inputs in the PFS appear to incur almost no physical footprint, and by this logic should probably be omitted from the indirect allocator formula.[33]
- Second, medical equipment maintenance costs are *not* considered indirect costs under the current PE methodology. Medical equipment maintenance is explicitly costed in the direct medical equipment amortization formula by adding 5% of the purchase price each year to each medical equipment item's *annual* direct cost.
- Third, just because 92229's AI *service* is represented by a *fee*, that does not imply there are no indirect practice costs incurred by using the service. We note that these indirect costs may be low, but appear equally likely to be similar in magnitude to most other medical supplies. For example:
    - The AI service must be performed via a client computer program installed on a computer workstation that is not accounted for in 92229's original direct input specification.
    - The AI service must be subscribed to by the physician or other personnel at the practice, incurring a small administrative procurement cost.
    - New users of the service must learn how to use the service, including undergoing a formal training. Given that the service produces input into clinical decision making, understanding its function and limits is an important user skill.
    - As the service evolves or users turn over, ongoing onboarding and training are incurred.
    - It is also possible 92229's written documentation may be stored somewhere on the practice, potentially incurring a similar physical footprint to most medical supplies currently included as direct inputs and therefore being used as part of the indirect allocator formula.

Finally, with respect to CMS's argument about the low physical footprint of the AI fee, it is worth examining 92229's AI fee supply input relative to similarly priced supply inputs. Recall that the AI fee was originally recommended by the RUC at $25 per service, and then Digital Diagnostics and Eyenuk argued

[33] To be clear, we do not believe CMS should omit direct supply costs from the indirect allocator basis either, however doing so would be a natural extension of CMS's logic.

in their public comments to the 2021 proposed rule that it should instead be $34. The nearest supply items to these direct cost levels (excluding kits) are as follows:

- The nearest supply input to the RUC's $25 is SC070 (catheter, hyperthermia, closed-end), priced at $25.00.
- The nearest supply input to the providers' $34 is SD252 (guidewire, Amplatz wire, 260cm) at $34.91.

Neither of these supply inputs is large in size, and as with all supply inputs, they do not incur maintenance.

Ultimately, as we have analyzed CMS's logic in their brief, key paragraph – key to the debate over the future of AI policy in the PFS – we have identified several critical flaws in the presented logic. While CMS's written rationale for avoiding indirect allocations for SaMD inputs does not hold up to any examination, we believe that CMS's inclination to be broadly cautious around PFS SaMD payment policy is appropriate for other reasons.

Specifically, because marginal increases in direct supply and equipment input costs translate close to at-cost reimbursement, CMS should be cautious when integrating new technologies into the PFS, to guard against innovators essentially naming their own price.[34,35]

4.2. Overview of the mechanics of the PE indirect allocation methodology

CMS's indirect allocator methodology is a standard cost accounting method modified for policy constraints. As with many cost accounting methods, overhead (defined as costs not attributed or attributable to individual services or products) is first measured in total and second allocated between individual services or products using some basis.

At a high level in the PFS, CMS first decides the total indirect PE RVUs to allocate to each specialty; second calculates a service-specific indirect PE allocation based on direct costs, physician work RVUs, and a ratio of direct-to-indirect practice expenses; and third adjusts the service-level indirect allocators to be consistent with the specialty-level indirect PE RVU allocations.[36]

At the specialty level, each specialty is first assigned a total allocation of indirect PE RVUs. This indirect allocation is based on the amount of physician time incurred by the services performed by each specialty (physician time for each services times volume of services), and then multiplied by an estimate of indirect practice expense dollars per hour from the AMA's Physician Practice Information Survey (PPIS).

[34] Once the market for a new innovation settles, with more vendors providing the service and more physicians familiarizing themselves with the service, it appears likely that the natural competitive forces would inhibit input prices from being inflated freely. However, before the market for a new innovation matures, it is unclear whether such dynamics will result in competitive prices *if CMS includes the new innovation as a direct input without limiting the amount of indirect PE dollars resulting from the direct input's cost*. That is, CMS may inadvertently prevent prices from reflecting any competitive market dynamics if they reimburse the direct input without any guardrails before those dynamics have a chance to play out.

[35] It is worth noting that this dynamic is also relevant for however CMS treats MCIT in the PFS. Most technologies that could be covered by MCIT will operate in monopolistic or highly concentrated markets for the 4-year duration of their MCIT coverage.

[36] Note that our description of the methodology presents the steps in a different logical order to CMS's descriptions in the rules, however, both descriptions are mathematically equivalent.

Importantly, holding volume constant, under this methodology, the amount of indirect PE RVUs received by the specialty will only change if *physician time* is changed. Equally, if other costs – such as software costs – are added to the direct inputs database, that has no effect on the specialty's indirect PE RVU allocation.

At the service level, CMS's current methodology begins by estimating indirect PE RVUs first using direct PE RVUs and a service-specific estimate of the ratio between direct and indirect practice expense costs (averaged over the specialties that bill the service). CMS then adds work RVUs, clinical labor PE RVUs, or both, depending on the type of service. This service-level approach violates the pre-determined pools of specialty-specific indirect PE RVUs (described in the previous paragraph).

To ensure the indirect PE RVUs for services billed by each specialty sum to the total allocated to the specialty (and the overall fee schedule), CMS scales the service-level indirect PE RVUs in four steps. First, CMS scales the volume weighted sum of service-specific indirect PE RVUs to fit within the overall pool of indirect PE RVUs available to all specialties (this is called the "indirect scaling factor" or "indirect adjustment factor" in CMS's description of the methodology). Second, CMS calculates an index for each specialty scales the indirect PE RVUs for its services to the specialty's total allocation of indirect PE RVUs (the "specialty-specific indirect practice cost indices"). CMS then calculates the average such index for each service over all specialties bill the service (the "service-specific indirect practice cost indices"), which mathematically ensures indirect PE RVUs over the fee schedule attain the overall indirect allocations specified for each specialty. Last, CMS multiplies the service-specific indirect allocators by the two scaling factors, and the final indirect PE RVUs are obtained.

This design of the indirect allocation implies two important things for evaluating how to handle software in the PFS:

1. Each *specialty's* indirect PE RVU allocation will not change because of including or excluding SaMD direct inputs.
2. Within the portfolio of services performed by a specialty, the relativities between its services' indirect PE RVUs will be primarily determined by the human labor (physician work and clinical labor) employed and the *direct costs* incurred when performing the services.[37]

4.3. How the cost bases determine PFS indirect PE RVU allocations under the 2022 proposed rule PFS

One substantive reason presented in CMS's paragraph explaining its concern about over-allocating indirect PE RVUs was that the absence of a physical footprint from the AI service suggested a low or zero indirect cost. Given this and the indirect allocator methodology overviewed in Section 4.2, it is useful to explicitly profile the determinants of indirect PE RVUs under the 2022 proposed PFS rule's methodology and data. Significantly, between medical equipment (noted in CMS's paragraph) and medical supplies, medical supplies is by far the larger determinant of indirect PE RVUs, although physician work and clinical labor are in turn much more significant determinants than either supplies or equipment.

[37] Secondarily, the mathematical dynamics of the indirect practice cost indices will adjust the relativities further.

The current PFS's indirect allocator methodology does not use physical space or equipment maintenance (or any other non-cost factor) as the basis for indirect allocation. Instead, the indirect allocator methodology uses physician work RVUs, direct clinical labor RVUs, direct medical supplies RVUs, and direct medical equipment RVUs as the overhead allocation basis. Additionally, CMS refines the contribution of direct clinical labor, medical supplies, and medical equipment RVUs by applying an estimated ratio of direct-to-indirect practice expense costs incurred for the mix of specialties billing the service.

Under the 2022 proposed rule methodology and data, Table 4.1 and Figure 4.1 present estimated percentages of the PFS's indirect PE RVUs by the underlying factors that drive them, and the corresponding indirect PE RVUs and volume-weighted PE rates.[38]

Table 4.1 Estimated Contribution of Drivers of Indirect PE RVU Allocations by Component, 2022 proposed methodology and data

	Estimated Percent	Estimated Indirect PE RVU Contribution	Estimated Indirect PE Rate Contribution
Total Indirect PE RVUs	***100.0%***	***811,187,474***	***$ 27,243,569,066***
Physician Work	57.2%	464,185,651	$ 15,589,582,237
Clinical Labor (e.g., nurses)	25.4%	206,273,585	$ 6,927,657,099
Medical Supplies	11.1%	89,795,102	$ 3,015,750,540
Medical Equipment	6.3%	50,933,136	$ 1,710,579,190

[38] Estimated produced using MCDA's replication of the 2022 proposed rule PE rate-setting methodology. Percentages estimated using the rate-setting specialties and then applied to the total PE RVUs presented in Addendum B, as presented in Table 3.2.

