Filed electronically via http://www.regulations.gov

May 9, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: *Medicare Program; Part B Drug Payment Model* [CMS-1670-P]

Dear Acting Administrator Slavitt,

International Oncology Network Solutions, Inc. ("ION Solutions") and International Physician Networks, LLC ("IPN"), both subsidiaries of AmerisourceBergen Corporation, are pleased to submit comments and share our concerns over the Centers for Medicare and Medicaid Services (CMS) 2016 proposed rule entitled "Medicare Program; Part B Drug Payment Model; Proposed Rule (CMS-1670-P)," which was published in the Federal Register on March 11, 2016.

I. About AmerisourceBergen

AmerisourceBergen is one of the largest global pharmaceutical sourcing and distribution services companies, helping both health care providers and biopharmaceutical manufacturers improve patient access to products and enhance patient care. Through its specialty division, AmerisourceBergen is the largest distributor of specialty drugs to all sites of care in the U.S, including physicians and health systems outpatient departments furnishing medications. With services ranging from drug distribution and niche premium logistics to reimbursement and pharmaceutical consulting services, AmerisourceBergen delivers innovative programs and solutions and services to aid providers in managing and improving their practices from both an efficiency and quality outcomes perspective.

ION Solutions, currently partners with 1,400 oncology practices with 4,500 physicians, representing more than half of the community oncologists in the U.S., who rely on ION Solutions for the technologies, resources, and expertise they need to improve clinical and operational management. Through our relationship with oncologists and manufacturers, ION Solutions has significant insight into the practice of oncology and the use of infused and oral drugs in the treatment of cancer, specifically in the areas of appropriate treatment selection, costs of therapy and associated practice economics, and increasing patient adherence to treatment. In support of this mission, IPN in turn offers a group purchasing network for community

oncologists ("ION"), while also providing support to more than 5,000 additional specialty providers in the areas of rheumatology, ophthalmology, urology, and gastroenterology.

General Comments

As you know, Medicare Part B covers most drugs administered in physician offices and hospital outpatient departments (HOPDs) as well as certain other drugs provided by pharmacies and suppliers (e.g. immunosuppressive drugs). As required in statute, these drugs are generally reimbursed at ASP plus a six percent add-on. Like other Medicare services, reimbursement for Part B covered drugs is subject to budget sequestration, which went into effect on April 1, 2013.

The Centers for Medicare and Medicaid Services' (CMS) proposal would alter reimbursement for Part B-covered drugs to ASP plus a 2.5 percent add-on payment for nearly 75 percent of providers later this year while later layering on a set of value-based purchasing arrangements in a second phase of the model. Few details are known about Phase II of the model, which is scheduled to begin sometime next year. Both Phases will interact with many other payment reforms that are currently being implemented, including other demonstrations underway or set to begin shortly through CMS.

We have considerable concerns and urge you to withdraw the proposal in its current form. We firmly believe the design and scope of its implementation will have significant, negative unintended consequences.

Based on our view of the Part B market, reducing the average sales price (ASP) add-on to the proposed level will blunt the adoption of, and access to, newer, more efficacious therapies since reimbursement will not cover the cost to acquire these therapies for practices, particularly those that are already struggling to face steady or increasing costs coupled with lower reimbursement, are located in underserved medical communities, or who serve a disproportionate number of Medicare beneficiaries. As a result, many providers will be forced to send patients to costlier settings to receive treatment.

CMS has stated that shifting prescribing behavior toward less expensive treatments is a primary objective of the model, but this presupposes that less expensive, alternative treatments are readily and widely available. To the contrary, in cancer care, for example, these less expensive treatments are typically older, less effective, and more toxic, resulting in more patient side effects. Because CMS intends to incentivize the prescription of these less expensive therapies through the proposed model, we would expect the treatment profile and standard of care for many conditions to resemble those seen 3-5 years ago with increased cancer relapses, higher mortality, increased prescription of and need for supportive care products such as opiates and anti-nausea drugs, and more patients experiencing and requiring treatment for side effects, including emergency room and hospital visits.[1]

Moreover, we are concerned that Phase II of the proposal, though loosely defined in the proposed rule, would erect further barriers to the most effective drug therapies and patient-centric care, particularly if a broad, representative array of stakeholder input is not integrated and

[1]ASCO, Clinical Cancer Advances 2016 Annual Report. Retrieved at http://www.cancerprogress.net/cca/how-far-weve-come-decade-review.

involved in the development of the model. We are also concerned that the interaction with various other payment changes and demonstrations could make it both difficult to discern effects of any particular change on the system and impede progress being made toward transitioning toward a value-based payment system.

The likely impact of the proposal, and the possible outcomes associated with it, are in direct contradiction with health care reforms set into place by the Affordable Care Act (ACA) as well as the Medicare Access and CHIP Reauthorization Act (MACRA) currently being implemented, and should be avoided, not encouraged, by Medicare payment policy.

If CMS is concerned that physicians are incentivized to prescribe higher cost drugs when equitable alternatives are available due to the six percent add-on, we urge you to work with stakeholders to identify whether this concern can be validated by a thorough review of available data before undergoing a national, mandatory experiment that patients cannot easily opt out of and could possibly jeopardize their care. We urge you to work with stakeholders to devise a new model that can help lower health costs while maintaining or improving quality of care, including decreasing emergency room visits, avoidable hospitalizations and readmissions, and unnecessary imaging and other services, while increasing utilization and development of better care coordination and management for those patients dependent on Part B-covered drugs.

