WHITE PAPER SUBMISSION

to

THE SENATE FINANCE COMMITTEE

in response to

BIPARTISAN EFFORT TO COMBAT WASTE, FRAUD, AND ABUSE IN THE MEDICARE AND MEDICAID PROGRAMS

June 29, 2012

Mr. Chairman and Members of the Senate Finance Committee, The van Halem Group, LLC applauds and strongly supports the Committee's attention on finding effective solutions solutions to combat waste, fraud, and abuse in the nation's preeminent healthcare entitlement program. Further collaboration between the public and private sector is critical to reestablish the efficacy, fairness, and efficiencies the Program was intended to have when it was created in 1965.

The van Halem Group, LLC, is one of the nation's leading consulting groups, based in Atlanta, GA. Our team has over 100 years of collective experience, including working on the government side, the provider side, and the payor side. Biographies of those who contributed to this report have been shared as a separate attachment to this White Paper [Exhibit 1]. The van Halem Group works with healthcare providers, legal counsel, law enforcement and other entities navigating complex issues related to Medicare. The firm provides consulting to providers regarding compliance issues and performs medical review and fraud investigative support for entities including the United States Department of Justice. We understand the complexities of the Medicare Program because we have all served in either the Department of Health and Human Services or private government contractors working on behalf of the Centers for Medicare and Medicaid Services (CMS). Based on our experience, we respectfully offer input in two of the Committee's identified categories.

- Program Integrity Reforms to Protect Beneficiaries and Prevent Fraud and Abuse
- Payment Integrity Reforms to Ensure Accuracy, Efficiency and Value

Across these two categories areas, we have identified nine areas that could help identify the Program's current shortcomings. We have also suggested proposed remedies for each with the aim of increasing the efficacy, fairness, and efficiency of the overall program.

1 - Lack of oversight of Medicare Zone Program Integrity Contractors (ZPICs)

Since the inception of the ZPIC Program, we have worked collaboratively and consistently with the PSCs and potential ZPIC contractors. We have first-hand knowledge of the challenges facing both CMS and contractors in the transition of this workload. In theory, the ZPIC program was a positive move forward in the fight against fraud, waste, and abuse. It removed the fragmentation of work in claim types (Part A, B, DME) of multiple PSCs across one geographic area. It provided a single contractor to provide all program integrity efforts across all lines of business in one geographic area. In theory, the ZPICs also consolidated all claims data into one central database for geographical areas, which allows contractors to cross-analyze data from multiple provider types, increasing the likelihood of identifying aberrancies and trends.

Previously, the PSCs often did not have access to cross-claims data and had competing interests with other PSCs, which prohibited sharing of information or data. Therefore, this type of analysis was lacking.

Weaknesses

As the ZPIC program has been implemented, there has been consistent issues with new ZPIC contractors and the awarded ZPIC task orders. One issue is the lack of knowledge and expertise of the ZPIC staff in their "new" areas of claims and geographic locations. A second issue is the lack of oversight by CMS of the new ZPIC contractors.

In a report published in November 2011[1], the Office of Inspector General (OIG) under the Department of Health and Human Services shared similar concerns over the lack of oversight by CMS of ZPIC contractors after only the first year of implementation. Without sufficient oversight or experienced staff, CMS has had no knowledge of the effectiveness of these contractors' ability to perform program integrity functions or correct situations in which contractors may not have been conducting work efficiently and properly.

Often the ZPIC contractors have had no experience in the areas of fraud and abuse for which they should be accountable. For example, if the PSC had only performed Part A work as a PSC and has no DME experience, their lack of knowledge, understanding and experience result in incorrect policy applications, errors in data analysis and unnecessary audits, reviews and investigations. The result is a loss to CMS of fraud and abuse funds and providers, many of which are small – medium sized businesses, are forced to spend thousands of dollars to address unfounded audits and investigations. This was recently evidenced when CMS lost $80 million of the $120 million paid to contractors, due to poor data when investigating fraud and abuse[2].

During the implementation of the ZPIC program in Zones 4, 5, and 7, we are aware of multiple providers that, as a result of poorly developed ZPIC investigations and prepay reviews, were not able to sustain operations. During the aggressive actions taken by the ZPICs, many providers were forced to lay off employees. Yet, most of these cases did not result in a referral to law enforcement and no fraudulent activity was identified. In one particular instance, a provider of enteral nutrition products was placed in prepayment review and had a significant number of claims denied for technical issues or insufficient documentation. His revenue was so affected, that his manufacturers stopped offering credit to his company and he was forced to purchase enteral nutrition on his own personal credit card to sustain his patients, who legitimately needed these products. This type of example is unfortunately common.

[1] http://www.oig.hhs.gov/oei/reports/oei-03-09-00520.pdf
[2] http://www.bloomberg.com/news/2012-06-14/medicaid-fraud-audits-cost-five-times-amount-u-s-found.html

OIG had concerns over the program integrity workload being conducted by the PSCs and issued a report in July 2007[3], citing multiple areas of concern. The overall theme of this report and a second report published in March 2006[4] is ineffective controls and oversight regarding contractors. In transitioning the workload from PSCs to ZPICs, it was understood CMS would develop more stringent requirements and have better control of the oversight of these contractors that will now be performing fraud investigation across multiple lines of business in a defined geographical zone. The significant lack of oversight of ZPIC contractors, who were awarded contracts averaging $81.9 million, is evidenced by the extreme and ill-founded actions taken by some ZPICs in unwarranted efforts to show CMS a return on investment. Contractors often employed significant, aggressive and over-zealous audits, claims reviews and investigations against legitimate, not fraudulent, providers of healthcare services. These broad brush actions cost legitimate providers huge amounts of time, money and energy – inhibiting their ability to provide care to beneficiaries. Some are forced to leave Medicare, if not health care services all together. ZPICs are large and powerful corporations with the backing of the federal government. They apply heavy handed processes in a punitive manner to many legitimate providers over minor document infractions.