Figure 4.1 Estimated Contribution of Drivers of Indirect PE RVU Allocations by Component, 2022 proposed methodology and data

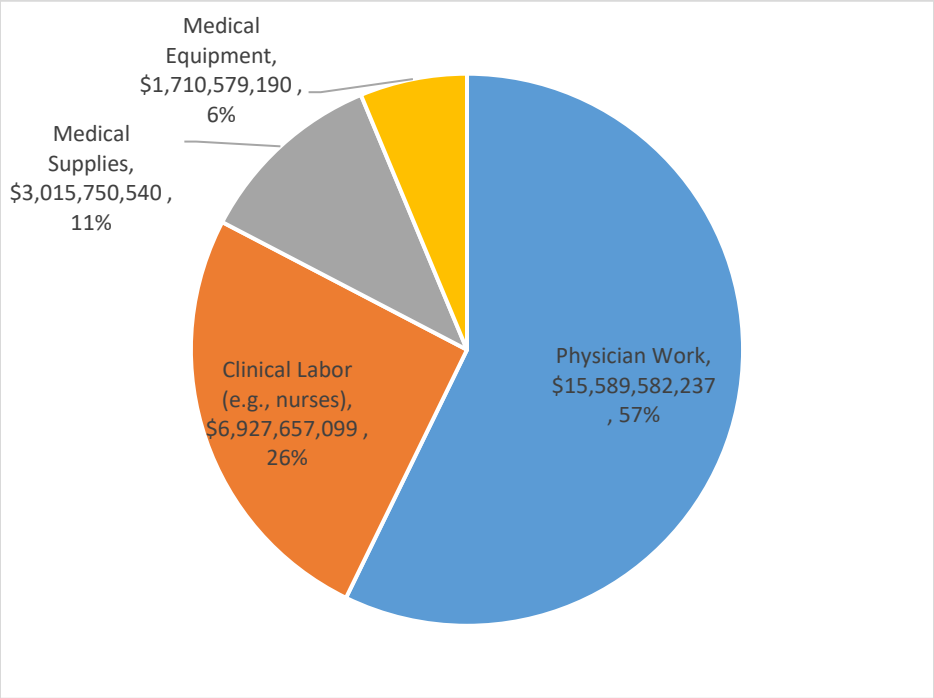


Table 4.1 and Figure 4.1 show that physician work determines 57% of the indirect PE RVUs under the 2022 proposed rule, direct clinical labor determines 26%, direct medical supplies determines 11%, and direct medical equipment determines the remaining 6%.

Again, no part of the current indirect PE RVU allocation methodology is based on factors such as physical space requirements of medical equipment. The indirect allocator methodology is an adapted standard cost accounting methodology that uses observable and estimated cost factors to impute the relative indirect PE RVUs between one service and another. Arguing that factors such as physical space or maintenance of medical equipment are relevant to the inclusion of a candidate direct input into the PFS is fully irrelevant to the current indirect allocator methodology's mathematics, and ignores the fact that none of the current system's indirect PE RVUs are determined that way.

Section 5. A Potential Approach to Mitigating PFS Reimbursement Strategy Abuse Risks

The PE methodology's idiosyncrasies can be exploited by vendors to extract Medicare Trust Fund (and beneficiary copay) moneys without corresponding benefit to Medicare beneficiaries. While truly nefarious vendors are hopefully rare, CMS's job, as stewards of the Trust Fund and the rights of Medicare's beneficiaries, is ultimately to wisely design and curate policy such to protect against such threats, while, critically, protecting patients' access to innovations, striking a balance between the risks of fiscal abuse and depriving patients of beneficial services.

Section 3 reviewed the direct costing methodology, concluding with the observation that, while the PFS apparently pays significantly below cost overall, direct supply and equipment inputs are, effectively, paid close to cost on average. This dynamic arises because of the PE indirect allocator methodology. Section 4 reviewed the indirect allocator methodology in detail, which while being a blunt force instrument, ensures that specialties are on average reimbursed reasonably for their overhead costs (at least in terms of relative costs incurred between the specialties). In both Sections 3 and 4, we highlighted problems and alluded to workarounds with respect to SaMD inputs.

This Section explores one specific draft of a potential middle ground that could support the viability of new technologies under the PFS while protecting the PFS from monopoly innovators effectively naming their own prices under the PFS. We suspect that this or some equivalent middle-ground approach is the optimal way for CMS to treat SaMD inputs under the PFS to guard against CMS's described concerns.

5.1. Motivation

In the PFS 2022 proposed rule, CMS's brief exposition on AI reimbursement was that they were concerned about over-allocating indirect PE RVUs. We suspect that this is not CMS's whole concern, and would encourage CMS to expand on their concerns and describe them in more depth in the future. However, this single breadcrumb is illuminating. In light of the broader context around the PE rate-setting calculation's dynamics, there are fictional but likely futures that CMS must consider in developing PFS payment policy around AI.

Specifically, CMS must protect the Medicare Trust Fund, and not allow any dynamic where the Trust Fund can be freely drawn upon by unvetted reimbursement proposals; but simultaneously, CMS must not disadvantage novel healthcare technologies relative to traditional (physical) healthcare technologies. Following are two ad-absurdum cases to help frame the risk-benefit situation that CMS is grappling with. An optimal policy lies somewhere between the policies suggested by each of these extrema.

Example A: In lieu of guardrails, a future AI innovator develops a very specific and beneficial service that would have no competitors until well after national PFS rates are established and which supplements for physician work and clinical labor. Understanding that the PFS dynamic allows close to at-cost reimbursement, the vendor chooses to sell directly to physicians rather than billing themselves. In order to support future revenue, the vendor accepts lower or negative profits to increase invoice prices for eventual review by CMS, essentially limiting volume to physicians willing to pay the higher price. CMS reviews invoices to set supply input prices. CMS sets direct inputs and for the next five years (or until the prices are

reviewed) that the PFS will pay close to the vendor-decided price. Medicare sets prices high based on invoices that do not reflect actual costs over that term.

Example B: Out of an abundance of caution, CMS decides to pay zero indirect PE RVUs for SaMD inputs, but allows direct PE RVUs to be paid. This new SaMD-based service would potentially save Medicare money relative to comparable services. However, because indirect PE RVUs are not paid under CMS's conservative policy, less than half the measured cost per service of the input is paid. Consequently, while this service would theoretically be more efficient than alternative services, it is systematically disadvantaged relative to those alternatives. Consequently, physician practices will be more profitable if they do not adopt the new SaMD modality in their work, and the SaMD service is avoided. Patients and Medicare both lose.

5.2. Capping Indirect PE RVU Allocations for SaMD Direct Inputs

Excluding indirect PE allocations for AI direct inputs will undesirably inhibit AI innovation, and including indirect PE allocations without any limits may create a risk to the PFS's future integrity. A natural middle-ground is capping the indirect allocation an AI direct cost can attract. Specifically, CMS could establish a high-cost outlier policy around AI direct inputs. This Section presents an outline of how such a policy could be implemented within the current methodology, and be automatically updated in each year's rule to avoid price inflation distortions over time.

Our idea is relatively simple: set direct PE RVUs using the current methodology without change, but limit the *contribution* of SaMD direct input costs to the indirect allocator so that only those SaMD direct costs below a cap are used to determine indirect PE RVUs. The question, then, is what the cap should be.

Table 5.1 presents per-service cost statistics for direct supply inputs, direct equipment inputs, and both direct supply and equipment inputs, based on the 2022 proposed rule data. The statistics are based on the total direct costs for each input in each associated service and weighted by the volume of services performed.[39]

Table 5.1 Direct Input Cost Statistics for Supplies and Equipment, 2022 proposed rule data

Statistic	Direct Supply Inputs	Direct Equipment Inputs	Direct Supply and Equipment Inputs
Mean	$ 2.17	$ 2.47	$ 2.28
Standard Deviation	$ 30.88	$ 22.50	$ 28.03
Median	$ 0.30	$ 0.19	$ 0.30
75th Percentile	$ 1.27	$ 0.58	$ 0.97
90th Percentile	$ 5.47	$ 2.32	$ 3.91
95th Percentile	$ 5.47	$ 3.91	$ 5.47
99th Percentile	$ 16.60	$ 57.52	$ 23.33
Max	$ 7,025.79	$ 1,118.80	$ 7,025.79
3.0 Standard Dev above Geometric Mean	$ 84.48	$ 90.48	$ 102.07

[39] For example, if a service uses two swabs, then the total direct cost for both swabs is added together in calculation of the statistics.

The first thing that becomes obvious from Table 5.1 is that the vast majority of per-service direct supply and equipment input costs are quite low – with 50% of inputs being less than $0.30 per service. This makes sense for the majority of inputs used in PFS services, which are small disposable supply items such as swabs or low-cost equipment items such as surgical tables. The preponderance of current direct supply and equipment inputs are significantly lower-cost than any of the SaMD direct inputs under current debate.

As CMS emphasized in their rule text, SaMD inputs are new, innovative technologies. They are the software analogue to traditional advanced medical devices. It is therefore reasonable to expect that SaMD cost levels would be significantly higher than the average direct supply or equipment input's contribution to a service's direct costs. Unfortunately, as there are so few SaMD inputs in the current PFS debate, it would be inappropriate to apply an overly stringent limit on SaMD direct costs that can contribute to indirect PE RVUs. Any guardrails around CMS's treatment of SaMD in the PFS should be intentionally *initialized* with adequate headroom to allow future, legitimate innovations to be viable under the PFS, but not so high as to allow innovators to effectively name the price that CMS's methodology then mechanistically reimburses close to cost.

For the purpose of developing a cap on SaMD direct input costs used to allocate indirect PE RVUs, the 99th percentile of current direct supply and equipment input costs – $23.33 – appears inadequate. The SaMD input in the 2022 proposed rule's primary case is CPT® 92229. Until 2021, Medicare had not reimbursed the new AI variation of the previously-reimbursed codes for remote detection and monitoring (CPT® codes 92227 and 92228) of diabetic retinopathy. Therefore, Medicare (nor any other payer reimbursing physicians based on the CPT® structure) has not reimbursed the AI version of the service based on the particular pricing levels of the two dominant vendors – Digital Diagnostics and Eyenuk. Each of these AI vendors currently has an active business, which we can reasonably assume involves contracts with numerous physician practices.[40] Combined, it appears the 92229 AI service in question in the current rule – estimated at $25 or $34 of direct costs per service – is operating in a relatively competitive market without distortions created by prior PFS rate levels. That both direct cost levels are above the 99th percentile of direct supply and equipment input costs suggests that the 99th percentile is an inadequate definition of an SaMD direct cost outlier cap.

A standard CMS approach to defining statistical outliers in its prospective payment systems is costs over three standard deviations above the geometric mean.[41] In Table 5.1, this threshold would be $102.07; this threshold would appear to balance the uncertainty about future reasonable cost levels and the policy benefits of facilitating valuable technological innovations against the risks of abuse by vendors and providers. That is, if CMS is interested in this type of policy guardrail, we believe that setting a SaMD cap at 3.0 standard deviations above the geometric mean, recalibrated each year, would be sound policy.