II. Flawed Premise for the Model

CMS' underlying justification and reasoning for the Part B model proposal belies a fundamental misunderstanding and assumptions for the interactions between reimbursement and medical practice and standards for Part B covered drugs.

Prescriber Behavior

According to CMS, the purpose of the proposed model is to test whether alternative payment approaches to drug reimbursement under Part B will lower costs and improve value for patients and the system. Yet nothing in Phase I of the proposal specifically indicates how this will be measured or evaluated. Further, CMS asserts that the current system incentivizes providers to prescribe higher cost drugs in order to recoup a greater add-on payment with no clear incentive for providing high-value care. However, CMS does not provide any empirical evidence that indicates providers are actually prescribing higher cost drugs at statistically significant rates when equivalent therapeutic alternatives are available.

After careful review, both ION Solutions and IPN have concluded that the fundamental premise and foundation of the model is both flawed and lacking in supporting evidence. There is no credible data indicating that the current formula drives prescribing habits toward more expensive drugs when comparable alternatives are available. At least 75 percent of oncology patients receive at least one generic product in their prescribed treatment regimen while less than 50% of patients will receive a more expensive, targeted therapy – the majority of which are received in later treatment episodes after disease progression or relapse.[2]

[2] IntrinsiQ Specialty Solutions. IntelliVIEW®. April, 2016. Available via subscription at www.intrinsiq.com.

CMS largely bases the Part B Model on Medicare Payment Advisory Commission's (MedPAC) Part B drug payment proposed policies in its June 2015 Report to Congress. According to this report, for the current payment methodology to actually create the incentive to use a higher priced drug, there must be alternative drugs with different prices available to treat a particular patient's condition. The proposal largely ignores this fact. There is currently no clear data that either quantifies the amount of total Part B drug spending accounted for by drugs that have differently priced substitutes available or indicates that more expensive drugs are prescribed when lower priced alternatives are available to any significant degree.

Further, according to MedPAC, the vast majority of drugs administered or prescribed under Part B are relatively inexpensive. In fact, 60 percent of Part B drugs receive a total reimbursement per administration of $50 or less and nine out of 10 Part B drugs used by most beneficiaries have an average ASP plus six percent add-on payment per administration of $13 or less. Due to newer, more expensive therapies being indicated to support more advanced disease or where no other therapeutic alternatives exist, a relatively small percentage of patients receive the costliest drugs under Part B. In fact, a large number of the most commonly prescribed medications that are the standard of care do not have a lower priced alternative available at present. If perverse incentives to prescribe higher cost drugs were an inherent and systemic problem within the system, we would see providers prescribing a much larger percentage of expensive drugs, particularly when cheaper substitutes are available, as their first therapy. We simply do not see this in the data.

Based on the current data and analytics available via IntrinsiQ Specialty Solutions ("IntrinsiQ", a corporate affiliate of ION Solutions and IPN as described more comprehensively in the Appendix), the data clearly indicates that when a lower priced alternative is available or enters the market, prescribing overwhelmingly shifts to these alternatives as physicians are incentivized in various ways to prescribe the most efficacious and cost-effective therapies, including helping to ensure patient adherence to treatment regimens. The selection of a treatment regimen is based on a number of factors associated with a patient's condition or previous response or lack thereof; thus, drug costs and reimbursement have little influence on prescribed therapies. When lower priced, clinically appropriate alternatives are available, data shows that providers overwhelmingly shift to these. If a lower cost alternative is not available and a provider is unable to obtain the appropriate therapy because the cost of acquiring it is too high, patients will have no other recourse other than to be shifted to higher cost treatment centers to obtain needed therapies.[3]

In fact, market data shows:

- When generic alternatives are available, the adoption of those agents is almost immediate. When there is unstable drug supply or inconsistent clinical outcomes, the utilization of the generic agent(s) will fluctuate until market dynamics are adequately addressed. Further, when new, equivalent or more effective oral therapies enter the market, prescribing behavior shifts toward their utilization even though these are not reimbursed through Part B.
- Utilization of branded drugs must be examined by specific indication, not in aggregate across disease states. A branded drug with well-established clinical evidence for a given

[3] IntrinsiQ Specialty Solutions analysis. IntelliVIEW®. April, 2016.

disease will be prescribed over a generic while the same generic will be prescribed over brand when they are considered to be clinically equivalent.

- Further, there is insufficient evidence to support the notion that the current ASP add-on incentivizes the use of more expensive targeted therapies. Data demonstrates that the adoption of targeted therapies is only higher in later lines of treatment after other treatment regimens have failed (see Appendix for analysis and examples).

III. Proposed Payment Changes Do Not Provide an Accurate Picture

As stated earlier, Medicare reimburses physicians and hospitals for the cost of Part B drugs at a rate tied to the ASP for all purchasers plus a percentage of the ASP. The current six percent add-on payment is then reduced to 4.3 percent under the budget sequester enacted in 2011. Under the new proposal, CMS would retain the current rates in some communities and set a reduced rate of ASP plus 2.5 percent in addition to a $16.80 flat fee in others. After the sequester is factored in, the add-on in the proposal's "test group" areas would be ASP plus 0.86 plus $16.53.

