

August 29, 2014

Marilyn Tavenner
Administrator
Chief Operating Officer
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

ELECTRONIC DELIVERY

Re: CMS–1614–P (End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies)

Dear Administrator Tavenner,

The Plasma Protein Therapeutics Association (PPTA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule, End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (The Proposed Rule).¹

PPTA represents the innovators and manufacturers of plasma-derived therapies predominantly used to treat rare, chronic and life-threatening diseases and disorders, including alpha-1 proteinase inhibitor deficiency, hemophilia, von willebrand disease, and primary immune deficiency (PID) diseases. Therapies include albumin, alpha-1-proteinase inhibitor, antithrombin III, plasma-derived and recombinant blood clotting factors,² C1 esterase inhibitor, fibrin sealant, immune globulin, hyperimmune immune globulin, prothrombin complex concentrate, and protein C concentrate.³ Collectively, these therapies are known as “plasma protein therapies.” PPTA’s U.S. manufacturer membership includes Baxter BioScience, Biotest, CSL Behring, Grifols, and Kedrion.

¹ End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies 79 Fed. Reg. 40,208 (July 11, 2014).

² Recombinant blood clotting factor therapies are those created using recombinant DNA technologies, which entail the integration of genes coding for the production of human blood clotting factor proteins into laboratory cell cultures. The cell cultures produce the blood clotting factor proteins, which are subsequently collected, purified, and further refined into safe and effective biologic medicines.

³ Human plasma is the clear liquid portion of blood that remains after the red cells, leukocytes, and platelets are removed. Due to its human origin, complexity, and richness in therapeutically useful proteins, human plasma is a unique biological material. See Thierry Burnouf, *Plasma Proteins: Unique Biopharmaceuticals – Unique Economics*, in 7 PHARMACEUTICALS POLICY AND LAW, BLOOD, PLASMA AND PLASMA PROTEINS: A UNIQUE CONTRIBUTION TO MODERN HEALTHCARE 209 (2005, 2006).

Plasma Protein Therapies: Unique by Nature

Plasma protein therapies comprise a unique class of biologics within the biopharmaceutical industry. From the human-derived plasma starting material, through the complex manufacturing process, to final physician-administration, plasma protein therapies and the rare disease patients that rely on these therapies for their lifesaving treatment consistently face distinct challenges and particular regulatory treatment. For example, nearly all plasma protein therapies treat rare diseases, and certain therapies treat extremely rare diseases that feature prevalence rates of fewer than 100 patients. As a result of the extraordinarily rare nature of many of these diseases and conditions, patients' access to specialist providers with the distinct expertise necessary to effectively treat their rare disease can be tenuous, and in the past, due to changes in reimbursement, patients have experienced difficulties in accessing treatments in their preferred site of care.⁴ Accordingly, it is especially important that reimbursement for plasma protein therapies is established at rates that maintain patient access to these lifesaving therapies.

Additionally, manufacturers employ different and complex fractionation and purification processes to derive each distinct brand within the plasma protein therapeutic class. Due to the distinct manufacturing processes used by the industry, plasma protein therapies are non-interchangeable, sole source biologics that produce different therapeutic outcomes on a patient-by-patient basis. The non-interchangeable nature of plasma protein therapies underscores the importance of reimbursement rates that ensure appropriate, timely, and uninterrupted access to all brands of plasma protein therapies.

The industry is further differentiated by the reliance on human donated plasma as the starting material for therapeutic production. The collection of human donated plasma from 430 collection centers dispersed across the United States is a time- and resource-intensive system that adds multiple layers of complexity and regulation, resulting in a 7-9 month production process. The extensive time and complexity associated with production of plasma protein therapies highlights the need for reimbursement mechanisms and levels that reflect these complexities and protect patient access to plasma protein therapies.

Subcutaneous Immune Globulin Products Should not be Included in the Competitive Bidding Program

We note that the proposed rule addresses the payment rules for drugs administered through external infusion pumps under the Competitive Bidding Program (CPB). Given that drugs administered through external infusion pumps include subcutaneous immune globulin (SCIG) products, we believe it is appropriate to share concerns about the inclusion of these products with the CPB. For reasons explained below, SCIG should not be included in future rounds of the CPB.