[40] If not currently available, it appears likely that Digital Diagnostics and Eyenuk may provide supporting data for our assumptions.

[41] The Inpatient Prospective Payment System and Outpatient Prospective Payment System use the 3.0 standard deviations above the geometric mean definition of statistical outliers to exclude certain costs and ratios for rate-setting purposes. In this report, we are suggesting the same definition be used, except directly in a high-cost outlier policy definition. Effectively, for rate-setting purposes, our suggestion is to "winsorize" the SaMD direct input cost contribution to the indirect PE allocator at 3.0 standard deviations above the geometric mean.

5.3. Implementing a SaMD Indirect PE RVU Allocator Cap Policy

The SaMD indirect PE RVU cap idea is to allow the indirect allocation that translates from any AI direct input cost up to a defined cap ($102.07 per the primary suggestion in Section 5.2), and then not provide any additional indirect allocation beyond that. Direct practice expenses would remain uncapped and be reimbursed under the usual methodology.

If this or some variation of the same idea makes sense to CMS, there are at least four technical policy questions that must be addressed before it becomes an actionable policy. We provide brief analyses and our conclusions for each question below.

1. Should indirect PE RVU allocations from SaMD inputs be allowed to vary based on the specific service's specialty mix, or should the maximum amount of indirect PE RVUs attracted by SaMD inputs be equal for all specialties and services?
2. How frequently should the SaMD high-cost outlier threshold be updated?
3. Should the cap methodology be reviewed and revised as the SaMD market matures and the PFS contains more services using SaMD inputs?
4. How, specifically, should the PE rate-setting calculation be modified to implement a SaMD cap?

5.3.1. Should indirect PE RVU allocations from SaMD inputs be allowed to vary based on the specific service's specialty mix, or should the maximum amount of indirect PE RVUs attracted by SaMD inputs be equal for all specialties and services?

Under the PE methodology, two services with identical physician work, clinical labor and overall direct costs will receive different indirect PE RVU allocations if the mix of specialties that bills each service is different. For our suggested SaMD cap policy, this implies that a cap on SaMD direct input costs allowable in determining indirect PE RVUs will translate to a variable cap on *indirect PE RVUs* that depends on the mix of specialties that bill the service. In theory, it is possible (though quite complex) to convert this whole policy idea to a specific cap on indirect PE RVUs resulting from SaMD direct inputs.[42,43] However, we suspect that this may not be the best policy one major reason.

Specifically, the idea of capping SaMD indirect allocator contributions is simply a policy guardrail. It is not attempting to fundamentally modify the indirect PE RVU cost accounting framework, which as discussed

[42] MCDA developed an implementation of this policy idea directly capping *indirect* PE RVUs resulting from SaMD direct inputs using an iterative algorithm. Specifically, iteratively set a SaMD direct input cap adjustment factor (which is applied to the $102.07 SaMD direct cost cap) for each service using SaMD, equal to $[\text{samd\_dir\_cap\_adj}]_{\text{HCPCS}} = (1.0 \times [\%\text{indir}]_{\text{Overall}}/(1 - [\%\text{indir}]_{\text{Overall}}))/([\text{IPCI}]_{\text{HCPCS}} \times [\%\text{indir}]_{\text{HCPCS}}/(1 - [\%\text{indir}]_{\text{HCPCS}}))$ and then run the indirect allocator, scaling factor and IPCI parts of the rate-setting methodology; iterating in this way, the $[\text{samd\_dir\_cap\_adj}]_{\text{HCPCS}}$ factors converge to levels that equalize the indirect PE RVUs resulting from the SaMD direct cost cap, and which attain IPCIs and the indirect scaling factor consistent with the policy. The initial values for $[\text{samd\_dir\_cap\_adj}]_{\text{HCPCS}}$ can be any positive number, however applying the formula using the previous year's IPCIs (or the IPCIs resulting from the uncapped policy) decreases the number of iterations required to attain convergence. The SaMD indirect allocator direct cost cap would become service-specific and equal to $\$102.07 \times [\text{samd\_dir\_cap\_adj}]_{\text{HCPCS}}$ for each service.

[43] We also note that CMS has implemented its own simplified indirect allocator override for the non-facility indirect allocation of certain high-direct cost/low work RVU codes in the PFS. While this is certainly an option, as cases such as this propagate or become more significant in volume, the inconsistencies in the current approach may become problematic for the accuracy of PE rate-setting. As a medium-term solution, however, it is not a bad option.

in Section 4 is specified to allocate specialty overhead costs to individual services using cost (RVU) bases. If CMS wishes to change the fundamental service-level overhead allocation basis from costs (RVUs) to something else (e.g., the physical footprint of an input) – a vast change in the philosophical framework and the data needed for determining 75% of PE RVUs – then CMS should approach this very carefully and systematically, and not use ad-hoc "salami tactics" to introduce such a change on small incremental pieces of the PFS.

5.3.2. How frequently should the SaMD high-cost outlier threshold be updated?

We believe any such SaMD direct cost cap should be updated annually. Doing so would sidestep future issues with suddenly accounting for price inflation such as being experienced around CMS's 2022 proposed clinical labor rate update.[44]

5.3.3. Should a SaMD cap methodology be reviewed and revised as the SaMD market matures and the PFS contains more services using SaMD inputs?

Whatever policy guardrails CMS proposes around SaMD in the PFS should be reviewed and revised as the PFS SaMD market matures, and CMS should be explicit about doing so when it initializes SaMD policy for payment purposes. As with any significant payment policy change, it is important to surveil data patterns and impacts to identify strengths, weaknesses, opportunities, and threats to the policy's integrity, and then to adjust accordingly. After a policy is initialized, it may make sense for CMS to perform a five-year review of the policy, but to explicitly state that they will monitor the situation and if refinements are needed before that time, they will propose appropriate adjustments through rulemaking. CMS, of course, always has this option, however explicitly noting this would provide additional clarity for existing SaMD vendors and providers, as well as future innovators and investors.

5.3.4. How, specifically, should the PE rate-setting calculation be modified to implement a SaMD cap?

Implementing a cap as described above under the current methodology would be relatively simple. In the 2022 proposed rule rate-setting calculation steps outlined in Section II.B.2.c(5) of the rule, only two changes would need to occur:

1. Calculate the SaMD indirect allocator direct cost cap based on weighted direct supply and equipment input cost statistics for the current rule. Specifically, calculate three standard deviations above the geometric mean across all service-specific supply and equipment inputs, weighted by volume adjusted by payment modifiers. Convert the cost cap to scaled RVUs by multiplying the cap in dollars by the direct scaling factor and dividing by the rate-setting conversion factor.
2. Calculate SaMD direct costs and scaled RVUs as the sum of direct costs for SaMD inputs for each service, and then calculate the SaMD direct RVUs as SaMD direct costs multiplied by the direct scaling factor divided by the rate-setting conversion factor.
3. Do not change the calculation of direct PE RVUs.

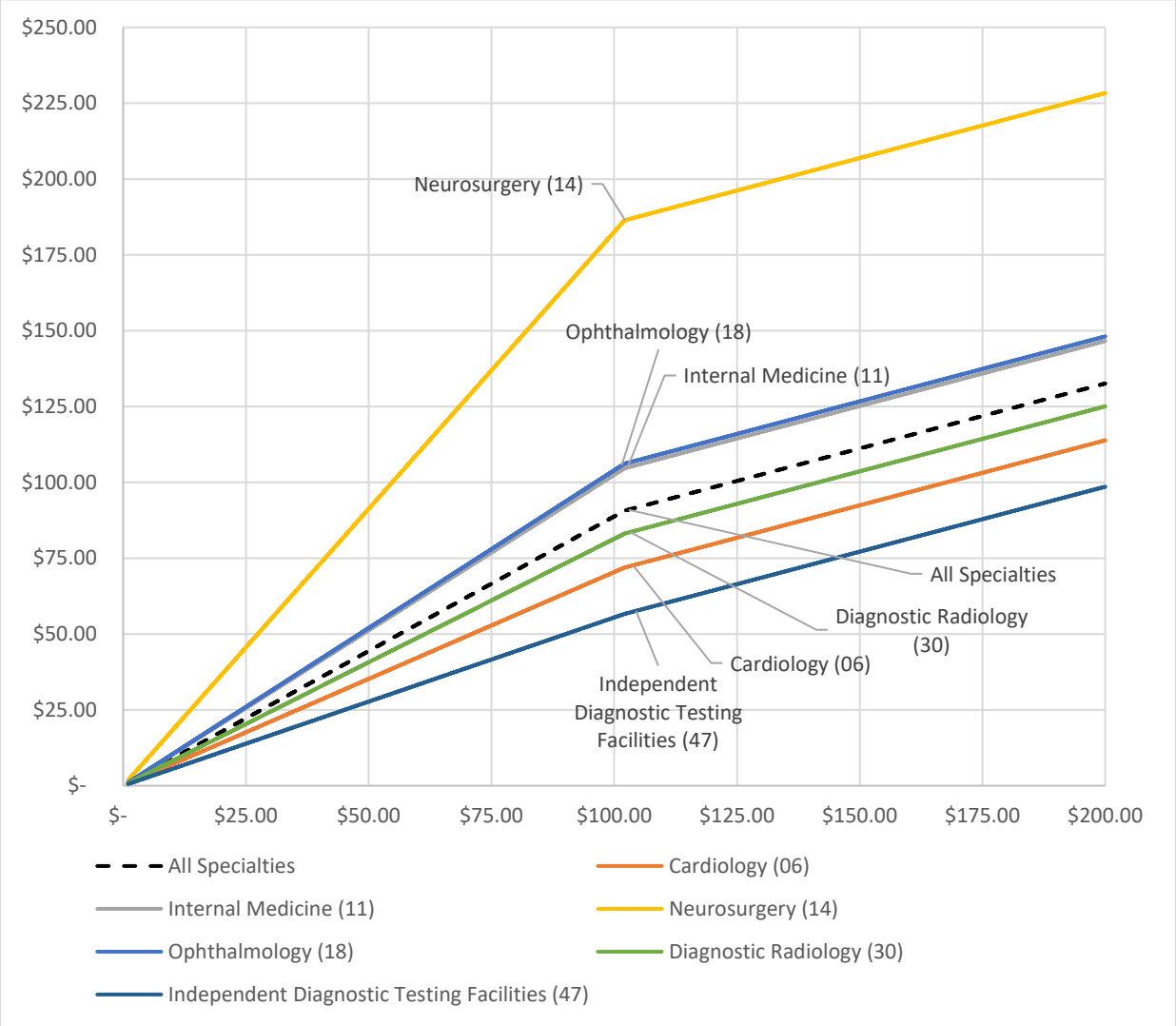
[44] In the 2022 proposed rule, CMS proposed to update the per-minute rates used to determine direct clinical labor costs. As they had not been updated in roughly 20 years, even a phased in approach causes significant redistributive effects in the PFS, increasing payments for services reliant on clinical labor and decrease payments for services reliant on direct supplies and equipment. In fact, the update is so disruptive that not updating the rates in such a long time has created an outside threat against them ever being updated.