Additionally, prompt pay discounts, which are factored into the ASP but are not passed on to providers, decreases total reimbursement further by one to two percentage points. Further, some states and localities impose taxes or assessments on drugs (e.g. Illinois has a one percent across-the-board assessment), which raises acquisition costs, but are not recognized in the reimbursement. Finally, the very definition of ASP means that many providers pay significantly higher rates to acquire some drugs. This means that the current methodology does not accurately reflect the true costs needed to obtain Part B covered drugs, particularly for smaller practices. Congress prescribed a six percent add-on payment to help provide a buffer for variations in acquisition costs, but even under the current system, Medicare reimbursement frequently does not cover costs needed to obtain, store, and administer more expensive drugs.

None of the foregoing is appropriately reflected under the CMS model. The reality is, even with the flat add-on fee, providers will be under water for all drugs above a certain threshold, making it more difficult to acquire needed therapies for patients. Recent analysis by Avalere has determined that under the proposed model, providers would see reduced reimbursements for any drug that costs more than $480 with payment reductions being heavily concentrated in a subset of drugs that patients depend on.[4] In fact, seven of the 10 drugs that will receive the largest reduction in reimbursement are used to treat cancer. We are extremely concerned that this will pose a significant barrier to providers' ability to readily obtain these drugs.

In its June 2015 report, MedPAC questioned the effect of changing the reimbursement level of Part B drugs on providers' ability to purchase drugs at a price within the Medicare payment rate. MedPAC indicated that due to variation in drug acquisition costs for various providers, many providers – particularly smaller ones – would not be able to purchase some expensive drugs at prices within the Medicare reimbursement amount.

[4] Avalere. (April 2016). Proposed Medicare Part B rule would reduce payments to hospitals and some specialists, while increasing payments to primary care providers. Retrieved from: file:///C:/Users//Downloads/1460041943_20160407_Part_B_Demo_Impact.pdf.

Under the CMS model, reimbursement post-sequester will be ASP plus 0.86% plus $16.53. We are concerned the vast majority of treatments may be underwater in the model. In order to understand the number of drugs covered by the proposed payment rate, IntrinsiQ conducted an evaluation based on the published wholesale acquisition cost (WAC)[5] for each drug. For therapeutic drugs within oncology, at least 50% of the drugs would be fully covered by the proposed rate if acquired at a cost of at least 40% off of WAC. However, this level of discounting on drug acquisition cost represents an amount far greater than what is actually available to providers in the commercial marketplace (refer to Appendix for method used for analysis).

In the proposal, CMS acknowledges that the changes in reimbursement may negatively impact the ability of providers to obtain certain drugs. In particular, CMS expresses its concern about how to treat drugs that are in short supply. Due to access concerns over obtaining these drugs, CMS proposes adding a safeguard and maintaining reimbursement with the current statutory payment methodology of ASP plus six percent add-on.

While we appreciate CMS' acknowledgement that the proposed payment methodology will likely make it even more difficult for providers to obtain these needed drugs, we believe that CMS is not fully considering the impact on payment changes for other drugs on providers' ability to obtain both drugs in short supply as well as more expensive drugs generally. Smaller practices, in particular, will be forced to bear the increased financial costs in administering these drugs to their patients, and forcing reimbursement below the rate of acquisition costs for many drugs with no therapeutic alternative will not only make it increasingly difficult for providers to obtain these drugs but will also make it more difficult to obtain drugs in short supply, particularly if they also have higher acquisition costs.

ION Solutions and IPN strongly believe that it is imperative for CMS to both understand and evaluate the actual Part B reimbursement rate as well as acquisition costs for various providers and the proposed changes' impact on acquisition for various drugs under the model. This must take place before implementing fundamental changes that are likely to have a significant impact on treatment for the majority of beneficiaries treated with Part B covered drugs.

IV. Negative Impacts on Patient Access and Treatment

According to CMS, the purpose of the model is to determine whether altering reimbursement for Part B covered drugs can reduce costs and increase quality for both beneficiaries and the system. ION Solutions and IPN are extremely concerned the model will actually have the opposite effect and that Phase I of the proposal could harm Medicare beneficiaries' access to both innovative therapies and community providers while potentially diminishing their quality of care depending solely on where they live. This could not only disrupt treatment but could also increase costs for Medicare as service is shifted to higher-cost providers.

There has been an undeniable shift toward consolidation in the health sector as independent provider practices find it increasingly difficult to absorb repeated reimbursement cuts when operation costs remain steady or increase. Further, as the population ages, Medicare beneficiaries

[5] Wolters Kluwer Clinical Drug Information – MediSpan Database via subscription.

increasingly make up a disproportionate amount of providers' patient populations making it difficult to offset Medicare reimbursement cuts with higher commercial insurance reimbursement. In particular, community practices are being acquired by hospital systems and converted to HOPD status in order to leverage the resources of larger health systems.