PPTA member companies are committed to improving patients' lives through timely and appropriate access to lifesaving plasma protein therapies. In furtherance of this

⁴ 2003-2010 Trends in IVIG/SCIG utilization by PID patients, by site of service, December 21, 2012, The Moran Company (which noted a significant shift in the site of service of IVIG utilization after implementation of reimbursement cuts as a result of the Medicare Modernization Act).

commitment and to provide CMS with objective data and information to help guide the Agency's effective implementation of the CBP, PPTA commissioned The Moran Company to analyze the potential effects of competitively bidding subcutaneous immune globulin (SCIG) on patient access to these lifesaving therapies. The Moran Company analysis, "Competitive Bidding for Subcutaneous Immunoglobulin Products: Considerations for Policymakers," (The Analysis) finds that competitively bidding SCIG may risk patient health by creating barriers to patient access to the best possible therapy and necessary medical training from specialty pharmacies. Moreover, current CBP regulations intended to ensure patient access to DME supplies do not reflect the unique and complex patient health requirements associated SCIG therapy. Accordingly, based on the following findings, PPTA recommends CMS not include SCIG in future rounds of competitive bidding:

1. To the extent that competitive bidding creates financial incentives to reduce patient access to a select few brands within the SCIG therapeutic class, inclusion in the CPB would risk patients' access to the SCIG brand on which they have been stabilized, and exposing patients to the potential of severe adverse events and irreversible damage to their health;
2. By awarding CBP contracts based on the current range of standards and generalized quality requirements that were originally implemented for durable medical equipment suppliers as opposed to suppliers of complex biologicals⁵, the suppliers of SCIG that are ultimately awarded infusion therapy contracts may not have the expertise necessary to provide appropriate training and medical support for this unique population of patients, undermining therapeutic adherence and patient health outcomes;
3. Patients requiring SCIG therapy are particularly vulnerable to receiving inadequate training where competitively bid payment amounts for SCIG are too low to cover the training and guidance necessary to educate patients on the proper administration techniques for the biologicals;
4. Current bid regulations requiring suppliers to submit bids for all items within a product category⁶ places significant weight on suppliers' capacity to provide infusion pumps and related equipment potentially directing contracts away from suppliers with expertise that is relevant to SCIG and the unique needs of the patients who rely on SCIG.

Based on the findings of The Analysis it is evident that competitively bidding SCIG has the potential to create irreversible damage to patient health for patients living with the chronic and rare diseases that are treated by plasma protein therapies.

Moreover, in past regulations, in recognition of the unique non-interchangeable nature of plasma protein therapies and distinct therapeutic needs of plasma protein patients, CMS and other agencies have consistently integrated exceptions for plasma protein

⁵ 42 CFR § 414.414.

⁶ 42 CFR § 414.402; § 414.414

therapies within regulatory, reimbursement, and payment regimes.⁷ In so doing, agencies have mitigated barriers to patient access and advanced health outcomes for the many patients living with the rare and chronic diseases that are treated with plasma protein therapies. Recognizing the success of these principles and their fundamental importance for patient health, PPTA recommends that CMS take a similar approach when implementing the integration of infusion therapies into the CBP by excluding plasma protein therapies from the program.

Conclusion

Thank you for your time and consideration of PPTA's comments on the proposed rule, "End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)." PPTA greatly appreciates the Agency's engagement of stakeholders in the implementation of the competitive bidding program, and we look forward to further engaging as implementation progresses.

Best regards,

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APPENDIX A

Moran White Paper

⁷ E.g. 70 C.F.R. 39022 (July 6, 2005) excluding clotting factors and intravenous immune globulin (IVIG) from the Medicare Part B competitive acquisition program (CAP); 42 C.F.R. 419.20 (October 1, 2006) providing an add-on payment for certain IVIG therapies infused in the hospital outpatient setting.

**Competitive
Bidding for
Subcutaneous
Immunoglobulin
Products:**

**Considerations for
Policymakers**

August 2014

Competitive Bidding for Subcutaneous Immunoglobulin Products: Considerations for Policymakers

The Centers for Medicare and Medicaid Services (CMS) has instituted a system of competitive bidding for certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) products provided to Medicare patients. The competitive bidding program's goals are two-fold. First, the program aims to better align Medicare payments for the products with the general healthcare marketplace. Prior to the competitive bidding, Medicare fee schedule amounts were widely considered to be outdated and overly generous. In addition, the program, with its supplier accreditation requirements, aims to reduce fraud and abuse in the DMEPOS system.