4. Modify Step 8 of the calculation logic so that, instead of defining the first term of the indirect PE allocator as "indirect PE percentage * (direct PE RVUs/direct percentage)", the each instance of the first term becomes "indirect PE percentage * (([direct PE RVUs] – [SaMD direct PE RVUs] + min([SaMD direct PE RVU cap], [SaMD direct PE RVUs]))/direct percentage)".

5.4. Implications of the Draft Capping Policy

Following the approach described in Section 5.3.4, we can model the relationship between SaMD direct costs and PE rates. For this exercise, we assumed the SaMD indirect allocator direct cost cap would be the $102.07. Figure 5.15.1 presents these relationships for a selection of specialties.

Figure 5.1 PE Rate Impact of Direct Supply/Equipment Costs under Attenuated AI Policy



Here, we see that SaMD direct input costs under this cap policy would be reimbursed under a similar dynamic as any other direct supply or equipment input up to the cap – in this calibration $102.07 per service – and then the marginal payment benefit of increasing per-service SaMD direct costs beyond the cap would be diminished. This would build in an incentive to keep per-service SaMD direct costs below the cap, but would allow limited compensation of costs above it.

To understand this incentive by specialty, Table 5.2 presents the marginal PE rate contribution of SaMD direct costs below and above the cap for the same set of specialties. On average over all specialties under the 2022 proposed rule data and methodology, each dollar of SaMD cost below the cap translates to a marginal PE rate increase of $0.880, and each dollar of SaMD cost above the cap translates to a marginal PE rate increase of $0.430.

Table 5.2 Marginal PE Rate Contribution per $1.00 SaMD Direct Cost Increase

	Marginal PE Rate Increase per $1.00 SaMD Direct Cost Increase		PE Rate Contribution at SaMD Cap
	Below SaMD Cap	Above SaMD Cap	
All Specialties	$ 0.880	$ 0.430	$ 90.64
Cardiology	$ 0.704	$ 0.430	$ 71.91
Internal Medicine	$ 1.025	$ 0.430	$ 104.65
Neurology	$ 1.826	$ 0.430	$ 186.38
Ophthalmology	$ 1.040	$ 0.430	$ 106.16
Diagnostic Radiology	$ 0.814	$ 0.430	$ 83.11
Independent Diagnostic Testing Facilities (IDTFs)	$ 0.555	$ 0.430	$ 56.62

5.5. Is a SaMD cap policy appropriate at all?

As noted, many of the reasons for implementing a SaMD cap policy in the PFS rely on theoretical arguments that could apply equally to many supply and equipment inputs. For example, innovative physical supply or equipment items may theoretically be subject to the same problems as a SaMD input with respect to innovator price setting that exploits the dynamics of the PE rate-setting calculation.

Why, then, should SaMD be singled out? Simply, the SaMD market is nascent, and therefore CMS is wise to:

- Proceed cautiously and deliberately around reimbursing new SaMD products, particularly as current payment policy decisions that create inertia limiting changes in the future.
- Monitor the situation closely, including potentially performing ongoing surveillance of SaMD input pricing data to observe how they evolve for new innovations over time.
- Explicitly be willing to evolve the policy as new data and facts become available, for example, potentially eliminating a cap if it is overly restrictive on valuable AI innovation, or adjusting a cap policy if CMS observes innovators clustering their SaMD input prices at the cap.

A major reason for setting a SaMD indirect allocator direct cost cap to be relatively high – e.g., our suggested 3.0 standard deviations above the geometric mean – is that such a cap is unlikely to be binding unless any of the theoretical risks with SaMD inputs actually occur. That is, such a policy is a backstop that would protect the PFS only if extreme situations arise, and has no effect if SaMD prices remain within the broad distribution of direct supply and equipment input costs currently used in the PFS.

Section 6. Specifying SaMD Direct Inputs

If CMS includes SaMD products as direct inputs, the next questions are how to specify those direct inputs to generate appropriate per-service direct cost estimates, and then how best CMS can obtain the data to needed to specify those inputs. The guiding principle with specifying direct inputs and obtaining data is to obtain the most accurate estimate of the per-service cost of the input as possible, such to maximize the accuracy of relativities between RVUs across the PFS.

Exactly what kinds of data to obtain and how to obtain them depends on the types of providers involved, the fee structures they use for selling their services, and the competitive dynamics within their market. The main considerations are whether the provider bills Medicare directly or as a vendor; whether they charge for each individual service, allow unlimited use after a fee for a limited or unlimited duration, or structure a maximum number of services to be performed per period under a periodic fee; and whether traditional invoice data are likely to reflect monopolistic price dynamics.

Subordinate to the fee structure question is a question of whether, if certain SaMD products are considered direct equipment inputs, the current CMS equipment amortization formula is appropriate as is or whether it should be modified.

Particularly important in evaluating the best approach to address each of these factors is the strategic nature of specifying direct inputs and obtaining the data. For technical component services in the PFS (the only types of codes for which SaMD technologies are currently being considered as direct inputs), the only determinant of PFS rates that stakeholders have influence over is the specification of direct inputs. CMS's need to structure those inputs and obtain data to specify costs, therefore, sets a strategic game between CMS and providers. This game is framed around significant information asymmetries between CMS (who needs the data) and stakeholders (who have the data but are not obligated to share it), with each holding significant power in the negotiation process, and with CMS having a theoretical option to simplify the game and reduce the information asymmetries interfering with CMS's statutory obligation to specify accurate RVUs.

Section 6 analyzes these considerations and is organized as follows:

1. How the SaMD provider's business model affects CMS's direct inputs specification task
2. When SaMD inputs should be considered supplies or equipment
3. Obtaining data from reluctant SaMD providers – game theoretic realities and CMS's options

6.1. How the SaMD provider's business model affects CMS's direct inputs specification task

Over the last two rulemaking cycles, CMS has begun tackling two illustrative cases of SaMD in the PFS, which conveniently span two of the three relevant Medicare billing situations for SaMD providers.

The first case was extended external ECG technical services, which triggered a debate between iRhythm (the largest of several major external ECG providers) and MCDA (the author of this report) over the data and direct cost estimation methodology to be used to value those services. In the extended ECG debate, one of a few current root impasses is what data are needed to specify direct inputs for a service for which

most services are billed directly by the software provider, but for which a subset of services are billed by physicians and performed using inputs provided by extended ECG companies sold in a vendor-customer model. A consequent component of this debate is whether CMS should base the direct cost specification on company internal data or traditional invoice data observable from sales of component direct inputs to billing providers (physician practices and independent diagnostic testing facilities (IDTFs)).

The second case, in the 2022 proposed rule, is the AI-based diabetic retinopathy detection and monitoring code, 92229. In this case, the two dominant providers of the AI service (Digital Diagnostics and Eyenuk) sell their services as vendors to physician practices, who in turn bill Medicare. In this case, traditional invoice data, in a competitive market, are available, however CMS also theoretically has the option of collecting direct cost data elements from the SaMD providers.

CMS's direct inputs and data needs decisions first trifurcate on whether the SaMD providers are vendors to physician practices, directly bill Medicare themselves, or both directly bill Medicare and sell their services as a vendor to physician practices; and second, within each of those business models, depend on how they structure the fees for their services.

The three categories of major business models are the following:

- SaMD providers are vendors to physician practices (such as Digital Diagnostics and Eyenuk for 92229). This cost accounting situation (and corresponding data collection) is considerably simpler than when the SaMD providers directly bill Medicare, as this is the classical framework of a PFS direct input. In this case, CMS or the RUC have the option to either collect "traditional invoice data" from physician practices or to obtain larger batches of equivalent invoice data from the SaMD providers, both in a competitive market. SaMD providers of this type may sell their services under at least the following fee structures:
    - Software as a service (SaaS) with fees accrued individually (per furnished-service)[45]
    - SaaS with unlimited services over a limited term
    - SaaS with a cap of service volume over a limited term
    - Locally installed software packages with unlimited usage
    - Locally installed software packages with a limited term

- SaMD providers directly bill Medicare (such as iRhythm's business model for extended ECG services). In this situation, CMS must obtain internal cost accounting data and service volumes from the billing SaMD providers. Critically, the internal cost accounting data need to be detailed enough to allow differentiation of direct and indirect costs consistent with CMS's direct cost categories – clinical labor, medical supplies, and medical equipment, and which per this report we argue SaMD costs should be included. Additionally, while CMS may receive arguments that research and development (R&D) costs should be included as direct inputs, CMS should evaluate such arguments carefully and using a high bar, as including R&D would require CMS to obtain data detailed enough to differentiate R&D exclusive to "maintaining" the SaMD service from development of entirely different services. Costs such as corporate overhead, sales and marketing,

[45] Sometimes this is referred to as "per-click", however that description is inappropriate for estimating per-service costs in the PFS. Specifically, the "denominator" used to calculate per-service costs should be furnished services rather than the quantity of digital transactions initiated by the provider.

staff travel, etc., should not be included as direct costs under any circumstances. Vertically integrated billing providers present the most fraught situation for CMS to obtain useable data.