Further exacerbating the problem are the individuals employed by CMS to oversee these contracts, who are often young and inexperienced and do not have healthcare or fraud investigation experience. As a result, when efforts are made by providers or groups such as ours to highlight the improper activities of these ZPIC contractors to CMS, it often goes unresolved and, in some instances, is completely ignored. This lack of response by CMS is due, in large part, to the lack of understanding by the CMS staff of the process, issues, and basic means and challenges in operating a healthcare provider operation, and sometimes their own CMS policies and procedures.

Recommendations

(i) CMS should employ, or at least educate and train, staff that are qualified in and familiar with healthcare operations, coverage policies, and healthcare fraud investigative techniques to oversee program integrity workload and contractors. While contractors regularly undergo performance evaluations, very clear and concise metrics and reporting requirements should be defined to assure their effectiveness. Law enforcement agencies should provide education and training to relevant CMS staffers on the rudiments of the False Claims Act and other related concerns.

[3] http://oig.hhs.gov/oei/reports/oei-03-06-00010.pdf
[4] http://oig.hhs.gov/oei/reports/oei-03-04-00050.pdf

(ii) CMS staff should be regularly involved in the decisions being made by government contractors. Many government contractors are given the authority to make decisions that have a significant impact on a healthcare provider's ability to remain operational and there is no mechanism in place for the provider to report or request assistance when these actions are taken.

(iii) CMS should implement a process for providers undergoing audits to be able to communicate with them if faced with issues they have been unable to resolve with the contractor.

2 - Lack of trust between provider community and CMS

The van Halem Group works to develop a collaborative and communicative relationship between healthcare providers and CMS[5]. These efforts have been largely unsuccessful due to the lack of trust of the provider community. CMS and its contractors often cultivate an environment of mistrust and suspicion that all providers of certain services are inherently fraudulent. The sentiment is widely shared by anyone that has worked with CMS contractors in the area of program integrity and a similar environment is probable within the CMS Program Integrity Group. This type of environment leads investigators, contractors, and CMS to pursue providers in an aggressive manner, sometimes unfairly, based on little evidence or collaboration of any wrongdoing. The providers' lack of information from contractors and CMS as well as the lack of ability to communicate directly with contractors or CMS has caused a lack of trust in the provider community also. To build trust between stakeholders, The van Halem Group helped create a group called the Fraud Eradication Advisory Team (FEAT) to develop ways in which to reduce waste, fraud, and abuse in the durable medical equipment industry. The group included a member service organization representing over a thousand independent medical equipment suppliers, consultants, and manufacturers. Also invited to participate in the group were leaders from various Medicare contractors performing oversight of these types of claims as well as CMS representatives from several Regional Offices and Central Office. In communicating unofficially about this group, Medicare contractor staff and CMS Regional Office staff expressed interest in participating. Their participation, however, was officially prohibited once an official invitation was sent to the Program Integrity Group at CMS.

Weakness

Without CMS support, the group lacked cooperation from those responsible for overseeing fraud and abuse activities on behalf of the government. The entity charged with overseeing the Medicare Program does not regularly engage in communication with the provider community

[5] http://www.vanhalemgroup.com/HME%20News_102808.pdf

on anti-fraud measures. It is important to understand that legitimate healthcare providers desire to reduce the amount of waste, fraud, and abuse within their own industry as well and can offer significant insight to CMS in their fraud fighting efforts.

Recommendations

(i) Implement programs which encourage participation and cooperation from provider groups and entities as well as CMS, similar to this request, which allows input and communication from other stakeholders in the healthcare industry. With more communication and collaboration comes trust and confidence. In turn, this will foster a collaborative environment to better fight fraud, waste, and abuse.

3 - Lack of Clinical Judgment in conducting claims reviews

Until June 2011, CMS Section 3.4.5.C of the Medicare Program Integrity Manual (Pub 100-8), guided contractors in performing complex medical reviews as follows:

> While MR staff must follow national coverage determinations and local coverage determinations, they are expected to use their expertise to make clinical judgments when making medical review determinations. They must take into consideration the clinical condition of the beneficiary as indicated by the beneficiary's diagnosis and medical history when making these determinations. For example, if a medical record indicates that a beneficiary is a few days post-op for a total hip replacement and femur plating, even though the medical record does not specifically state that the beneficiary requires the special skills of ambulance transportation, MR nurses and physicians must use their clinical knowledge to conclude that ambulance transportation is appropriate under such circumstances.

Weakness

In June 2011, after this section of the Manual was often referenced in successful Medicare appeals, CMS removed this citation from instruction to the Medicare contractors. Clearly, the Contractors' medical review staff's expertise is a very necessary element in identifying intentional fraud, waste, and abuse. Currently, ZPIC and Medicare Administrative Contractors (MACs) are employing clinical staff; however, they have no ability to use that expertise. As a result, CMS is requiring and paying for clinical expertise but not receiving the cost savings benefit of the expertise. Additionally, a provider under review may be subject to significant claim denials and scrutiny because of issues with insufficient documentation that are not associated with fraudulent activity. As examples, a ZPIC in one instance denied claims for

oxygen equipment for a Medicare beneficiary who was awaiting a lung transplant, clearly not lack of medical necessity or coverage. In another, a ZPIC denied claims for the rental of a ventilator for a patient using an "iron lung" since the 1950's. Without the equipment, the beneficiary would likely die within minutes. Due to the fact that the clinicians performing these reviews were unable to use their clinical judgment, these claims were denied against all reasonable and rational sensibility.