Although there have been implementation delays, currently, the competitive bidding program is up and running and applies to 100 metropolitan service areas (MSAs) and 8 product categories, as well as a nation-wide competitively bid mail order program for diabetic testing supplies. After the first year of the program (in which only 9 MSAs were included) CMS estimated a savings of about \$200 million, which corresponds to roughly a 42% cut in fee schedule amounts. CMS has continued to expand the program and is moving to replace DMEPOS fee schedule payment amounts with competitively bid amounts, as envisioned in the legislation that created the program as it is presently constituted.

One category of products that could be subject to competitive bidding in the future is drugs and biologicals infused through Durable Medical Equipment (DME). This category includes subcutaneous immunoglobulin products (SCIg) used to treat primary immune deficiency.

The Moran Company was asked by our client the Plasma Protein Therapeutics Association (PPTA) to investigate some of the issues that would need to be addressed were a competitive bidding program that applies to SCIg products to be implemented. In order to address these issues, we conducted a series of interviews that included SCIg manufacturers, specialty pharmacies, patient groups and provider organizations. We supplemented these efforts by reference to literature and other materials on SCIg use and delivery.

This report details a number of findings that policymakers considering implementing competitive bidding for SCIg products may wish to take into account.

Highlights of Our Findings:

- Participants in the project and the literature suggest that there are differences between the SCIg products, making it potentially ill-advised for patients to switch between therapies.
- In addition, policymakers seeking to apply competitive bidding to SCIg products may wish to consider patient training and other services that are currently included in the delivery of these products to Medicare beneficiaries.

- Interviewees indicated that the nursing services that can be needed for effective use of SCIg in the home are separately reimbursed by private payers, but often not separately reimbursed by the Medicare program.
- Concerns were raised about whether competitive bidding would cause reductions in some of the nursing and other services currently provided by specialty pharmacies.
- If it is not economically advisable to participate in competitive bidding, we would expect specialty pharmacies and other entities now supplying SCIg to Medicare patients would not participate.
- Policymakers may wish to consider whether, in light of these issues, competitive bidding is advisable for SCIg products and if so, what safeguards should be in place to ensure that patients have access to the SCIg therapy best suited for them.
- Based on our analysis, we believe that the concerns about applying competitive bidding to SCIg products present significant challenges to designers of competitive bidding programs. Unless each of these challenges can be explicitly overcome, a successful competitive bidding program in this area may not be technically feasible.

The balance of this paper discusses:

- The competitive bidding program as it has been implemented to date.
- Background on the use of SCIg and Ig products and the choice of particular products for particular patients.
- Discussion of specialty pharmacy services that accompany delivery of SCIg products under the Medicare program currently.

Statutory Background

The competitive bidding program as it is presently established was enacted under the Medicare Modernization Act (MMA) as section 1847 of the Social Security Act. In addition to establishing the prescription drug benefit for outpatient drugs under Part D of the Medicare program, the MMA also made changes to reimbursement for other drugs and biologicals that had been covered under Medicare Part B. As a result of these changes, reimbursement for most Part B drugs was reduced from 95% of Average Wholesale Price (AWP) to 106% of Average Sales Price (ASP), with the possibility that these drugs would be subject to a separate competitive acquisition program, distinct from the competitive bidding program that is the subject of this paper. However, drugs infused through DME were designated by the MMA for continued reimbursement under 95% of the AWP in effect for these products as of 2003.¹ In addition, these drugs are included within the categories of products potentially subject to competitive bidding.

¹ In the case of products first marketed after 2003, CMS has used the first AWP available for each product.

Medicare DMEPOS Competitive Bidding Programs to Date

The DMEPOS Competitive Bidding Program, as described by the MMA, was to begin in 10 metropolitan statistical areas (MSAs) in 2008 and expand to 80 MSAs in 2009. The first round of bidding did occur for 10 product categories, with contracts taking effect on July 1, 2008. Products categories were selected in order to capture the highest cost and highest utilization DMEPOS products. Products were identified by Healthcare Common Procedure Coding System (HCPCS) codes.