It has been repeatedly shown that consolidation of independent practices with larger health systems has driven up the cost of care for the system. For example, a recent Milliman study tracked shifts in site of service care for chemotherapy patients from 2004 to 2014 and estimated that in 2014, alone, Medicare spending would have been $2 billion lower if the site of service shift had not occurred.[6] The study further estimated that per-patient-per-year spending in 2014 would have been 7.5 percent lower for Medicare beneficiaries receiving infused chemotherapy while it would have been 5.8 percent lower for patients with commercial insurance.[7]

In addition, price variation is likely to continue as the disparity between smaller practices – particularly in underserved areas – and larger health systems – particularly in more affluent areas – is much wider now than it was when the current payment methodology was instituted. MedPAC believes that this would likely lead to smaller practices sending patients to larger practices or HOPDs for certain expensive drugs. While HOPDs would also be subject to the proposed changes, they are expected to fare better than physician offices since they generally have greater resources than independent physician offices to absorb and offset any negative financial impact. If these types of shifts in site of care occurred, the effect on beneficiaries would likely include increased travel, cost-sharing and other expenses, and treatment adherence would likely be negatively affected.

We strongly believe that Phase I of the model will lead to further site of service shifting for patients and potentially lead to further provider consolidation as practices continue to struggle to maintain operation in the current environment. We are particularly concerned about the effects this may have on patients in underserved medical areas. It is clear that the shift in site of service has significantly increased costs for patients and taxpayers and we implore CMS to examine the likely impact that this proposed demonstration and other current payment policies and proposed changes would have in both the HOPD and physician office setting.

Further, we are extremely concerned that providers will face additional challenges in obtaining drugs with higher acquisition costs that are necessary for patient care, which could lead to suboptimal and delayed treatment. This could further lead to higher use of drugs to manage side effects and/or increase the need for emergency room or hospital visits. Because of the impacts of these models, we are extremely concerned that patients in areas with the experimental reimbursement structure will also have delayed access to the newest, most promising therapies.

For example, new therapies such as immuno-oncology therapies, which leverage a patient's own immune system to fight cancer, have the promise of being both highly efficacious while producing little if any toxicity or severe side effects. These therapies are costly to develop but

[6] Fitch, K., Pelizzari, P., & Peynson, B. (April 2016). Cost drivers of cancer care: A retrospective analysis of Medicare and commercially insured population claim data 2004-2015. Milliman. Retrieved from: http://www.communityoncology.org/pdfs/Trends-in-Cancer-Costs-White-Paper-FINAL-20160403.pdf
[7] Ibid.

may have substantial benefits that could lead to lower down-stream costs, including less need to treat side effects through additional therapies or inpatient services and dramatically improved clinical outcomes. We still do not have enough experience with utilization of these therapies to accurately predict their effectiveness on a broad population in a real-world setting, but initial findings indicate that the utilization is shorter and thus the associated cost compared to other agents, including oral options, is less.[8] The proposed demonstration poses a significant threat to the proliferation of such promising therapies because of the added acquisition barriers inherent in the design.

It is also imperative to note that for a large number of treatments which represent the standard of care for particular conditions, there is currently no alternative to a branded drug or a combination of a branded drug with another therapy. For example, the use of Herceptin to treat HER-2 positive breast cancer represents is the standard of care, but has no current generic alternative. Studies have shown that when used in conjunction with other chemotherapies, the use of Herceptin cut the risk of recurrence in half compared to using chemotherapy alone, improving quality of life and outcomes while also reducing downstream costs.[9]

While we appreciate that CMS has included an appeals process in the model for both beneficiaries and providers, we do not believe there are enough details on how the process will be implemented and are also concerned that the length of time to exhaust the appeals process could interfere with a provider's ability to provide treatment without interruption or a beneficiary's ability to said treatment.

All of these potential negative effects will certainly harm both quality of care and quality of life for patients while potentially leading to higher costs through more complications, hospitalizations, and less successful outcomes. The proposal does not fully account for these likely negative effects, especially in complex conditions like cancer. We strongly believe that the proposal's focus on costs (particularly using the flawed methodology as described earlier) at the expense of patient quality of life and outcomes is diametrically opposed to the Administration's drive toward patient-centric, value-based, and outcomes-driven care modalities.

V. Interference with Transitioning to a Value-Based System and Medical Innovation

ION Solutions and IPN are extremely concerned that the proposal is scheduled to take place at the same time as a number of other payment changes and demonstrations, including those driven by MACRA such as the push toward Alternative Payment Models (APMs), which are helping the system to move toward paying for value over volume. This will not only make it difficult to discern changes and success in the system from one change or another, but could also halt progress on transitioning to APMs for providers and their patients.

[8] IntrinsiQ Specialty Solutions. IntelliVIEW®. April, 2016. Available via subscription at www.intrinsiq.com.
[9] Slamon D, Eiermann W, Robert N, et al. for the Breast Cancer International Research Group. Adjuvant trastuzumab in HER2-positive breast cancer. N Engl J Med. 365(14):1273-83, 2011.

To date, many current and forthcoming demonstrations and APMs are voluntary. Providers evaluate their ability to participate and succeed in a particular model, submit applications, and are selected based on these criteria. ION Solutions has been particularly interested in the Oncology Care Model, which will begin later this year. Providers who applied to participate in the model did so under certain assumptions, including the maintenance of the current reimbursement method for Part B drugs, which these practices heavily utilize. The proposed changes will likely impact the ability of providers to succeed under the demonstration and could halt progress toward transitioning toward a system that reimburses for the volume of care rather than value.