Many denials are unfounded and irrational due to the prohibition of allowing ZPIC's clinical staff to use their clinical judgment and expertise. As a result, these denied claims must be appealed, often times up to the ALJ level. This process of denying claims and conducting appeals costs the government a significant amount of money only to see a significant number of the decisions overturned. In theory, many of these types of investigations cost the government more money in resources than necessary. If contractors were able to draw upon their expertise and make clinical judgments on claims, there would be fewer denials and appeals and the investigations would be resolved more quickly so that the ZPIC can focus its efforts on identifying other areas of potentially fraudulent or abusive behavior. The error rates published by Medicare Administrative Contractors and Comprehensive Error Rate Contractors are so high in many instances, it supports that removing this section of the PIM has resulted in more claims being denied which in turn reduces a Medicare beneficiary's access to the care that they truly need. A recent widespread prepayment review conducted by a DME MAC yielded an error rate of 74%[6]. Does CMS actually believe that 74% of individuals receiving oxygen do not need it?

It is not uncommon for a provider undergoing a ZPIC investigation to have 80 – 100% error rates based on these types of reviews. Therefore, the investigation continues on and both contractor and provider workload is increased to support this investigation that is clearly not an issue of intentional fraud. These denials are often upheld in the first two levels of the Medicare appeal process by the Redetermination and Reconsideration contractors because they follow these same guidelines. However, the same denials are often overturned at the Administrative Law Judge level where judgment, expertise, and reason enter the equation.

Recommendation

(i) Reinstate the above referenced section of the CMS PIM and allow the contractors' clinical staff to apply their expertise to the claim records review process.

4 - Lack of Experience and Training of ZPIC staff

[6]https://www.noridianmedicare.com/dme/reviews/results_of_widespread_prepayment_review_of_oxygen_and_oxygen_equipment.html%3f

Weakness

As noted above in Issue 1, there is great risk and costs associated with the lack of experience and training of the ZPIC staff. In communicating with a member of management at a ZPIC regarding issues surrounding numerous errors being made by staff, a ZPIC Manager said he was not only aware of the errors being made but attributed them to issues related to workload, exhaustion, or lack of training. In our experience, we have found many ZPIC investigators lacking sufficient training in coverage and reimbursement policies for the services under their review.

In one case, a provider contacted their local congressman to address concerns over incorrect denials in a ZPIC audit. The congressman's office contacted CMS Central Office and our client, the provider, submitted 11 examples of claims denied in error. In the written response from CMS [Exhibit 2], they agreed that 7 of the 11 claims were in fact denied erroneously. However, the letter went on to state that regardless, the provider's error rate remained high so they will remain under investigation. This, despite the fact that they had just received confirmation in the very same response that the error rate calculated was incorrect because of errors made by the contractor. This not only supports a lack of training, but a lack of appropriate oversight and fairness.

We can provide numerous examples of claims denied in error by the ZPICs and MACs. Most important is mandating that investigators and reviewers performing program integrity functions have significant and on-going training on Local and National Coverage Determinations, claims submission guidelines, coding, and other reimbursement principles so they can understand and communicate intelligently on the issues surrounding the investigation or review.

Recommendations

(i) Staff training and education. If the ZPIC staff was better trained and educated, the staff would then be better able to identify fraudulent practices, develop more solid referrals and recoveries and provide a better return on investment for the Medicare Trust Fund dollars used for program integrity efforts. CMS should require mandatory training of ZPIC staff by those who will receive their referrals (i.e. OIG and FBI) to better understand the type of cases they would prefer to receive.

(ii) Field experience. We also encourage the use of more of a "feet on the street" approach to allow investigators to get into the field and visit providers and patients. This approach is an excellent tool and better prepares investigators to obtain the knowledge they need to better meet CMS goals.

(iii) Program Integrity Networking Groups. When the members of the van Halem Group worked for Medicare fraud and abuse contractors, we were funded with and provided quarterly networking groups for stakeholders – Medicare PI, Medicaid, PI, FBI, OIG, DOJ, IRS, etc. We accessed national speakers, pro bono, and other industry leaders to provide a key note speaker event and had exchanges amongst the stakeholders of what, how, when, where and why their investigations were occurring. This built partnering relationships, training and knowledge of all areas of program integrity and created effective and efficient teamwork across the industry. This should be a key element for each Zone of every ZPIC.

5 - Intense focus on Clinical Records for Ancillary Services

Recent ZPIC and MAC audits have focused intensely on the content of a beneficiary's clinical record. While we agree that the content of these records is very important and the only way a contractor can determine if services are reasonable and necessary, it has become a significant issue for providers of ancillary services prescribed by physicians.

Weakness

For example, a physician may order a hospital bed for a patient that is provided by a supplier of this type of equipment. When audited, the claim may be denied because the physician did not document clearly that the head of the bed must be elevated 30 degrees, which is one of the criteria that must be met in order to obtain coverage. CMS and its contractors spend an enormous amount of time, energy, and money in conducting these reviews and denying claims associated with insufficient physician documentation. Meanwhile, the beneficiary may not be given the access to care for services that they truly need.

Lack of Funding for Education

When it comes to educating physicians on the requirements and policies for coverage of these ancillary services, the various contractors (i.e. DME MACs or Home Health and Hospice MACs) who oversee the claims for ancillary services are not funded to educate physicians, nor are the contractors who oversee the physician claims. This creates a tremendous disconnect of information between contractors and physicians and providers. CMS' omission of education puts the responsibility of educating the ordering physician about proper documentation requirements and coverage policies surrounding the services they order upon the provider of the ancillary services and this leads to multiple issues and problems.

One issue is that physicians are not liable for this documentation, so there is no incentive or reason for compliance. It becomes a significant challenge for providers to educate a physician

on how they should document their patients' conditions. Physicians often overlook these requirements and the ancillary provider is forced to either assume liability or decline the referral, both of which have a negative impact.

In many instances, it is not mandated that the ancillary provider have this documentation in their files, but rather provide it upon request. Many physicians are aware of this rule, therefore, are less apt to comply with requests for documentation on a regular basis. This is widely accepted as one of the most challenging problems facing ancillary providers. Most importantly, it results in a misdirected focus for clinicians and investigators and undue costs to the Program.