However, the Congress intervened and terminated the Round 1 contracts with the passage of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). MIPPA delayed the competitive bidding process and authorized a national mail order program for diabetic testing supplies.

In response to MIPPA, CMS instituted the Round 1 Rebid, which included 9 of the 10 original MSAs, and 9 of the 10 original product categories (negative pressure wound therapy products and services were excluded):

- Oxygen Supplies and Equipment;
- Standard Power Wheelchairs, Scooters, and Related Accessories;
- Complex Rehabilitative Power Wheelchairs and Related Accessories (Group 2);
- Mail-Order Diabetic Supplies;
- Enteral Nutrients, Equipment and Supplies;
- Continuous Positive Airway Pressure (CPAP), Respiratory Assist Devices (RADs), and Related Supplies and Accessories;
- Hospital Beds and Related Accessories;
- Walkers and Related Accessories; and
- Support Surfaces (Group 2 mattresses and overlays).

The two-year Rebid contracts went into effect January 1, 2011 and CMS estimates that in the first year of the program, savings of about \$200 million were achieved. CMS states that this was a 42 percent savings over what would have been paid under the fee schedule. CMS also reported no major beneficiary access problems in the competitive bidding areas.

After the Round 1 Rebid contracts ended, CMS opened a Round 1 Recompete, in which contracts were negotiated in essentially the same areas as the Round 1 Rebid. Product categories also largely remained the same, but negative pressure wound therapy pumps and supplies and external infusion pumps and supplies were added. Contracts under this round of competitive bidding went into effect on January 1, 2014.

Round 2 of the DMEPOS Competitive Bidding Program contracts went into effect July 1, 2013 and are still in effect. Round 2 added 91 MSAs and largely kept the same product categories as the Round 1 Recompete. One major change was that mail order diabetic testing supplies were bid on a nationwide basis, rather than in the 100 MSAs. CMS projects average savings under Round 2 of 45% compared to current fee schedule prices. For diabetic testing supplies, CMS projects average savings of 72%.

PPTA asked us to gather information to assess how, in light of this context, patient access to SCIG might be affected by competitive bidding.

Benefits of SCIG for Some Primary Immune Deficiency Patients

Patients with primary immune deficiency can generally receive either IVIg or SCIG treatment. The National Home Infusion Association states that “clinicians must remain vigilant in managing adverse reactions, and in selecting the most clinically appropriate product for each patient.”² Studies show that switching from IVIg to SCIG could be beneficial to some patients. The benefits of switching to SCIG include:

- Mitigating specific barriers as compared to IVIg, such as the need for IV access, the need for trained personnel, and the use of specialized facilities.
- Allowing for a more even distribution of the drug over a period of time in order to alleviate side effects such as malaise, fatigue, arthralgias/myalgias, and increased infections;
- Reducing infusion related systemic adverse events;³
- Reducing need for premedication with corticosteroids and antihistamines;
- Alleviates the need for an infusion nurse; and
- Patients report improved convenience, a better quality of life and fewer absences from work when using SCIG therapy.⁴

In addition to the clinical and quality of life advantages that SCIG can bring, according to Canadian researchers, “the key to slowing the growth of health spending is unlocking innovation to reduce labor-intensity of care, and home based SCIG appears to provide a less labor-intensive means of care that hospital or office based IVIG.”⁵ Under this assumption, researchers performed a study to show that using SCIG would reduce health costs and would help alleviate a nursing shortage in Canada by freeing up nurses to perform other services. Researchers concluded that the switch from IVIG to SCIG would indeed reduce overall health care costs in Canada and assist with the looming nursing shortage.⁶ And Misbah et al note that “avoiding visits to hospitals or doctors’ offices and eliminating visiting nurses results in lower long-term costs” when using SCIG therapy.

² Siegel, J. *Case Management of the Challenging IgG Patient: Clinical Considerations for the Most Effective and Safe Therapy*. Adapted by Jeannie Counce and Nancy Kramer from the original presentation at the National Home Infusion Association, March 2, 2009 Annual Conference and Exposition.

³ Berge, M., et al. *Bioavailability of IgG Administered by the Subcutaneous Route*, Journal of Clinical Immunology, March 1, 2013, 33:984-990.