- SaMD providers both bill Medicare directly and sell components of their services to physician practices as a vendor (such as iRhythm's main competitor, BioTelemetry's, business model for extended ECG services). CMS must decide whether obtaining traditional invoice data from the physician practices, in a competitive market, is adequate for the task of specifying direct inputs, or whether they will attempt to obtain internal component cost data from the SaMD provider. Generally, however, it appears that CMS would obtain more appropriate, competitive market price data if CMS prefers to use physician invoice data rather than manufacturer internal cost data; additionally, this would likely simplify the reimbursement strategy dynamics between CMS and those manufacturers.

It is worth emphasizing the importance of competitive markets in specifying direct inputs, particularly in light of the case of obtaining detailed internal cost data from vertically integrated SaMD providers who directly bill Medicare for their services. Under the traditional PFS framework, a physician purchases an input from a vendor, and then invoice data are created and may be observed by CMS to specify direct inputs. These physician practice invoices will reflect prices based on the broad set of costs incurred by the upstream SaMD vendor, with the SaMD vendor pricing their service such to be competitive against other methods the physician may use to treat the same patient – either other flavors of the same SaMD input, or completely different ways of addressing the patient's clinical need. In either case, CMS side-steps the need to delve into the complex and variable cost structures of the SaMD providers.

In contrast, for vertically integrated providers that directly bill Medicare – particularly where the SaMD provider is the SaMD service's inventor who, by definition, begins as a monopolist – CMS must attempt to obtain detailed internal cost data in a way that is appropriate for specification of the direct input. It must exclude the costs of other direct inputs included in the CPT® code's specification, and must exclude indirect cost categories such as corporate overhead, sales and marketing, etc.. Arguments to include, or not, outlays for research and development then immediately inject subjective cost accounting decisions, raising the question of whether CMS must consider Generally Acceptable Accounting Principles (GAAP) in their efforts, and implicitly requiring CMS to develop a subjective judgment about what a "fair price" would be if the vertically integrated SaMD provider counterfactually sold the SaMD as an input under the traditional physician-vendor framework. All of this is exacerbated by providers not being obligated to share any data at all, and having control over the form and type of the cost data they share; CMS must also trust that shared data are accurate, though if a stakeholder knowingly provided misleading or inaccurate data to CMS in their reimbursement negotiations, it appears possible that would constitute lying to a government official, i.e., violation of 18 USC §1001.

While unavoidable in certain situations, in any case that CMS can side-step these problems if the SaMD product is also sold in the traditional physician-vendor framework (where physician invoices for the specific SaMD input are observable), then that will generally be preferable.

6.2. When SaMD inputs should be considered supplies or equipment, and CMS's data needs

Before discussing how SaMD provider business models affect CMS's task of specifying SaMD direct inputs, it is useful to first address one basic decision CMS must make: When should CMS cost a SaMD direct input as a medical supply item, and when should CMS cost a SaMD direct input as a medical equipment item? As discussed below, it appears that specifying SaMD inputs as medical supplies is preferable in most cases, and that medical equipment is really only an option when the SaMD product is a locally installed computer program used in at most one service at one time.

While PFS direct supply and equipment items are often intuitively thought of as physical – disposable supply items such as scalpels and re-usable equipment items such as CT scanners – that is a narrower interpretation than the mathematical cost accounting properties require. Mathematically, a medical supply item is any items for which a per-service direct cost available or estimable, and a medical equipment item is any item for which an overall purchase price will be spread over multiple services. Theoretically, any input where a per-service cost can be estimated can be properly accounted for as a PFS supply input; and any input used for multiple services can be properly accounted for as a PFS equipment input (so long as the required data can be obtained) [46], though certain cases would require the equipment amortization formula be modified.

The current CMS formula for costing direct equipment items relies on one key assumption: that the equipment item is in use for at most one service at one time. This is because the current formula attributes each equipment item's purchase price to individual services by first estimating an annual cost per year, second making an assumption about the minutes per year the equipment would be in use, and third assigning cost to each service based on the number of minutes the equipment would be employed in the service. If the equipment were in use for multiple services simultaneously, under the current specification of the equipment amortization formula, equipment costs would effectively be double-counted.

This restricts the kinds of the SaMD products for which the equipment amortization formula could apply. Specifically, it only applies to SaMD products where a specific license's price can be obtained, and where that license is used for at most one service at one time. This appears to restrict the usefulness of SaMD equipment items to locally installable computer programs, where the program is not installed on a common server for use by multiple practitioners at the same time.[47]

We note that, theoretically, the equipment amortization formula could be recast to use a different basis (than minutes per service) to attribute equipment costs to services. Specifically, it would be possible to modify the equipment amortization formula to use an explicit estimate of the annual number of services that could be performed on the SaMD input each year. However, this would then require CMS to obtain valid estimates of total annual service volume that could be performed on each SaMD license. In practice, that would likely be difficult for CMS to obtain. Essentially, CMS would need either collect an annualized

[46] At the extreme, CMS could convert all current medical equipment items to medical supply items costed at the same rate per service as the amortization formula indicates. This would be inadvisable to say the least but demonstrates the flexibility of the methodology and the wide range of regulatory options CMS has available to address changes to the physician services market.

[47] We note in MCDA's public comment and technical report on extended ECG reimbursement issues, MCDA presented invoice data on locally installable SaMD software used in the services. This was an example of a specific case where the direct equipment formulation of SaMD direct costs would be appropriate.

estimate of the number of services that could be performed on a given license and the term of that license, or for new products obtain a best guess on what that service volume would be. This is not impossible, but would unnecessarily add to CMS's data collection burden, and strikes us as extremely "gamable".

The simpler approach for other products is to specify the SaMD input as a direct supply item. In this case, CMS's goal is to calculate a per-service cost for the input, and CMS's data needs then would turn on the SaMD provider's business model.

If the SaMD providers is a vendor to physician practices, then CMS must collect two data points – invoice price and total services performed under the invoice – which could either be collected from physician practices or centrally from the SaMD vendor(s). CMS may then choose whether they wish to specify per-service cost as the estimated mean, or whether they wish to calculate, for example, the weighted median per-service cost over all invoices in the data collection. The main requirement is simply that the invoice data being used to calculate the statistic have consistent numerators and denominators – the price refers to the same period as the count of services.

If, on the other hand, the SaMD providers directly bills Medicare for their services, CMS must base a supply input on internal cost accounting data from the SaMD providers. As discussed above, these data must be detailed enough that CMS can isolate direct costs of the service. This issue continues to be a central issue in the extended external ECG debate. Specifically, in that debate, we understand that iRhythm provided CMS with total cost data divided by total services furnished, but did not exclude unambiguously indirect cost categories – corporate overhead, sales & marketing, and research & development. The extended external ECG saga teaches valuable lessons about CMS's data collection problem: CMS must be very strict about *requiring* those types of data to specify their codes, and cannot set a supply item's cost in lieu of having the exact type of data they need.

Finally, as is the case in the extended external ECG market, some SaMD services will be a mixture of both of the above cases, with some SaMD services being provided as a vendor to the physician practice and others being billed directly to Medicare by the SaMD provider. In this case, CMS must choose which type of data to use as the vignette for the supply input. As discussed above, CMS's ultimate goal is an unbiased estimate of average cost per service. For new services, or services whose payment rates are fluctuating, we note that using invoice data in the traditional vendor model may be affected by whatever the payment rates currently are; but that strictly defined direct cost data collected from the SaMD vendors (excluding unambiguously indirect costs) are more likely to yield reasonable and accurate estimates of the direct cost per service.

6.3. Obtaining data from reluctant SaMD providers

A theme throughout Section 6's discussion so far is the difficulty CMS faces in collecting usable source data with which to specify direct inputs. Ultimately, this difficulty arises because of the strategic game between CMS and providers when specifying a code's direct inputs, which is marked by a substantial information asymmetry between CMS (who need the data but do not have it) and the SaMD providers (who have the data but are not required to share it).

Where CMS has the ability to collect traditional invoice data from physician practices, CMS can side-step the difficulties of obtaining the data from providers, but as noted at the end of Section 6.2, there are cases where obtaining detailed internal cost accounting data directly from SaMD providers is preferable

to obtaining traditional invoice data when the SaMD services are directly sold to physician practices. Therefore, CMS's ability to obtain detailed internal cost accounting data from SaMD providers is a critical issue in many cases CMS will need to tackle now and in the future.

CMS has considerable power in the reimbursement negotiation process since CMS has ultimate authority over setting PE RVUs. Neither the RUC nor providers have the final say about what a PE RVU will be. On the other side, providers have a different power arising from their ability to choose which data they will share with CMS, and their ability to make assertions around another issue CMS cares about: access to care. Unfortunately, this sometimes leads to impasses between CMS and providers when providers are unwilling to share data that will likely result in CMS setting rates lower than what they would like; and CMS occasionally being stymied by not having appropriate data to specify direct inputs, with providers attempting to force CMS's hand by asserting access to care will be harmed if CMS sets the rate below the provider's preferred level.

Currently, CMS deals with this situation in at least two ways. First, CMS can simply do what they believe is right based on their own independent analysis of the costs of services. For example, when a publicly listed company provides just one type of service, their SEC filings may contain some or all of the detailed data CMS needs to specify the SaMD direct input. Second, CMS can defer payment that would normally be a national rate to local decisions through the Medicare Administrative Contractors (MACs) – carrier pricing. Under carrier pricing, providers must then negotiate individually with MACs to obtain rates. This can either result in a fruitful outsourcing of CMS's research to the MACs to specify rates, with the MACs collecting data that may be available to CMS down the road; or it can result in uninformed payment rates when the MACs have no better success in obtaining data than CMS had.