Recommendations

(i) Provide funding to educate referring physicians and CMS contractors.

(ii) Hold physicians accountable for the services they prescribe. Temptation would be diminished if physicians knew that they were responsible for causing a cost to be incurred to the Program. This allows additional safeguards and requirements to be in place to ease this unnecessary burden on ancillary providers for lack of physicians' responsibility to document the need for the ancillary services. Physician's liability in prescribing durable medical equipment and home health services was addressed in an OIG Special Fraud Alert[7] issued in January 1999.

(iii) Audit the referring provider as well as the ancillary provider. CMS is aware of the problem of physicians not being held accountable for the services ordered, as noted in CMS' CERT Report for 2010[8], where it states (p.12 – 13), "Given the importance of receiving medical record documentation to substantiate the necessity for DME items billed, beginning in 2011, CMS will notify the physician when a DME item ordered by that physician is selected for CERT review. The notification reminds physicians of their responsibility to maintain documentation of medical necessity for the DME item and submit requested documentation to the supplier." More recently, CMS issued a final rule[9] that continues to require the NPI of the ordering provider to ensure "… that only qualified, identifiable providers and suppliers can order or certify certain medical services, equipment, and supplies for people with Medicare." This rule also gives CMS the ability to tie specific claims to the ordering or certifying physician or eligible professional and to check for suspicious ordering activity. If the ancillary provider is audited and found to lack the required clinical records, there will also be an audit of the ordering provider. This will create an incentive for all

[7] http://oig.hhs.gov/fraud/docs/alertsandbulletins/dme.htm
[8] http://www.cms.gov/CERT/Downloads/Medicare_FFS_2010_CERT_Report.pdf
[9] http://www.cms.gov/apps/media/press/release.asp?Counter=4342

participants to comply with the necessary documentation of medically necessary services.

(iv) Implement use of approved forms. One may argue that implementing the use of forms to document medical necessity of ancillary services would make it easier for fraudulent and abusive providers to file false claims. However, it's important to note that these fraudulent providers are not complying with current rules regarding clinical documentation. The current rules accomplish little and make the process more complex and difficult for legitimate providers. Again, the error rates released by the Medicare contractors are strong evidence of this. The advent of electronic medical records supports this type of system and would significantly ease the burden on providers, physicians, and beneficiaries. CMS can draft approved forms that are designed to ascertain the information necessary to determine coverage. Physicians who complete these forms must be made aware of their liability in completing the forms and there should be a face to face requirement for most services to be prescribed initially. Implementing a process such as this would allow beneficiaries to receive coverage for the services they qualify for and provide CMS with a simpler means of determining coverage. As the frontline gatekeepers to the Medicare Program, the physician must certify that the information is true and accurate.

(v) Consider current documentation. Similarly, CMS contractor clinicians and reviewers are often prohibited from considering documentation dated after the specific date of service in question. For example, a claim for medical equipment ordered for a beneficiary gets audited and the physician drafts a letter supporting why he ordered the equipment for this patient at the time of the audit. The letter is dated currently and references the patient's condition at the time he ordered the services, which is usually within a reasonable period of time. The CMS contractors upon initial review or in the appeal process will not consider this documentation despite that it contains relevant information that would show the patient qualifies for coverage. Many physicians are willing to provide support for these ancillary services if the claims are audited and often do so in this manner. When a case is appealed to an Administrative Law Judge, they will often consider this evidence as part of their review. We agree that the information contained in the document must be accurate and should be collaborated by other clinical notes and consistent with the beneficiary's medical history and diagnoses, but precluding contractors from even considering this type of documentation increases denials for equipment or services that a beneficiary needs and is entitled to under the Program. Again, from our experience, this does not increase the likelihood of fraudulent activity, but lessens the workload burden on audit and appeal contractors as well as the Office of

Medicare Hearings and Appeals.

6 – Absent or Complex Payment Policies

Weakness

CMS and its contractors have consistently implemented complex payment rules and policies surrounding reimbursement of benefits in the Medicare program. Policies vary from state to state or contractors administering the Program interpret and apply policies inconsistently. Often times, rules or guidelines are changed without any discussion or communication regarding the effect on the provider and beneficiary communities. This is true even in instances in which contractors are open and communicative with each other, such as the Durable Medical Equipment Medicare Administrative Contractors, whose Medical Directors meet and discuss policies regularly and keep the content of policies consistent across the various jurisdictions. There are still inconsistencies in the ways in which the reviews are done and policies interpreted among them. Often times, the Local or National Coverage Determinations include vague language that makes it unclear and difficult for legitimate providers to comply. In many cases, it is well-known that not only can you get different answers amongst different contractors but even from different staff within the same contractor. It makes it difficult for providers to ascertain exactly what is required and needed when even Medicare representatives have difficulty interpreting the guidelines. This is relevant to all published guidelines and instructions, not just coverage policies. Other documentation requirements are often implemented with no consideration of the complexities and challenges in providing healthcare services and the burden this may have on a provider.

In other instances, there is a complete lack of coverage or payment rules for some services billed to Medicare. It is impossible for an experienced and skilled reviewer or investigator to demonstrate a violation of significance, by fraud or abuse (excessive and/or unnecessary services) when standards are absent or so vague as to preclude reasonable pursuit. Subsequently, it is difficult for ZPIC contractors to find violations that have prosecutorial merit.