We are also concerned about the impact this model would have on the implementation of the Merit-Based Incentive Payment System (MIPS). The Administration has taken into account a good deal of feedback from the provider community in preparing to transition to MIPS, and we are appreciative of those efforts. However, this feedback did not take into account the current Part B demonstration. We believe that major challenges could be especially problematic if CMS makes 2017 the first performance year and baseline against which future improvement will be measured under MACRA. The impact of the demonstration on provider practices and patients could significantly impact the ability of CMS to accurately gauge cost and quality baselines and improvements consistently across the various sectors which would impact both MIPS and APMs performance measures.

We strongly believe that the goal of reducing overall costs while maintaining quality of care could be better achieved through focusing the resources otherwise allocated to the Part B demonstration towards implementation and evaluation of these programs and ensuring success in these promising approaches rather than be diverted to managing effects of such a wide-scale reimbursement change.

Finally, we are extremely concerned about the confusing and seemingly contradictory approaches being taken to more efficiently deliver patient care. There is widespread support for the Administration's Cancer Moonshot, Precision Medicine Initiative, increased National Institutes of Health funding, and the move toward adding value in the system. These are all worthy programs determined to develop innovative, curative therapies for devastating diseases while also rewarding higher quality, coordinated, and more efficient care. However, the Part B demonstration counterintuitively undermines these initiatives by curtailing certain treatment choices available to patients simply because these therapies are above a certain price threshold, thereby limiting access.

VI. Lack of Clarity Around Phase II of the Model

Phase II of the proposed model considers various approaches for applying value-based purchasing tools. As stated previously, we are generally supportive of the move to transition the health system toward one that is based on reimbursement for value rather than volume – this is true for both drugs and other medical services. The proposed rule does not detail how the various tools would be utilized in the model. We urge CMS to provide more specificity and granularity on these approaches. It will be virtually impossible to assess the proposals accurately or provide detailed feedback without this information.

While there is not sufficient detail in the proposal, we are still concerned about a number of stated approaches CMS proposes to utilize in Phase II of the model. In particular, we are concerned about the potential inclusion of reference pricing in Phase II of the model. The interchangeability of certain drugs is a core premise behind the use of reference pricing, in which the effectiveness of drugs within a disease group are reimbursed based on the least expensive option. As we have pointed out, many Part B covered drugs do not have therapeutic equivalents or alternatives. Even in cases where there are multiple treatments for a condition, it is false to believe that all available drugs in that class would have equal efficacy or effect on every patient. Like other aspects of the proposed demonstration, this would have significant, negative consequences for patient treatment and outcomes.

While we urge CMS not to finalize the Proposed Rule with respect to the Part B demonstration, if CMS moves forward with any iteration, we implore CMS to offer a formal comment period once the details of Phase II are more thoroughly detailed. We further urge CMS to solicit and take into account stakeholder input by issuing a request for information before developing more detailed proposals.

Phase II of the model is substantially more complex and difficult to implement than Phase I. While there is potential to design a value-based purchasing demonstration in a way that could lead to quality outcomes and help transition to a value-based system, there is a high potential for implementing it in such a way that would have the reverse effect. Because of this, it is imperative for CMS to include stakeholders with expertise in value-based purchasing design and arrangements as well as providers who currently engage in patient treatment and experience in the development of these proposals.

VII. Conclusion

There is a strong potential that these proposed changes will have serious, negative consequences for both patients and providers. Based on the areas outlined, ION Solutions and IPN strongly implore CMS not to finalize the Proposed Rule.

It should be noted that MedPAC is in agreement with this notion. In its most recent public meeting, MedPAC declined to include any recommendations to modify the ASP methodology as the Commission acknowledges that further study and evaluation of the current system is needed before changes are considered. The Commission does not intend to include any recommended payment changes for Part B drugs in the June 2016 report to Congress.[10]

In light of these issues, we urge you to work with stakeholders to identify whether the problems raised by CMS exist through a thorough review of available data before enrolling cancer and other patients in a national experiment that may jeopardize their care. As you undertake study of alternative payment methodologies, we urge you to work with stakeholders to evaluate payment approaches that lower health costs while maintaining or improving patient access and quality of care. It is vital to keep patient treatment and access to vital therapies paramount in any considerations going forward.

[10] MedPAC April 2016 Public Meeting, Medicare Part B Drug and Oncology Payment Policy Issues session transcript. Retrieved at http://www.medpac.gov/documents/default/april-2016-meeting-transcript.pdf?sfvrsn=0.

ION Solutions and IPN appreciate your careful consideration of our comments and stand ready to serve as a resource to CMS. We look forward to working with you to help ensure a successful transition toward reimbursement based on value while guaranteeing patient access to the best care available.