⁴ Misbah, et al. Subcutaneous Immunoglobulin: Opportunities and Outlook, Clinical and Experimental Immunology, August 20, 2009, 158 (Supplement 1): 51-59.

⁵ Gerth, et al. Implications to Payers of Switch from Hospital-based Intravenous Immunoglobulin to Home-based Subcutaneous Immunoglobulin Therapy in Patients with Primary and Secondary Immunodeficiencies in Canada, Allergy, Asthma & Clinical Immunology 2014, 10:23.

⁶ Ibid.

Participants in the interviews we conducted noted the benefits and convenience of SCIG therapy and raised concerns about the impact that competitive bidding could have on access to this therapy.

Choice of SCIG Brand Can be Affected by Patient Specific Factors

A key consideration raised in our interviews with various stakeholders, and supported by our review of various sources, is the importance of choice of particular brand of SCIG for use in treatment of primary immune deficiency. Several interviewees noted their concern that, depending on the structure of the competitive bidding program, bidding entities could attempt to restrict access to particular brands or shift patients already stabilized on a course of SCIG treatment to a different brand.

For patients who opt for SCIG treatment, there is evidence to suggest that switching SCIG products mid-treatment could cause harm to the patient. Various stakeholders in the field of immunology note that “in general there are slight differences or safety differences among products in this class” and those Ig products are in general safe, but at the level of the individual patient some products may produce fewer adverse events than other.⁷ Consequently, The Immune Deficiency Foundation (IDF) has argued that those patients who are stabilized on a particular product, whether intravenous or subcutaneous immunoglobulin, should not be forced to change products outside of the decision of the treating physician.⁸

All interviewees emphasized that the SCIG products currently on the market are not interchangeable due to the different concentration levels and stabilizers used. Discussions with project participants suggest that the key difference between the products is in the side effects profile, with patients responding in different ways across brands, despite the fact that the bioavailability of Ig across brands appears to be similar.⁹

Our review of the literature confirms this finding and suggests that the varying components that make up an Ig product can affect how patients tolerate one product over another. Chemical components such as sodium content, stabilizers, osmolarity, IgA content, concentration and pH can vary from product to product; therefore, Ig products are chosen on a case by case basis based on the clinical condition of the patient and the patient’s comorbidities.¹⁰ The literature suggests that differences in the sugar, salt, and overall osmolarity of the products are particularly important when selecting products for patients with comorbidities such as renal dysfunction, diabetes mellitus, vascular disease, or heart failure.¹¹

⁷ Immune Deficiency Foundation, *Medical Advisory Committee Resolution Regarding Formulary Changes that Limit a Physician’s Ability to Determine the Most Appropriate Immunoglobulin Replacement Therapy*, November 16, 2011

⁸ Ibid.

⁹ CSL Behring News Release, March 2, 2012. <http://www.cslbehring.com/news-room/IgG-Bioavailability-Consistent-across-Class> Accessed July 25, 2014.

¹⁰ Rhodes, R.T., *Immune Globulin: Each Product is Unique*, www.IGLiving.com, February/March 2014

¹¹ Siegel, J. *Immune Globulins: Therapeutic, Pharmaceutical, Cost, and Administration Considerations*, Pharmacy Practice News, January 2012.

Interviewees indicate that some patients chose products based on Ig concentration levels, since some patients prefer higher concentrations to reduce the volume needed for an infusion, reducing the number of injection sites. However, higher concentrations also increase the potential for adverse events. The interviewees stressed the importance of allowing patients and their doctors to select the brand with the best side effects profile for each individual. Side effects discussed including swelling, headaches and fluid overload. Interviewees explained that differences between the products are clear due to divergent FDA labels, as well as guidance from physician specialty societies that note the brands are not interchangeable. They also noted that the potential for adverse events is heightened when patients switch products, which could be a concern in competitive bidding. Consequently, they expressed concern that if competitive bidding creates access issues to patients' product of choice, that this could shift volume back into the physician office or Hospital Outpatient Department.

In addition to the concern about adverse events, interviewees noted that retraining could be required for patients shifting to SCIG with different concentrations, since this would result in a change in the number of injection sites. Interviewees also explained that much of the training on SCIG use is done in the hospital creating the potential for a disconnect between the product in the hospital and those available under competitive bidding.