Recommendations

(i) Simple rules for a complex program. The Chicago School of Law has long held there must be simple rules for a complex world, otherwise complex rules for a complex world will be overwhelming such that no one believes the rules could be followed. Since it is inevitable that the complex rules will be violated – why try to follow them? We recommend that CMS develop workgroups with representatives from state and national associations, provider groups, member service organizations, and CMS to develop more consistent and precise coverage rules and policies throughout the

country for all services billed to Medicare. While this is a daunting task, doing so would provide more clear, specific guidelines for legitimate providers on what is required, therefore reducing the overall error rate. Clearly, the current system is not working. When implementing new procedure codes, they should be accompanied with specific policies and guidelines related to billing and reimbursement to avoid future vulnerabilities and protect the integrity of the Program reducing abusive practices and improper payments. Subsequently, contractors performing program integrity workload will have greater clarity for interpretation and be able to process reviews more quickly and accurately resulting in an increased focus on identification of truly fraudulent and abusive providers who are often not following payment rules at all. Clear and concise rules make it easier to identify and prevent fraud, waste, and abuse as opposed to the current system, where coverage is left to interpretation or to strict adherence to complex and unreasonable policies.

7 - Prepayment Review of Claims

The Medicare "pay and chase" system is antiquated and inefficient. Prepayment reviews can provide necessary education and correction, as well as identify risks. In fact, FEAT suggested and recommended that new durable medical equipment suppliers undergo a mandatory prepayment review in the first 6 months of operation [Exhibit 3]. The recent prepayment pilot program announced by CMS on claims for Power Mobility Devices was met with significant support by the provider community as long as the interpretation is consistent and reasonable.

Weakness

In our experience, we find that the use of prepayment review is being abused by contractors that perform it. For example, it is not uncommon for a ZPIC to implement a 100% prepayment review of a provider's claims with no notification. Based on our previous experience, we are aware that this decision was likely based on data analysis or complaints. We believe CMS must provide clear instructions and guidance to contractors performing these types of reviews. Currently, the ZPICs have little, if any, limitations on the prepayment review process and have no timeliness requirements in which they must respond. Therefore, a provider being placed in 100% prepayment review results in what could effectively be deemed a payment suspension of 90 days minimally. We have seen countless providers placed in prepayment review for an extended period of time during which they have had to lay off staff or reassign staff normally dedicated to patient care or quality improvement. After 9 – 12 months, they are released from the prepayment review with no additional action. In some cases, they may receive a vague ZPIC education letter and a referral to the MAC for educational purposes. In our opinion, this is an ineffective use of available resources. Futhermore, it allows for contractors to report artificially

inflated savings to the Program, when many of these denials are often overturned in the appeal process. Prepayment review is costly to the provider and the current system is time-consuming without demonstration of adequate return in protecting program funds. Unfortunately, due to the long history of CMS fragmented data from various administrative contractors over the last 50 years from numerous proprietary claims systems, the data can have flaws. There is also a lack of communication between contractors as well as CMS regarding data and activities. For example, ZPICs in areas where CMS had implemented competitive bidding for durable medical equipment suppliers, had placed DME companies awarded competitive bid contracts under 100% prepayment review, only to later learn the ZPIC was unaware that these companies were actually CMS competitive bid winners.

Recommendations

While we agree prepayment review is an effective tool and encourage its continued use, the contractors performing these reviews must better understand the impact of these reviews, be better educated on how and when these reviews should be undertaken and realize the burden this places on providers. Therefore, we recommend that:

(i) CMS should implement clear and concise guideline for all contractors that perform prepayment review. This should include reliable evidence of potentially fraudulent activity or incorrect claims being submitted. Often times the contractors are relying on data analysis, but as former fraud investigators, we have all seen instances in which the data analysis is flawed or incorrect or was easily explainable.

(ii) CMS should measure a contractor's understanding of the data and have input in the analysis. Being competitive bid winners does not preclude a provider from being audited; however, if the data analysis reflected that this provider showed an aberrant spike or increase in claims volume (a common metric used by ZPICs), then that is data that would be anticipated and understood in the context of the competitive bid program and not reflective of fraudulent or abuse behavior. Therefore, the analysis of that data is flawed and the contractor should be aware of these types of issues and the impact it may have.

(iii) Draft policies and guidelines for prepayment reviews. The contractor should have guidelines and instructions on when it is appropriate to implement 100% prepayment review as opposed to a more focused approach, as well as very strict and clear instructions to contractors on timeliness and removal of the edit. In other words, it should not take a ZPIC contractor 9 months to determine that no fraud exists and a referral for education is warranted. Without extenuating circumstances, a prepayment review should rarely last longer than 3 months as that is ample time for an investigator and clinician to determine what action is appropriate.

(iv) CMS staff should be involved and aware of the prepayment review process and be monitoring it closely. Right now, CMS Central Office staff is often unfamiliar with what actions are being taken by ZPICs which goes back to there being little oversight and understanding by CMS as discussed above.

(v) Contractors should correct their errors. Providers whose claims are denied erroneously by a ZPIC contractor should be reopened and corrected by the ZPIC contractor as opposed to utilizing the appeal process. We often see a number of ZPIC denials overturned at Redetermination because the ZPIC denials were incorrect. However, the Program Integrity Manual does not mandate that the ZPICs correct the error rate they are calculating. Therefore, providers are still being scrutinized for the error rate, which is erroneously inflated due to ZPIC errors. We highly recommend that CMS implement more quality improvement controls and measures over the ZPICs and other audit contractors to better quantify and qualify their performance.

By implementing these additional limitations and controls, it will allow investigators to spend more time focused on truly fraudulent activity. Wayne van Halem recounts that as a Medicare Fraud Investigator, he spent a majority of his time and efforts in making sure that "T's were crossed and I's were dotted" rather than investigating fraudulent activity. This sentiment is shared by several of our consultants and current ZPIC investigators with whom we interact. Many of these individuals have the ability and background appropriate to identify and investigate fraudulent practices, yet they lack the healthcare training and guidance or understanding of the complex policies and how they should be applied. As a result, they spend a majority of their time denying claims for legitimate providers adding a significant workload burden on CMS appeal contractors and the Office of Medicare Hearings and Appeals. A review of the appeal statistics support that a majority of claims denied are overturned in the appeal process, which costs the government millions of dollars each year.