Sincerely,

Vicki Albrecht
SVP and GM, ION Solutions and
IntrinsiQ Specialty Solutions

Mark S. Santos, R.Ph
President
International Physician Networks

Appendix

This appendix, based on analysis completed by IntrinsiQ Specialty Solutions, Inc[11]., a division of ION Solutions, supplements ION Solutions' comment letter addressing the Medicare Program: Part B Drug Payment Model Proposed Rule. The analysis and figures below illustrate inaccuracies in CMS' premise that Medicare's Part B drug reimbursement methodology – ASP +6% -- influences practitioners' prescribing behavior. If physicians were incentivized to utilize higher priced medications in oncology, there would be evidence of three market dynamics:

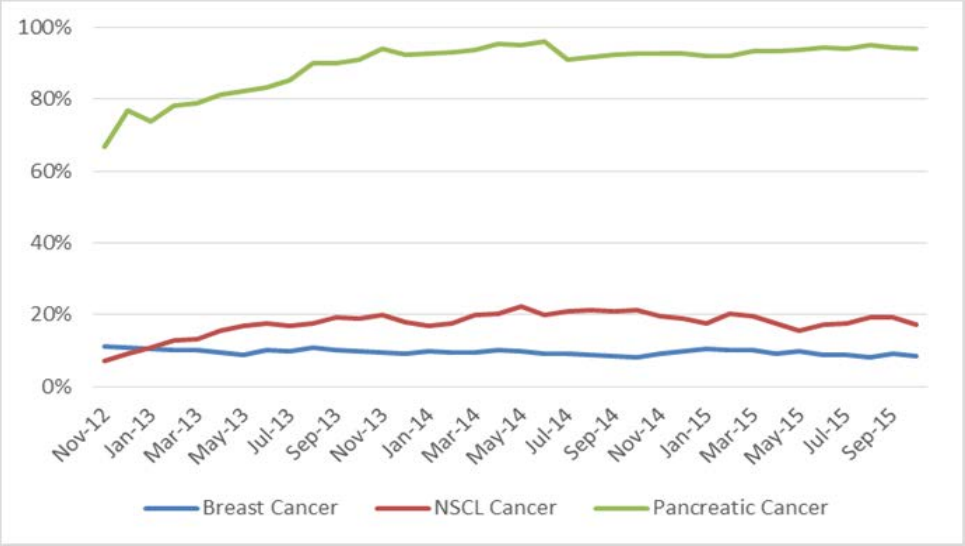
- Lower use of generic oncolytics;
- Higher use of targeted therapies and biologics; and
- Lower use of oral oncolytics.

The following data present real world, practice-based evidence of prescribing patterns of cancer drugs across a sample of sample of diagnoses. The data show providers prescribe the most clinically appropriate, evidence-based therapy regardless of the financial method on which these treatments are reimbursed.

In Figure 1, the utilization rate of Abraxane® is compared across three dominant indications: breast, non-small cell lung (NSCL) and pancreatic cancer. Physicians could also use the generic alternative, paclitaxel. This graph shows that indeed in breast and NSCL cancer physicians are prescribing the paclitaxel over Abraxane®. While in pancreatic cancer, they are prescribing predominantly Abraxane® due to differentiated clinical evidence over paclitaxel.

[11]IntrinsiQ Specialty Solutions provides a range of custom analytic solutions, from healthcare resource utilization trends to treatment sequencing analyses. The analysis in this appendix are based on IntrinsiQ's IntelliVIEW platform.

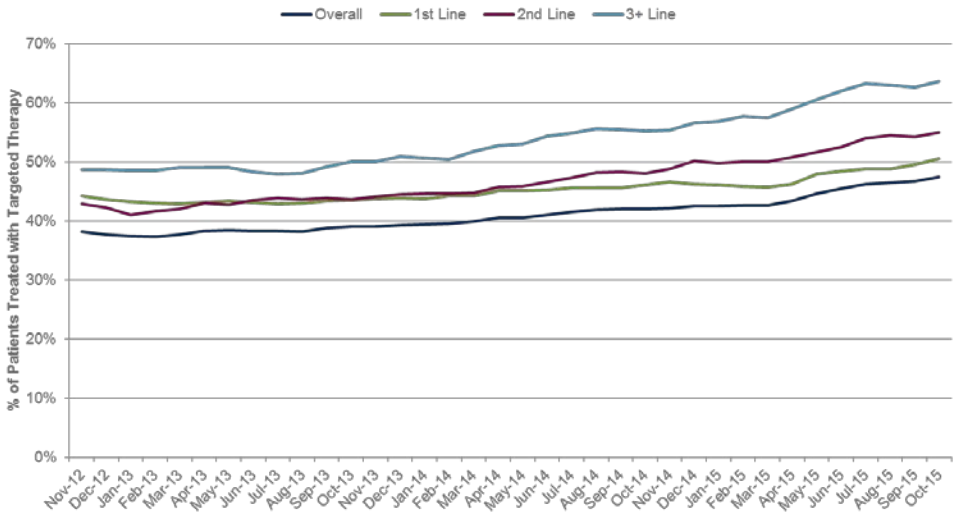
Figure 1. Utilization Rate of Abraxane® for Approved Indications



Ref: IntrinsiQ Specialty Solutions. IntelliView. April 2016.

With respect to the use of targeted therapies in oncology, Figure 2 shows that the use of targeted therapies are in the later lines of therapy, that is, in patients with advanced disease and/or disease progression. Overall less than 50% are treated with a targeted therapy in all patients regardless of age. This utilization is growing faster within the later lines of therapy, which is consistent with the current indications of newly approved targeted therapies.