That is, CMS's current approach has significant limitations when providers simply do not wish to share their data. These limitations, ultimately, risk setting PE RVUs that threaten CMS's statutory obligation to specify PE RVUs such to reflect relative resources incurred between services. It is therefore worth asking, is there any way CMS can restructure the strategic game so that providers will not exploit the information asymmetry in ways that degrade PE RVU accuracy?

One potential option is to establish a clear, strict policy that a direct input will receive a zero cost if appropriate data are not shared, or if there is a similar service of the same general clinical function, adopt the next most resource intensive code (so long as CMS confidently knows that it will have a lower cost) as a proxy[48]. If such a policy were established, then stakeholders would face a starker option – either participate in the direct inputs specification process, or effectively receive a zero or low reimbursement for the input until they do. In cases where providers are simply unable (for example, for contractual or legal reasons) to share their data or where there are legitimate policy disagreements over how to use the data (for example, if the providers believe CMS has made calculation errors or other misspecifications

[48] For example, in the extended external ECG debate, the next most resource intensive code is traditional Holter monitoring, paid at roughly half of the prevailing MAC rate. If CMS established a clear policy that implausible assertions of direct costs would be met with lower reimbursement, or potentially zero reimbursement, it appears likely that reluctant stakeholders in that process would have shared detailed cost data more willingly.

using the data they provided), then CMS should consider deferring payment to the MACs and continue to work with providers to resolve those issues.[49]

Needless to say, this type of strict zero/low-directs policy would both serve as a powerful incentive to share data, and vex stakeholders wishing to exploit the information asymmetry in their reimbursement strategies. However, it would also simplify reimbursement negotiations between CMS and providers, yield more appropriate direct inputs data, and result in more accurate PE RVUs, improving CMS's compliance with its statutory obligations.

[49] The purpose of any policy like this is *not* to be cruel to providers in genuine binds, but to set clear boundaries and rules that would have consequences if broken. Extenuating circumstances do validly occur.

Section 7. CMS's General Solicitation of Input on PFS SaMD Policy

In the 2022 proposed rule, at the end of the section discussing 92229's reimbursement, CMS solicited public input on a range of summary questions regarding the PFS's treatment of SaMD. In this section, we present CMS's questions and brief analyses and responses.

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 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 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 experienced 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 were spread over a larger pool of individual services as more physicians adopted extended external ECG for remote cardiac monitoring.

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 right 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 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.

Section 8. Implications for Other Services under Consideration

Through this report, we have focused on 92229, diabetic retinopathy detection and monitoring through AI. We focused on 92229 because it is the primary case around which CMS is currently evaluating whether and how to account for such costs under the PE methodology. However, there are a handful of other, live cases in the PFS:

1. Trabecular bone score (TBS) dual X-ray absorptiometry (DXA) analysis, code 77X01
2. Estimation of fractional flow reserve (FFR) using advanced analysis software, code 0501T
3. Extended external ECG monitoring, codes 93243 and 93247

CMS has solicited public comment on crosswalking the first two of these services (0501T and 77X01) to proxy PE RVUs in lieu of determining specific direct inputs specifications for the code. The last, extended external ECG, is still in the process of a larger debate triggered by CMS's challenges in obtaining useable cost data to specify the code coupled with policy disagreements about which types of data are appropriate for valuing codes 93243 and 93247.

In this section, we briefly examine each of these cases in light of the analysis presented through the previous Sections of this report.

8.1. Trabecular bone score (TBS) dual X-ray absorptiometry (DXA) analysis, codes 77X01 and 77X03

In the 2022 proposed rule, CMS solicits feedback on using a crosswalking methodology to value CPT® technical component code 77X03 (*Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical calculation only*), to existing code 71101's technical component (*Radiologic examination, ribs, unilateral; including posteroanterior chest, minimum of 3 views*). CMS then adjusted the PE RVU for 77X01 (the global component in the group) so that it would equal the sum of the component codes 77X02-77X04.

The codes in the 77X01-77X04 group – particularly the technical component code 77X03 – are designed around the "TBS iNsight™ (Osteo)" software service produced by Medimaps Group.[50] Medimaps describes TBS iNsight™ (Osteo) as "Used in the field of osteoporosis, TBS iNsight™ (Osteo) is an advanced imaging software application for bone densitometers (DXA). It provides doctors with a simple solution to better predict a patient's risk for bone fracture; to fine-tune therapy decision; and to improve patient management." They additionally point out that "TBS iNsight™ is a Medical Device that is CE 2797 marked & has been cleared to be sold in the US." [51] That is, it is an FDA-cleared SaMD product.[52]

[50] See pp.1889-1920 of the RUC January 2021 meeting minutes, available at https://www.ama-assn.org/system/files/jan-2021-ruc-meeting-minutes.pdf.
[51] See https://www.medimapsgroup.com/tbs-osteo/.
[52] See https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K152299.

According to the RUC's January 2021 meeting minutes, The RUC recommended the direct inputs as submitted by the specialty society.

The "TBS iNsight™ (Osteo)" input was specified as a supply input with a per-click fee of $25.00 per service. The RUC described the invoice as follows:

> *This is a recent 2020 invoice for the TBS iNsight Software. This software is currently sold "per click" or per scan. As this is a single-use item, we have included this as a supply item and not an equipment item, which is typically accounted for by minutes used. The invoice depicts that this is a TBS iNsight 1-year License and covers a total of 100 scans. The total unit price for the license is $2,500; therefore, we are estimating the cost to be $25 per patient (or scan).*

And the RUC expanded on this in their summary recommendations:

> *The Subcommittee agreed that it would be warranted to include a per encounter software licensing fee for the TBS software for CPT codes 77X01 and 77X03. The software is currently sold "per click" or per scan. As this is a per-patient, single-use item, it is appropriately included as a supply item and not an equipment item, which is typically accounted for by minutes used. The RUC recommends the direct practice expense inputs as submitted by the specialty society.*

Given CMS's hesitance around including SaMD direct inputs, CMS did not use the RUC's recommendations around 77X01 and 77X03 to calculate its proposed PE RVUs. Instead, CMS set the global component code 77X01's PE RVU equal to 71101's, and then derived 77X03 as 77X01's PE RVU minus the PE RVUs of the other components in the group, 77X02 and 77X04. However, CMS did present the RUC recommended direct inputs (excluding the TBS iNsight™ fee) and the assumed utilization data in their underlying PFS rate-setting files, allowing simulation of what the rates would have been had CMS adopted the RUC recommendations.

Using the 2022 proposed rule rate-setting data (including those for 77X03), Table 8.1 summarizes the direct inputs and resulting PE RVUs and rates for:

- The proxy code, 71101;
- 77X01 as published;
- 77X01 if it was valued under the standard methodology using the RUC recommendation,
    - first *excluding* the TBS iNsight™ fee, and
    - second *including* the TBS iNsight™ fee.

Here, we see that CMS's proxy methodology results in a slightly higher PE rate for global code 77X01 using the proxy code 71101 ($32.58) than if CMS had used the RUC recommendations ($29.22). It is in the right ballpark, however. If, on the other hand, CMS had proposed to exclude the TBS iNsight™ software fee from the code, the PE rate would have decreased by $20.15 (69%), from $29.22 to $9.07, likely rendering the service fully unviable for Medimaps and physicians. That is to say, including the $25.00 analysis fee increases the PE rate under the 2022 proposed rule methodology by $20.15, largely, but not completely covering the costs of the analysis service, but without that cost, it appears unlikely physicians (or Medimaps) could justify performing the service.

Table 8.1 Direct Inputs, PE RVUs, and PE Rates for 71101 and 77X01, proposed and simulated alternatives

	Radiologic examination, ribs, unilateral; including posteroanterior chest, minimum of 3 views	Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual Xray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture risk		
	Proxy Code	Published 77X01	77X01 RUC Recommendation w/ and w/o TBS iNsight™	
	71101	**77X01 as proposed**	**Excluding $25 analysis fee**	**Including $25 analysis fee**
Physician Work RVU:				
Work RVU	0.27	0.20	0.20	0.20
Direct Costs:				
Clinical Labor:				
Radiologic Technologist minutes (@ $0.69/min)	23		9	9
Total direct clinical labor cost:	$ 15.87		$ 6.21	$ 6.21
Medical Supplies:				
TBS iNsight™ Software items (@ $25.00/item)	n/a		-	1
Patient gown items (@ $0.59/item)	1		n/a	n/a
Total direct medical supplies cost:	$ 0.59		$ -	$ 25.00
Medical Equipment:				
Technologist PACS Workstation minutes (@ ~0.022/min)	23		7	7
Professional PACS Workstation minutes (@ ~0.061/min)	6		6	6
Basic Radiology Room minutes (@ ~$0.933/min)	17		n/a	n/a
Total direct medical equipment cost:	$ 16.73		$ 0.52	$ 0.52
Total direct inputs cost (before budget neutrality scalar is applied):				
Total direct costs	$ 33.19		$ 6.73	$ 31.73
PE RVUs and Rates				
2022 proposed rule (simulated for 92229):				
PE RVU	0.97	0.97	0.27	0.87
PE Rate (at proposed 2022 CF of $33.5848)	$ 32.58	$ 32.58	$ 9.07	$ 29.22

Table 8.2 presents the same analysis for the technical component code, 77X03, but without the proxy code presented. Under CMS's proxy approach, the PE rate for 77X03 is $27.20, where if CMS had built the code from the RUC recommendations it would have been $25.19. Because CMS had derived the "proxy PE RVU" for 77X03 by subtracting the other components from the global code 77X01 (which was directly set to 71101's PE RVU), the effect of "adding" the SaMD analysis fee is not the same as for the global component code. If the $25.00 SaMD analysis fee were excluded (but other RUC recommendations

adopted), then 77X03's PE rate would have been $4.70, a full $20.49 (81%) lower than including the fee. Again, this would likely not be viable for neither physicians nor Medimaps.