8 - Increase funding and focus on innovation and enrollment

CMS has recently touted new and innovative techniques to better monitor claims on a prepayment basis, such as the use of predictive modeling software to identify potentially fraudulent claims and the swipe-card pilot program in process in Indianapolis for physicians who prescribe medical equipment. We applaud these efforts.

Weakness

There is a critical need for increased funding to provide research and implement more innovations consistent with controls in place within the credit card industry that will identify suspect claims immediately. CMS and its contractors must have real-time data analysis capabilities and be required to implement and develop innovations related to their analysis and use of this data. CMS should continue to develop ways in which to stop claims immediately upon receipt prior to payment, but also be able to do so in a timely and effective manner.

Recommendations

(i) Implementing more precise payment policies and processes as suggested in this Paper would reduce the monetary burden placed on the Administration and provide additional funding in researching and developing the most innovative front end tools.

(ii) The OIG report on the effectiveness of the ZPICs previously cited found that, "The inaccuracy and non-uniformity of ZPICs' data prevented a conclusive assessment of ZPICs' program integrity activities."[10] This further supports the concern of CMS' lack of oversight of ZPIC contractors. Having seen the struggles that ZPICs encounter managing their data to track their effectiveness, chances are they are unable to manage the claims data effectively to identify legitimate aberrancies and patterns or trends; therefore, it is not too surprising to see the "false positive" data findings which lead to unfounded audits and investigations. Creation of a national, accurate, complete centralized claims database is possible and we have offered to present such tools to CMS and its contractors on numerous occasions. However, due to the structure of the CMS contracts and its contractors, there was no audience provided.

(iii) Developing and implementing new and innovative techniques must be a performance measure for CMS contractors. If the contractor is not effective, CMS can choose to invest its funds elsewhere for companies that are better equipped to pioneer and advance the investigation of healthcare fraud.

(iv) We support CMS efforts in the area of provider enrollment and feel strongly it should maintain its focus in this particular area to assure that individuals entering the Medicare program plan to participate properly. The only recommendation we have in this particular area, again, is to increase the education and training for the front-line individuals responsible for processing these enrollment applications and implementing a prepayment review process for all new providers for a specified period of time.

[10] http://www.oig.hhs.gov/oei/reports/oei-03-09-00520.pdf

9 - Increased beneficiary education and accountability

While the Agency of Aging is doing a good job of educating beneficiaries, its abilities and funds are limited. The CMS ad campaign for protecting your Medicare identity is also good, but limited.

Weakness

Many significant frauds in the US are being committed in specific ethnic communities, yet very little outreach or education focuses on these groups. Additionally, many beneficiaries have responsibility to meet certain expectations in coverage policies, yet are often unaware of the importance of their involvement. For example, in order to qualify for oxygen on an on-going basis, a beneficiary must visit their doctor for a reevaluation. If the beneficiary does not comply, the provider of the service is liable, not the beneficiary.

Recommendations

(i) It is important for CMS to infiltrate and provide easily understandable educational information to both ethnic and low income beneficiary groups who are seemingly easier and more likely targets for unscrupulous providers. Included in this communication should be education and communication on the beneficiaries' role and responsibility in their care and their benefits, up to and including their liability if they participate in or are negligent in reporting potentially fraudulent activity.

(ii) Increasing the accountability for the Medicare beneficiary in the care and treatment they receive will lessen the burden on providers and reduce the risk of claims being submitted that are not necessary. For example, if the oxygen patient is made aware up front of the reevaluation requirement, but does not comply, they should be made liable for those services for the non-compliance and the notification of the requirement would serve as the advanced notice. If they don't need the equipment and don't comply, they will either return it or be required to pay for it themselves. Without patient accountability, the Medicare program is much more vulnerable to abuse by both beneficiaries and providers. In the minimum, increasing accountability with beneficiaries will increase awareness and involvement from this particular area, which in our opinion, is lacking. The number of Medicare beneficiaries is increasing and will continue to do so. As a result, they are quite integral to the integrity of the Medicare program.

Conclusion

The van Halem Group commends the Committee on its effort to bring together the ideas and suggestions of experts in both the public and private sector to combat fraud, waste, and abuse.

When the program was implemented, it was done in the spirit of trust and integrity. Since the program's inception however, its amended and growing charge has often confounded beneficiaries and providers, troubled oversight agencies, and allowed for fraud and abuse with the system – costing Americans billions of dollars. Complex and vague payment policies and aggressive action taken by large and powerful government contractors that have little oversight and liability is not the best approach. Their actions have made providers and physicians want to avoid taking Medicare patients. For those making efforts to comply with these policies, it has become increasingly expensive and ultimately increases the overall cost of providing care which is not often matched with increased payments.

In discussing that the primary principle of benefit integrity is to pay claims correctly , The Medicare Program Integrity Manual (Pub 100-8), Chapter 4[11] states, "The Centers for Medicare & Medicaid Services (CMS) follows four parallel strategies in meeting this goal: 1) preventing fraud through effective enrollment and through education of providers and beneficiaries, 2) early detection through, for example, medical review and data analysis, 3) close coordination with partners, including PSCs, ZPICs, ACs, MACs, and law enforcement agencies, and 4) fair and firm enforcement policies." It is clear that these strategies, while sound, are not being implemented effectively or efficiently.

A partnership consisting of all those involved in the participation, administration, oversight, and receipt of these benefits is a positive step in the right direction.