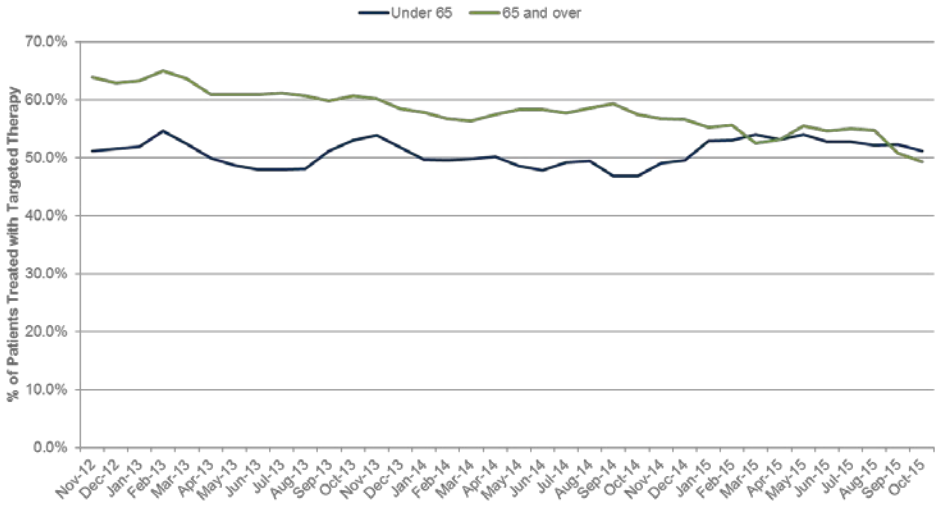
Figure 2. Targeted Therapy Utilization Higher in Later Lines of Therapy After Disease Progression/Relapse



Ref: IntrinsiQ Specialty Solutions. IntelliView. April 2016.

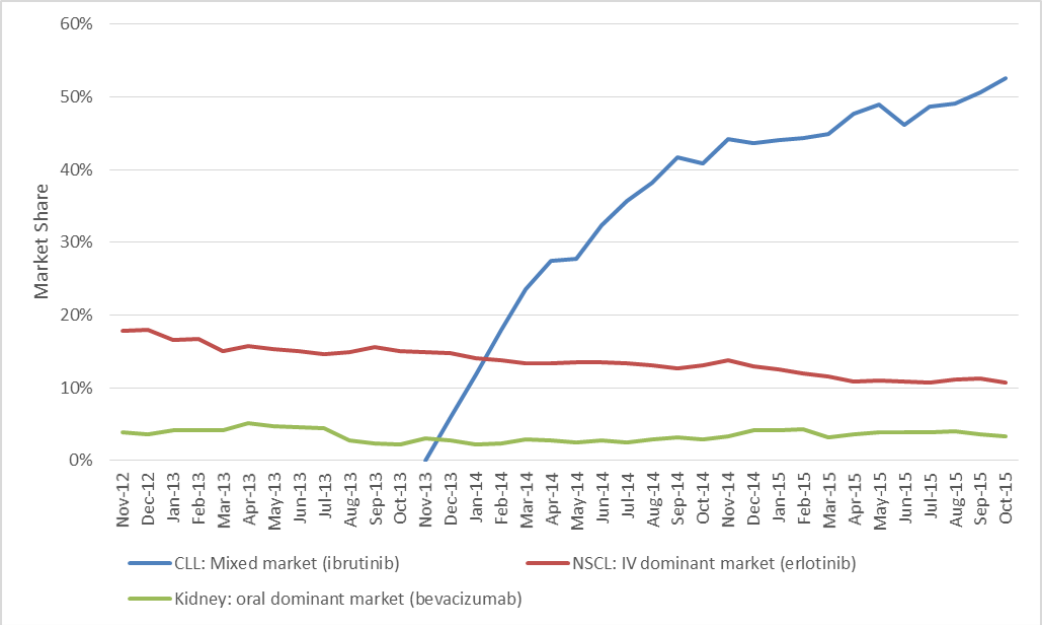
When considering the potential differences that may exist between the Medicare and commercial patients, the rate of targeted therapy use was assessed in multiple myeloma, a disease with increasing prevalence in the elderly population. As demonstrated in Figure 3, the utilization rate of these targeted agents have been declining within the Medicare patients compared to the commercial patients, which has remained consistent over the last three years even with the approval of newer targeted therapies.

Figure 3. Targeted Therapy Utilization in Multiple Myeloma Patients Declining in Medicare Population



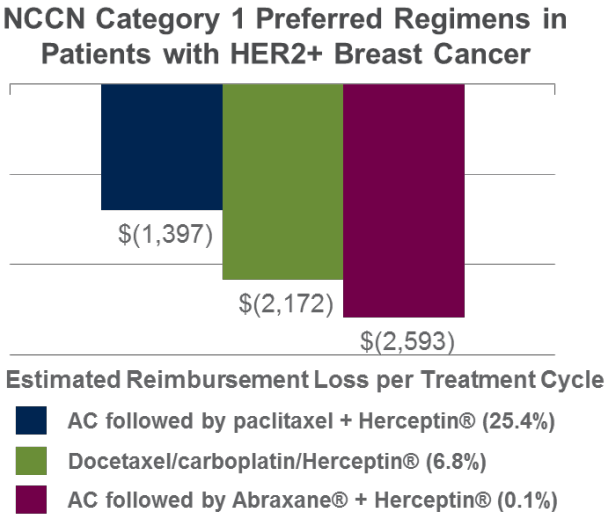
Lastly, if provider prescribing behavior was influenced by the ASP + 6% mechanism to prescribe higher priced drugs, the use of oral oncolytics should be relatively low given the availability of injectable drug options. An evaluation of chronic lymphocytic leukemia (CLL), NSCL and kidney cancer was conducted to assess the adoption of oral oncolytic drugs given prominence of IV-based therapeutics. Figure 4 shows that in the case of CLL, an oral agent, ibrutinib, has been utilized in more than 50% of patients being treated even when IV options existed. This is consistent with superior clinical evidence for which the drug has been approved.