Table 8.2 Direct Inputs, PE RVUs, and PE Rates for 71101-TC and 77X03, proposed and simulated alternatives

	Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical calculation only		
	Published 77X03	77X03 RUC Recommendation w/ and w/o TBS iNsight™	
	77X03 as proposed	**Excluding $25 analysis fee**	**Including $25 analysis fee**
Physician Work RVU:			
Work RVU	-	-	-
Direct Costs:			
Clinical Labor:			
Radiologic Technologist minutes (@ $0.69/min)		7	7
Total direct clinical labor cost:		$ 4.83	$ 4.83
Medical Supplies:			
TBS iNsight™ Software items (@ $25.00/item)		-	1
Patient gown items (@ $0.59/item)		n/a	n/a
Total direct medical supplies cost:		$ -	$ 25.00
Medical Equipment:			
Technologist PACS Workstation minutes (@ ~0.022/min)		7	7
Professional PACS Workstation minutes (@ ~0.061/min)		-	-
Basic Radiology Room minutes (@ ~$0.933/min)		n/a	n/a
Total direct medical equipment cost:		$ 0.15	$ 0.15
Total direct inputs cost (before budget neutrality scalar is applied):			
Total direct costs		$ 4.98	$ 29.98
PE RVUs and Rates			
2022 proposed rule (simulated for 92229):			
PE RVU	0.81	0.14	0.75
PE Rate (at proposed 2022 CF of $33.5848)	$ 27.20	$ 4.70	$ 25.19

As with diabetic retinopathy code 92229's situation, CMS has proposed a proxy that approximately attains the PE rate that would have resulted from simply adopting the RUC's recommendations. And, as with 92229, both the RUC recommendations and the CMS proxy appear to be reasonable payment levels. Indeed, in lieu of establishing policy that allows the inclusion of SaMD direct inputs in the direct (and indirect) PE RVU calculations, CMS's proxy approach is a reasonable interim, temporary solution.

8.2. Estimation of fractional flow reserve (FFR) using advanced analysis software, codes 0501T and 0503T

Unlike the diabetic retinopathy code 92229 or the trabecular bone score codes 77X01 and 77X03, estimation of fractional flow reserve global component code 0501T and technical component code 0503T do not have published RUC recommendations or CMS analysis of RUC recommendations to analyze the service's direct inputs. While CMS noted that they have been attempting to identify usable 0501T and 0503T costs with which to specify direct inputs since 2018 – presumably with little success – they did note that the Outpatient Prospective Payment System (OPPS) geometric mean cost per service for 0503T was $804.35 in the 2021 OPPS final rule. According to the outpatient hospital Medicare claims data, approximately 7,220 0503T services were performed in 2019 and 2020; under both the 2021 final OPPS rule and the 2022 proposed rule, 0503T is classified as a new technology APC with a payment rate of $950.50 per service.

Currently, 0501T and 0503T are carrier priced under the PFS, with an extremely small number of services being reimbursed in 2019 and 2020. Indeed, according to the 5% physician claims data, an estimated 740 0501T services were paid under the PFS in 2019 and 2020, and fewer than 220[53] 0503T services were paid over the same period. Mean payments per service were $76.49 for 0501T and $38.22 for 0503T, with most of the handful of 0503T technical component services being billed by HeartFlow, the dominant provider of 0503T, who is certified as an IDTF. These payment rates are consistent with at least one MAC's fee schedules for the codes, with Novitas currently listing rates of $174.46 for 0501T and $34.42 for $0503T in Houston, Texas. Given how much lower these rates are than the costs hospitals incur when performing the same service, it is not surprising that physician office volume is substantively equal to zero.

It is worth noting one important characteristic of 0503T with respect to PFS payment policy. 0503T, just as much as the 77X01-77X04 trabecular bone score codes discussed in Section 8.1, is an imaging procedure, albeit image analysis rather than image capture. In the PFS discussion around 77X01-77X04, CMS pointed out that they consider those codes, including technical component 77X03, to be imaging services. CMS wrote, "We believe these codes meet the definition of imaging services under section 1848(b)(4)(B of the Act, and thus, should be subject to the OPPS cap." The OPPS cap limits PFS technical component payments for imaging services to be the lesser of the PFS technical component rate and the OPPS rate. That is, it is not possible for the PFS to pay 0503T more than $950.50 (or successor OPPS rates in the future), even if somehow the PFS rate-setting methodology calculated rates above $950.50.

There is clearly a value to Medicare beneficiaries in developing a direct inputs specification for 0503T in the PFS, however in order to do so, CMS or the RUC must obtain detailed cost information adequate to specify the direct inputs for the code. Without an understanding of *internal* cost structure of the service, and the true direct costs incurred when the service is performed, it is impossible for CMS to draft, propose and solicit public comment on the specification with any confidence that the direct inputs reflect true direct costs.

[53] This threshold of 220 is 11 in the 5% sample weighted to the population. The actual count in the 5% sample is less than 11 services, the threshold below which we are not permitted to publish counts using the claims data.

According to the UK's National Institute for Health and Care Excellence (NICE)'s 2017 review of HeartFlow's technology[54]:

> *After a clinician decides to request a HeartFlow test, anonymised data from a CCTA scan (of at least 64 slices) are sent from the local imaging system, by secure data transfer to HeartFlow's central processing centre in the US. A case analyst employed by the company then uses the image data to create 3D computer models of the coronary arteries, incorporating coronary flow characteristics. The results are presented in a report which is sent, by secure data transfer, to the referring clinician within 48 hours. The report includes both 3D images of the coronary anatomy and calculated functional information, including the estimated FFR values (known as FFRCT values). Clinicians can then use the report to help guide the management of suspected coronary artery disease*

From this, it is apparent that there are at least four direct cost components in the service. First, a "case analyst" develops 3D computer models using the CCTA scan data (and potentially other data inputs) in some specialized way that allows other software to model cardiac fluid dynamics. Second, there is likely specialized software to simplify the case analyst's sophisticated data entry and model setup activities. Third, there is specialized software that models the heart's dynamics. Fourth, there is presumably a significant validation and refinement task to ensure that the resulting modeling is physically and clinically sound before results are sent to the physician, potentially adding clinical labor to assist. All software components of this process flow could be considered SaMD.

From this crude sketch of what *might* be involved in HeartFlow's technical service, one could imagine a basic framework CMS or the RUC could use to specify direct inputs. This framework is inevitably incomplete given the minimal information we have based it on, but some variation of the same basic approach may be workable for national rate-setting. Obviously, HeartFlow would be far better placed to inform the exact makeup of the service.

1. Confirm the workflow to perform the service.
2. Estimate mean technician, clinical labor, etc., time to perform the work
3. Obtain confidential cost information from HeartFlow that separately identifies at least:
    a. Total number of services furnished in the year (which should probably be 2019 given the distorting impact of COVID)
    b. Total costs over the entire business
    c. Corporate overhead, including all salaries and bonuses except direct clinical labor, travel, buildings, administrative software, etc.
    d. Sales, marketing, and promotion activities
    e. All other overhead/indirect cost categories except research & development
    f. Research & development costs
4. Calculate direct clinical labor and any other straight-forwardly identifiable direct costs using the usual direct input specification approach.
5. Calculate residual other direct costs as total costs minus the indirect cost categories collected above, and divided by the total number of services furnished in the year. Use this as a supply

[54] See https://cdn-corpweb.heartflow.com/assets/docs/heartflow-ffrct-for-estimating-fractional-flow-reserve-from-coronary-ct-angiography-64371991952581/heartflow-ffrct-for-estimating-fractional-flow-reserve-from-coronary-ct-angiography-64371991952581.html#div_5a6d_86.

input to capture hard-to-identify specific direct costs involved in the service. This price could be considered the SaMD direct input and be subject to any SaMD indirect allocator direct cost cap.

6. Calculate the PE RVU in the usual way, assuming 100% of billing for 0503T by IDTFs, and soliciting input into the mix of specialties likely to bill 0501T, 0502T and 0504T.

This type of approach is similar to one option MCDA has presented around the external extended ECG reimbursement situation. However, with extended ECG, the largest provider, iRhythm, had SEC filings detailing enough of the above information to sensibly estimate "residual" direct costs with which to specify a direct input. HeartFlow, however, is not a publicly traded company subject to the same reporting requirements. Therefore, CMS or the RUC would need to obtain the needed data directly from the company subject to its willingness to do so.

In lieu of obtaining such data, it appears unwise for CMS to use an alternative method such as setting direct costs equal to the OPPS geometric mean cost for 0503T. Besides the fact that these costs (incurred by the hospital) are based on prices through which HeartFlow covers its indirect costs, under the dynamics of the PFS PE calculation, setting a rate that over-specifies the direct costs would set up a dynamic where HeartFlow would never have an incentive to share data that CMS could use to isolate the true direct costs of the service.[55] That is, it appears far better for CMS to work with HeartFlow to obtain appropriate data to correctly specify direct inputs for a PFS service than to attempt to specify those direct inputs in absence of any real knowledge about the actual direct costs of the service.

If a provider[56] is reluctant to break apart direct costs such that SaMD costs can be isolated, then CMS might consider applying any SaMD indirect allocator direct cost cap policy to the closest level of analysis that includes the SaMD costs (such as all direct costs per service in aggregate with a confirmation that no indirect costs were included). This would essentially expand the scope of such a cap policy but providers would also benefit from sharing adequately detailed data to narrow the scope of such a cap.

8.3. Extended external ECG monitoring, codes 93243 and 93247

Finally, extended external ECG monitoring technical component codes 93243 and 93247 also involve SaMD cost inputs. In MCDA's two 2020 reports on the subject, we reviewed invoices for the software licenses to use the locally-installable versions of the SaMD software sold by BioTelemetry, the second-dominant provider in the market. Specifying SaMD direct inputs based on those invoices as equipment items, we estimated the direct cost per service to be between $3.95 and $9.95 per service depending on the assumptions about minutes of use and the tier of the license (as more and less advanced versions of

[55] To emphasize the problem of including indirect costs, according to the PPIS, approximately two thirds of IDTF practice expense costs are indirect. While the particular cost structure of a clinical image analysis provider will likely be different to the IDTFs surveyed in 2007-2008 when the PPIS was collected, a rough rule of thumb is that CMS would be roughly tripling the direct cost estimates by including the entire OPPS geometric mean cost in a direct input. This would plainly violate CMS's obligation to set RVUs based on relative resources incurred between services.