[11] https://www.cms.gov/manuals/downloads/pim83c04.pdf

The van Halem Group

Wayne H. van Halem, CFE, AHFI is an author, consultant, and President of The van Halem Group, LLC. He has over 15 years of experience in the industry having previously worked in leadership roles at various Medicare contractors. Although his most recent position with Medicare was managing second-level Statutory appeals nationally, a majority of his career was focused on program integrity and anti-fraud functions. He served in various positions including Fraud Analyst, Medicare Fraud Information Specialist, and Supervisory Investigator. He is well-known in the industry for his fraud-fighting efforts and in depth knowledge of the Medicare and Medicaid Programs. He is an Accredited Healthcare Fraud Investigator through the National Health Care Anti-fraud Association (NHCAA) and a Certified Fraud Examiner with the Association of Certified Fraud Examiners and has served on the faculty of both organizations.

Dr. Kenneth M. Nelson, MD, MPH, CFE serves as Medical Advisor for The van Halem Group. Dr. Nelson has had extensive experience with Medicare and Medicaid statistical analysis and fraud investigation, both in the federal government and with government contractors. His experience covers 30 years, including 20 as the Medical Advisor with the Office of Inspector General, US Department of Health and Human Services and the remaining time as Medical Director for multiple Medicare contractors. Throughout his career, he has provided medical support for federal auditors and criminal investigators reviewing Medicare and Medicaid records both with the OIG and with Medicare contractors. Dr. Nelson is a Past Regent of the Association of Certified Fraud Examiners. He has also served on the teaching faculty of that organization as well as at the Department of Justice National Advocacy Center.

Pam Felkins Colbert, JD, AHFI currently serves as the Vice President of The van Halem Group and leads the compliance division of the practice. As an attorney for more than twenty years, Pam has both public and private health insurance experience in the areas of fraud, waste, abuse, costs savings, contracts and compliance. Pam also has the unique experience of working on the oversight side as the Manager of a Medicare Fraud and Abuse Unit with a CMS contractor. Pam has conducted national Medicare fraud training at CMS Regional Anti-Fraud Conferences and at various legal continuing education seminars. Pam has litigated for insurers as well as for providers on national litigation teams. Pam also brings experience as Vice President and Corporate Counsel for a regional healthcare data company.

Carrie Nienberg, RN, CLNC, CPC serves as the Clinical Operations Manager for The van Halem Group. Carrie has 30 years of nursing experience in multiple settings including a hospital, physician office, ambulatory surgery center, and a Medicare Program Safeguard Contractor (PSC). Her specific areas of expertise include peri-operative (including Pre-Op), operating room, surgical assistance, recovery, and Medicare medical review and benefit integrity. During her time with a PSC, Carrie was responsible for traditional medical review functions and medical review in support of benefit integrity. Carrie is also a Certified Legal Nurse Consultant and Certified Professional Coder.

EXHIBIT 2

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop AR-18-50
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Program Integrity

OCT 11 2011

The Honorable Jeff Miller
United States House of Representatives
4300 Bayou Boulevard
Suite 13
Pensacola, FL 32503

Dear Mr. Miller:

I am writing in response to your August 18, 2010, letter on behalf of your constituent, REDACTED REDACTED, regarding the prepayment review of REDACTED by SafeGuard Services, LLC (SGS). In her letter, REDACTED raised several concerns: SGS and the Centers for Medicare & Medicaid Services (CMS) lack of responsiveness; the denial of an extension to submit Additional Documentation Requests (ADR) for claims being medically reviewed; inconsistencies with the medical review decisions; and questioning how the Zone Program Integrity Contractors (ZPICs) are paid.

CMS strives to be as responsive as possible concerning investigations. SGS has been contacted by REDACTED and has responded on several occasions:

- Congressional inquiry from Senator Bill Nelson's office on April 7, 2011;
- Telephone conversation with the SGS investigator regarding the prepayment review on May 20, 2011;
- Previous Congressional inquiry from your office on June 27, 2011;
- Prepayment review education letter on June 29, 2011 detailing the claim denial rate and rationale; and
- An additional phone conversation with the SGS investigator in July 2011.

Additionally, CMS has responded to all of REDACTED concerns in two previous Congressional inquiries; one from Senator Nelson's office in April 2011 and a previous inquiry from your office on August 1, 2011. CMS also held a conference call with REDACTED to address her concerns in July 2011.

REDACTED expressed concerns regarding the time period to provide ADRs to SGS. On August 4, 2011, SGS communicated to REDACTED that an extension would be granted to submit the ADRs. REDACTED was given an additional 15 days to respond to the ADRs with medical records to substantiate the claims being reviewed.

REDACTED also expressed concern regarding the inconsistencies of the medical review decisions. REDACTED alleged that some claims were paid one month and then denied in the

EXHIBIT 2

subsequent months for the same item/code when the same information was submitted. On July 20, 2011, the supplier was asked to submit examples of the alleged inconsistencies. Eleven oxygen or oxygen related claims were submitted by the supplier and were reviewed again. Of the 11 claims that were reviewed again, four were reviewed correctly. The additional review identified seven claims that were incorrectly reviewed.

SGS implemented a new process where once a claim is reviewed for oxygen or oxygen related items, if it includes all necessary documentation, it is set to pay automatically. Three of seven claims incorrectly reviewed were reviewed prior to the implementation of this new process and should not have been denied. Subsequent claim submissions for these beneficiaries with oxygen or oxygen related items have approved to pay in light of this new process.

I acknowledge that the remaining four claims from the seven incorrectly reviewed had incorrect determinations by the SGS medical reviewer. The medical review errors have been addressed by SGS and proper quality control measures were taken. REDACTED should appeal these four incorrectly denied claims to the redetermination level at the Medicare Administrative Contractor (MAC) as outlined in Chapter 29 of the Internet Only Manual (IOM), Publication 100-04 (Medicare Claims Processing Manual).

Finally, REDACTED inquired as to how the ZPICs are paid. The ZPICs are not paid based on the number of claims they deny. Rather, ZPICs are paid on a cost reimbursable basis in accordance with the Allowable Cost and Payment clause in the Federal Acquisitions Regulation (FAR) 52.216-7.