Figure 4. Adoption of oral products is often dependent on the availability of meaningful clinical data



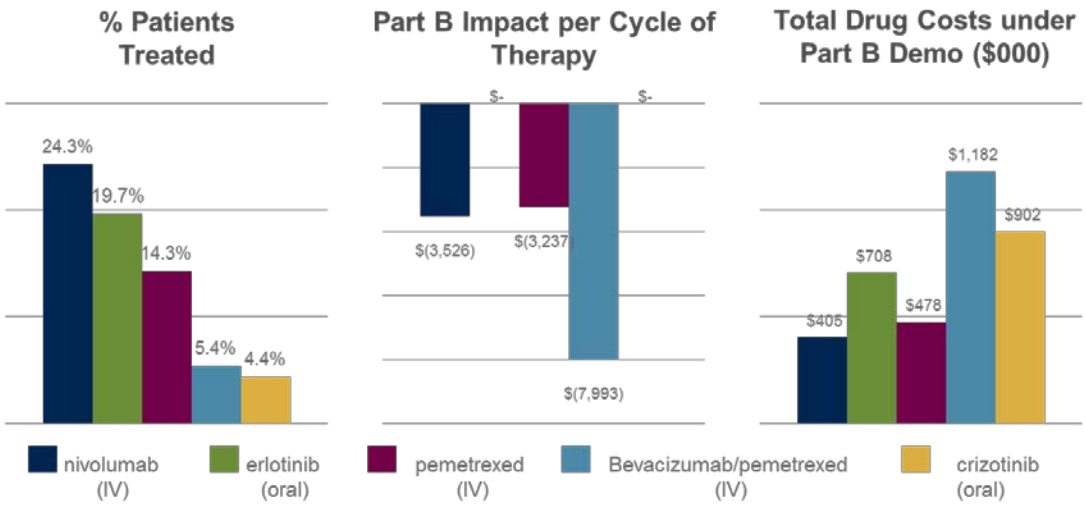
Cancer patients are typically treated with a regimen consisting of more than 1 drug. More than 70% of cancer patients receive at least one generic drug as part of that regimen. However, there are clinically relevant factors that may require newer therapies such as genetic or genomic risk. In the case of HER2+ breast cancer, National Comprehensive Cancer Network guidelines recommend the use of Herceptin® in combination with or after chemotherapy agents. There are currently no generic alternatives for this targeted therapy. When considering the top three treatment regimens used in these patients, the decrease in reimbursement is significant. As displayed in Figure 5, every regimen will be significantly impacted by the proposed payment rate, which when added up over to 9 to 12 cycles of treatment may exceed $12,500 in total.

Figure 5. Use of Expensive Targeted Therapies Recommended by Clinical Guidelines Result in Significant Reimbursement Losses



In cases where there are significant losses that may impact the ability of the providers to purchase the drugs, they may decide to use a drug such as an oral oncolytic which is not impacted by the Part B demonstration. Below in Figure 6, we have provided an example of the relative impact on the different treatment options for the top five regimens used NSCL cancer patients. More expensive regimens such as bevacizumab/pemetrexed are used less frequently while newer treatments such as immunotherapy is currently the more utilized. However, both of these have significant impact from a reimbursement perspective at more than $3500 per cycle of treatment while the oral treatment option, erlotinib, will have no impact under the proposed demonstration. If the provider cannot access nivolumab and chooses erlotinib instead, then the total drug cost impact over the average course of treatment will be higher for Medicare.

Figure 6.



Note: Reimbursement impact based on 1Q16 ASPs where the impact is defined as the difference is between the current ASP+4.3% and the proposed ASP+0.86% +$16.53. Calculations are based on average dose and administrations for each drug within a given regimen.
Source: IntrinsiQ Specialty Solutions and IntelliVIEW, March 2016

The complex nature of cancer care requires a broader understanding than a single drug approach. To better understand the ability of the community oncologists to access these drugs, an analysis of the oncology therapeutic drugs was conducted by evaluating the required discount off of wholesale acquisition cost (WAC) by drug compared at the current ASP+0.86%+$16.53. This accounted for the average dose per drug, which may include more than one maximum billable unit or administration of the drug based on the treatment regimen. Figure 7 shows the percent of drugs where the actual cost per administration was covered by proposed payment rate. We can see that less than 50% of these drugs are above water with up to a 40% discount off of WAC. Given that discounts offered at this rate are not routinely available in the marketplace, it would be very difficult for smaller practices to acquire drugs at this steep a discount, which would be required in order for them to remain viable under the economics of the Proposed Rule. Their long-term viability would be in question if the proposed payment rate was applied for an extended period of time without some adjustment.

Figure 7. Percent of Oncology Therapeutic Drugs Covered by Proposed Part B Payment