In light of these differences in patient response to different Ig products, all of the participants in interviews we have conducted to date emphasized the importance of allowing the choice of Ig therapy to be made by patients and their physicians.

Specialty Pharmacy Services Currently Provided Under Medicare

SCIG products are often delivered by specialty pharmacies, which are pharmacies designed to deliver medications that require special handling, storage and distribution requirements. Specialty pharmacies employ health care professionals that can provide patient education, help ensure appropriate medication use, promote adherence to the use of the medication, attempt to avoid unnecessary costs and, assist in the coordination of information sharing among the providers treating the patient.¹²

Patients receiving SCIG generally require at least some nursing services. Many patients receive 3-4 nursing visits to be trained on the use of the product and some always require a nurse to perform the infusion. One program provided by Wellpartner Specialty Rx Services provides each SCIG patient with a full clinical review, which includes services such as complete lab work and full chart note assessment prior to the patient receiving SCIG.¹³ Wellpartner also provides every SCIG patient with support systems of clinical pharmacists, reimbursement specialists and patient care coordinators.¹⁴ In addition to providing clinical care and support, specialty

¹² Calla, N. *What is a Specialty Pharmacy?* Specialty Pharmacy Times, Nov/Dec. 2013.

¹³ Kramer, S. and Ness, S., *IVIG and SCIG: A Look at Wellpartner Pharmacy*, Specialty Pharmacy Times, November, 2011.

¹⁴ Ibid.

pharmacy programs can also help with the care of patients by collecting data about each patient during treatment.¹⁵

Lima and Clarke, in their paper titled *IgG Therapy for the Home-Based Patient Administration and Delivery Method Considerations* stress the importance of specialty pharmacy providers in their role in the delivery of SCIg therapy by noting that specialty pharmacy providers “can play a critical role in patient monitoring by collecting supporting documentation on the therapeutic effectiveness of IgG regimens including information such as:

- Response to therapy
- Abatement of symptoms and,
- Quality of life.”¹⁶

Lima and Clarke state that this information provides meaningful feedback to physicians in order to assist in finding the correct dosage for each patient. Lima and Clarke also write that specialty pharmacy care teams often map out a regimen of dosing based on the dosage as prescribed by the physician and in doing so, the specialty pharmacy must consider the needs of individual patients, the total volume of therapy, the numbers of fractionations and the sites to be used for infusions.

Interview participants noted the importance of nurse training on the use of SCIg and other specialty pharmacy services as vital to the effective use of SCIg for Medicare beneficiaries. Interviewees noted that these services are often subject to separate reimbursement by private payers, but tend not to be separately reimbursed under Medicare.

Some interviewees stated that specialty pharmacies may be providing these training, follow-up and medication management services at a loss and noted that this practice would be unlikely to continue under competitive bidding. They also raised concerns about the potential selection of bidders without experience in providing nursing services.

Conclusions: Policymakers May Wish to Consider the Potential Impact of Competitive Bidding on Continuing Use of SCIg in Medicare

A general theme throughout the interviews we conducted was whether competitive bidding would threaten the continuing viability of SCIg care in Medicare. While policymakers may have concerns about the continuing use of AWP-based reimbursement for DME-infused drugs, participants in the project suggested that the current reimbursement amounts make it possible for patients to receive the training and other services necessary to make effective use of SCIg in treatment of primary immune deficiency.

Policymakers considering expansion of competitive bidding to SCIg and other DME-infused drugs and biologicals may wish to note the importance of specialty pharmacy services in the use

¹⁵ American Society of Health-System Pharmacists, *Specialty Pharmacy Presents Opportunities for Hospitals, Health Systems*, Pharmacy News May 1, 2014. www.ashp.org. Accessed July 28, 2014.

¹⁶ Lima, H. and Clarke, A., *IgG Therapy for the Home-Based Patient Administration and Delivery Method Considerations*, April 26 presentation at the 2012 National Home Infusion Association Annual Conference and Exposition.

of SCIG and the differences in patient response to particular SCIG products. Based on our analysis, we believe that the concerns about applying competitive bidding to this product segment present significant challenges to designers of competitive bidding programs. Unless each of these challenges can be explicitly overcome, a successful competitive bidding program for SCIG may not be technically feasible.