Addressing improper payments in the Medicare fee-for-service (FFS) program is a top priority for CMS. The prepayment review will not be lifted at this time. The denial rate remains high and the investigation is still ongoing. Please contact Lindsy Massuda of my staff at if you have any questions.

Sincerely,

Olin Wells for

John Spiegel
Director
Medicare Program Integrity Group

FEAT
Fraud Eradication Advisory Team

BACKGROUND

As partners in the fight against Medicare fraud, waste, and abuse, we are all aware of recent news articles and headlines discussing fraud in the durable medical equipment industry. Since the beginning of 2008, there have been over 800 hits in the media on this topic. These have accounted for 114.5 million media impressions and the advertising equivalent of $30 million. The coverage is overwhelmingly negative and no partner in this fight is immune including CMS, its contractors, or DME suppliers.

For years, we have all worked in our own rights to attempt to curb fraud and abuse. In many instances, we may have worked against each other or pointed blame. However, we all have the same goal in mind: to reduce Medicare fraud and abuse. This team is made up of individuals who have worked for or with providers, legal counsel, government agencies and Medicare contractors. We have seen the commitment and desire to combat fraud from each of these perspectives. The time has come for us to come together and begin a unified charge to end this unrelenting crisis that afflicts each of us.

We proposed a unique advisory council, called FEAT, made up of DME industry leaders who have shown a commitment to ending fraud and abuse, anti-fraud experts, Program Safeguard Contractor representatives, and CMS Program Integrity Staff. The dictionary definition of "FEAT" is a deed notable especially for courage and an act or product of skill, endurance, or ingenuity. We feel this acronym was appropriate as combating rampant fraud and abuse is a FEAT in and of itself.

MISSION

To create a unified charge to eradicate the unrelenting fraud and abuse crisis by utilizing expertise from all stakeholders, collaborating on ideas and solutions, and combating this problem with short term and long term solutions.

FEAT SUGGESTIONS

FEAT will serve as a fraud advisory council, involving active participation from industry representatives, stakeholders, CMS and contractor staff. The group would meet quarterly to brainstorm and share ideas to curb fraud and abuse both in the short term as well as long term. Working collaboratively with CMS to ensure that these existing fraud-defeating mechanisms are utilized effectively and efficiently:

- Marketing practices – Eliminate advertising and marketing practices that already cross the line, very similar to what is being done to drug plans in Medicare Part B.
- Site Inspections.
- Background Checks – Establish a way to perform background checks on providers/business before provider number is issued.
- Reporting Process – Have a viable and accountable source/system for the sole purpose of handling reports of fraud, waste and abuse. This would include providing an informative situation that

shows the informant just what is needed (e.g. evidence, documentation, etc.) to process a complaint. CMS/OIG will then need to follow up on all complaints.

- Increased Funding for Data Analysis – Allow for additional funding and focus on proactive real time claims data analysis and edits to assure quicker response to egregious behavior.
- Education – Provide better education for audit staff in relation to policies and claims submission requirements.
- Increased focus on non-suppliers – Increase scrutiny on individuals/companies that are not enrolled suppliers, but serve as gatekeepers or ringleaders to fraudulent or abuse practices (e.g. Consultants, Billing Companies, Distribution Centers).
- Expand or increase current exclusion authority to include all positions (not just management or owners) within any entity that either bills or advises companies that bill (including consultants) any federal government entitlement program such as Medicare and Medicaid.

ADDITIONAL CONSIDERATIONS & RECOMMENDATIONS

Licensure – Encourage and support the initiation and implementation of a consistent and comprehensive State licensure program throughout the country. This would include a Code of Ethics program in which the licensure board has review and reporting authority.

- This would help allow the industry to police its own. Require licensure at the state level by forming DME Licensure Boards similar to the Pharmacy Boards in each state. The boards would have the capacity for quick response to complaints of fraud and abuse (board has investigatory powers) and if warranted remove state license to provide DME in the state.

Enhanced New Provider Scrutiny – The following recommendations are being made for all new suppliers who apply for a provider number to bill Medicare:

- Providers should be required to maintain $65,000 in surety bonds for the first three years of operation, pursuant to the statute existing in the MMA of 2003. This requirement would expire after three years if the supplier has not had any discrepancies.
- New suppliers should also be subject to automatic prepayment review within the first 6 months of operation.

Enhanced Non-Supplier Scrutiny – Consultants, billing agencies and distribution centers acting as conduits of fraudulent or abuse behavior should be targeted for investigation as well since their actions could directly or indirectly result in damages to the federal government.

Policy Review – Implement policy group or procedure code specific prepayment reviews in addition to the provider specific prepayment reviews already conducted. The results of these general reviews can then be analyzed by F.E.A.T. to determine appropriateness and reasonableness of the policy resulting in evidence-based policy development or revisions.

Mandatory Reporting – Establish mandatory fraud and abuse training for all accreditation surveyors and clarification of the policy, which requires accrediting bodies report suspected fraud or abuse. This policy would include direct reporting capabilities from surveyors to the appropriate investigative entity

as well as the requirement for investigative staff to directly communicate with surveyors to obtain information. The policy should also include oversight and accountability of accrediting bodies that do not report suspected fraudulent or abusive behavior or accredit organizations that knowingly participated in suspicious behavior.

Fraud Tracking Capability – Develop an online tracking and reporting system to acknowledge and track complaints. This is accomplished by extracting non-sensitive information from existing case tracking databases. When a complainant provides information, an acknowledgement should be sent which could include a case tracking number. The complainant should then be able to utilize this case tracking number to track the general status of the case. Many individual providers do not report suspicious behavior because of the lack of feedback on previous complaints made which creates a false sense that no action is being taken. The status would include "general" information such as pending with contractor, OIG, DOJ, CMS or indicate when a case has been resolved or closed. This provides more accountability for agencies responsible for reviewing allegations of fraud and abuse as well as increases industry confidence resulting in increased reporting of fraudulent behavior.

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