[56] To be clear, we are not suggesting that HeartFlow would be such a reluctant provider. HeartFlow's mission statement as advertised on the job-search website zippia.com is: "To make cardiovascular care easier for doctors and safer for patients. Physicians get the critical information they need without the added risks and costs of an invasive procedure." Fulfilling this statement in any way beyond the short term requires sound, long-term, viable public payment policy to be established, which in turn implies collaboration between HearthFlow and CMS on the data needed to specify their core service under the PFS within CMS's statutory framework.

the SaMD product are available).[57] As we have previously argued, we believe that it is appropriate for these SaMD costs to be included in the direct input specifications for 93243 and 93247. Given that the SaMD costs per service are apparently modest for extended ECG services, their indirect allocations would not be bound by the SaMD indirect allocator direct cost cap we described above.

Next, we are aware of iRhythm's public statements indicating it continues to pursue reimbursement methodologies outside the standard PFS methodology. Since the 2021 final rule and the subsequent decision of MACs to revise the prevailing rates to levels based on using the standard PE rate-setting methodology (in the order of $110 per service depending on the locality), iRhythm has publicly expressed that they are exploring alternative payment methodologies to work around PFS's standard methodology and potentially persuade MACs to deviate from current PFS standards. Specifically, iRhythm has mentioned proposing a payment idea inspired by "clinical diagnostics," referring to policy used in the Clinical Laboratory Fee Schedule (CLFS). There are a few possible routes iRhythm could be pursuing in this theme. Each has flaws.

First, under the current CLFS methodology, hospitals and independent clinical laboratories are required to report private pay prices for each clinical lab test performed, and CMS sets CLFS payment rates for most tests based on the weighted median of private pay rates for the test. Importantly, this statutory methodology was set up through the Protecting Access to Medicare Act (PAMA) as a budget pay-for, as follows. Unlike almost all other medical services, prior to PAMA, clinical lab tests tended to be paid *less* by private insurers than by Medicare. In the PFS, this relationship is the reverse, with private pay rates being 143% (as estimated by Kaiser Family Foundation) of the same Medicare rates. It would be inappropriate to apply a median (total) private pay rate methodology to a PFS diagnostic service as the context that made this statutorily appropriate under the CLFS does not apply – at all – under the PFS. This was the original attempt at national PFS reimbursement in the 2021 proposed rule for extended external ECG reimbursement, not finalized by CMS.

Second, iRhythm may be referring to two CLFS policy mechanisms used to reimburse CLFS tests that are too new for private pay rate data to exist: crosswalking, used when an existing similar test is available to set the rates; and gapfilling, where no comparable test exists and so payment rates must be concocted based on best available information to reimburse the test. CLFS crosswalking is analogous to CMS's current proxy code approach basing the choice of proxy code on a both clinical and likely cost similarity. CLFS gapfilling is analogous to deferring payments to the MACs, leaving each MAC to perform its own research and determine its own best available information judgment about what the test should be paid.

Under both the crosswalking and gapfilling methods, there is one critically important feature of CLFS policy. CLFS will only apply a crosswalk or a gapfill for a test *until the usual data to price the test become available under the standard CLFS methodology*. CMS CLFS policy does not allow a crosswalked or gapfilled code to remain outside the normal rate-setting calculation once the primary methodology is viable (i.e., when private lab test payments data have been submitted for the code). The PFS applies essentially the same policy when it must deal with gaps in necessary data – proxy direct inputs, RVUs or utilization

[57] In MCDA's reports, we estimated PFS rates both using invoice data from BioTelemetry's product and using cost data from iRhythm's Security and Exchange Commission (SEC) filings. PFS rates under both specifications were similar, suggesting that the BioTelemetry software cost data were likely similar to iRhythm's internal software operating costs.

data may be used in the short term, but when data specific to the code are available, CMS replaces the proxy data so that the code can be reimbursed under the standard methodology.

Short of iRhythm recertifying itself as a Clinical Laboratory and persuading the AMA to create an 80000 series CPT® code for extended external ECG diagnostic tests, it would be wholly inappropriate for CMS or the MACs to apply an adapted version of the CLFS methodology to reimburse extended external ECG services.

While adjustments to the methodology are sometimes appropriate, CMS is wise to approach methodological changes with a high degree of caution and reject any below a high bar. Our own policy sketch presented in Section 5 should be met with no less. The potential ripple effects are simply too vast to do otherwise. If any stakeholder wishes for a methodological override for their particular code or group, and that methodology would be inappropriate if extended to the whole PFS (in extended external ECG's case, technical component services involving SaMD and whose ***current*** billing providers are primarily vertically integrated), then that methodology is inappropriate for the PFS.

For patients wishing to gain access to PFS services involving SaMD inputs, providers and manufacturers providing the services and inputs (and the societies representing them), investors supporting the SaMD companies, innovators developing future SaMD products, CMS, and the Medicare Trust Fund itself, it is critical that CMS establish policy around SaMD in a way that is methodologically integrated into the PFS in a *sustainable way*. That is, as the inevitable expansion of SaMD products plays out, CMS must ensure that the policy is unlikely to create a mess for all that undermines future access to innovations for patients and the work of all of the upstream stakeholders.

Conclusions

This report has presented our analyses and perspectives for a policy framework for CMS and the MACs in their work to reimburse Software as a Medical Device (SaMD) costs under the PFS. The topic is expansive and complex, with many intricate features of the PFS's technical methodology, including the SaMD market's characteristics, the strategic realities of CMS-stakeholder negotiations when specifying codes, and indeed the annual budget that the PFS is allowed to pay for its services.

Ultimately, while SaMD presents an expansive and complex policy situation, CMS should be commended for being both cautious to guard the PFS against unintended consequences arising from inadvisable payment policy decisions and simultaneously working aggressively to understand the complex issues towards developing viable and sustainable PFS SaMD payment policy.

In addition, while through this report we have recognized and accounted for the strategic realities of stakeholders wishing to maximize reimbursement, this is purely in the context of the realities underlying negotiations between CMS and stakeholders – it is not an aspersion, and indeed it is a perfectly understandable and generally ethical for providers to pursue reimbursement to serve their patients and run their businesses viably.

There are, however, important design features built into the PFS that, under the reality that the PFS budget is constrained by a mechanism established by statute, that mean that providers generally cannot (and should not) obtain workarounds to reimbursement outside the methodology.

One esoteric exception to this is that there exists an artefact of the methodology that medical supplies and equipment are reimbursed close to cost (where overall practice expenses are paid significantly below cost, at least according to CMS's own data used to set the rates). This feature (arguably not a bug) of the system may explain why many advanced medical devices are viably performed under the PFS, despite the PFS overall paying significantly below cost.

Just as with traditional advanced medical devices – the newest member of the medical device club, Software as a Medical Device (SaMD), can be viable under the PFS methodology. All that is required is for CMS to include SaMD medical devices as direct inputs in the PFS, just as they would any other medical device.

However, because SaMD is nascent, its economics, its efficacy considerations, and impacts on the broader practice of medicine, are in the early stages of playing out and being understood. It is unlikely that we will fully understand the policy considerations until SaMD grows and matures further, at which time any interim policy treatment in the PFS should be reviewed and revised accordingly.

Because of the newness of SaMD for the PFS, we believe that CMS's caution around valuing it is warranted and wise. Specifically, we believe it would be reasonable for CMS to limit the close to one-to-one translation of direct costs to total PE payments for SaMD. Capping the indirect allocations that can result from SaMD direct inputs at an intentionally high level (unlikely to be binding for most SaMD products) would allow the usual PFS reimbursement dynamics up to a point, and then SaMD direct costs over that level would still result in increased PFS payment but at a decreased rate. As the SaMD market evolves, such a policy may turn out to be warranted or not, but in the mean time would both provide guardrail and allow payment as the policy community continues to learn the policy dynamics and considerations.

This payment guardrail could be accompanied by an efficacy guardrail if CMS wishes to establish policy on that front. Specifically, CMS could require that prospective SaMD inputs be FDA cleared. As the FDA has been working actively for a number of years in updating its efficacy and safety policies for SaMD product applications, it appears to be the furthest along agency in the Executive Branch in its understanding the unique characteristics of SaMD products. In addition to the FDA's potential role as gatekeeper from an efficacy standpoint (albeit with the limitations of its historical processes), the American Medical Association (AMA) also serves an implicit gatekeeper role through its role in creating CPT® codes in the first place. Specifically, if the AMA does not create a CPT® code to reflect a clinical service, then the PFS will not be asked to pay for it (except potentially through a HCPCS code created by CMS, through which CMS would retain its own gatekeeper role for those services). As the AMA generally prefers to only create sensible CPT® codes reflecting valuable clinical services, it appears likely that they will be averse to creating CPT® codes to reimburse useless or ineffective SaMD services.

While CMS is right to be cautious, CMS should also not delay establishing PFS SaMD policy any longer than necessary. The current placeholder policy of crosswalking SaMD codes to proxies who attain the payment level that would result from simply including SaMD as a direct input becomes problematic if used for longer than a year or two. We expect CMS to receive an increasing number of SaMD codes to value, and CMS simply cannot allow this workaround to become status quo policy.

Finally, we again emphasize our appreciation for CMS working intently and actively on the topic. We believe that SaMD has the potential to provide genuine benefit to Medicare's beneficiaries, providers, and the ongoing investment in improving healthcare over the coming decades. CMS's treatment today is the predicate for SaMD technologies' value and availability in the future.