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September 29, 2004

Dana Edwards, ARNP, MSN
Medicare Medical Review Unit
1133 SW Topeka Blvd., Bldg, D, 4th Floor
P.O. Box 3543
Topeka, Kansas 66601-3543

Re: August 9, 2004 and August 26, 2004 Letters.

Dear Ms. Edwards:

Our offices represent Dr. Patrick Nemechek. We are writing in response to your August 9, 2004 letter ([Exhibit 1](#)) and your August 26, 2004 audit letter ([Exhibit 2](#)). This letter is written for settlement purposes only and should be used for no other purpose whatsoever.

I. NOTICES.

A. Notice of No Additional Claims and Pending Action.

Until your offices can provide consistent, medically based policy rationale for auditing and providing coverage for IVIg under your LMRP (Local Medical Review Policy), Dr. Nemechek will no longer provide services to his otherwise qualified Medicare IVIg patients. After conferring with CMS representatives and reviewing the storied history of this case, we are convinced that your agency lacks the capacity and independence of judgment as a CMS contracted intermediary in the arena of intravenous immune globulin (“IVIg”) injection healthcare related issues to adequately render any meaningful guidance to practitioners on the use of IVIg.

B. Notice of Imminent Harm to Patients.

During the pendency of your prior audits the periods of interruption in IVIg treatment of many of Dr. Nemechek’s patients caused serious medical complications. Several patients died after suspension of their treatment. Dr. Nemechek is extremely concerned that lack of IVIg treatment for his current patients will again result in serious medical complications, and for some patients may hasten death. Based on his experience with patients who have had their IVIg treatments interrupted based upon past Medicare audits, Dr. Nemechek estimates that of the

twenty four patients who will be prevented from receiving IVIg, one to two will likely die within two to three months and another twenty five percent of the remaining patients within one year from the time their treatments cease. The remaining patients will suffer widely varying degrees of chronic recurrent infection.¹

C. Wrongful Basis For Prior And Current Audits Resulting In Freedom Of Information Act Request.

Lives of patients were lost under circumstances wherein we are left to conclude that financial considerations have been given priority by your agency over sound medical judgment. The current audit appears to be geared toward the same financial motive. We have evidence that strongly implicates administrative members of your carrier in carrying out the purely economic incentive for conducting these audits which we will share with you herein. Further, we will provide abundant evidence that your agency has disregarded the issues of medical necessity of IVIg and have not otherwise conducted an audit of Dr. Nemechek for any appropriate audit purpose.

Your agency has left Dr. Nemechek with no reasonable alternative but to recruit assistance broad enough to combat your collective efforts. We are considering all remedies available to Dr. Nemechek and his patients to remedy your carrier's actions.

Please be advised that our offices are submitting appropriate Freedom of Information Act requests to secure copies of all manner of correspondence, internal directive or related information which may directly or indirectly relate to your audits of Dr. Nemechek or his use of IVIg and HIV policies; any internal memorandums from your offices or CMS relating to Dr. Nemechek or IVIg and HIV fiscal or other policy; and copies of all files relating to the prior audits of Dr. Nemechek. Any compromise or destruction of evidence which may bear on this matter may subject you or your agency to civil or criminal penalties such that you should act to preserve such evidence and govern your actions accordingly.

II. BACKGROUND.

A. Scope and Purpose of Third Audit.

As you should now be aware, Dr. Nemechek has been in relatively constant communication with Dr. Arnold Balanoff and Jacquelyn Standard of CMS in reference to his receipt of your respective letters above referenced.

In conferring with CMS and other medical professionals about the current LMRP IVIg policy and the continued audits of Dr. Nemechek and similarly situated physicians in the region, consensus has been reached that demands immediate action against your intermediary carrier to prevent more senseless death and illness to immunocompromised patients. The consensus is that you, your predecessors, and others in the Kansas intermediary carrier office remain intent on

¹ Attached hereto as [Exhibit 3](#) are letters from patients named in your August 26, 2004, letter, the majority of whom you have audited before. These letters are pleas from the very people you are targeting with your audit letter who discuss the magnitude of harm the loss of IVIg will have. There names have been redacted for privacy purposes although we have their written consent to publish each such statement.

terminating legitimate claims for IVIg. You have endeavored to accomplish this purpose through constant re-drafting and re-interpretation of the LMRP IVIg policies.

There is further consensus that you and your agency are employing oppressive tactics against Dr. Nemechek to harass and deter him from continued use of IVIg therapy. These tactics have included the repetitive auditing of Dr. Nemechek to the point he can no longer emotionally or fiscally withstand your incessant audit demands. These tactics further include your agency's constant threats of referral of Dr. Nemechek for criminal prosecution by the Medicare Fraud Area should he continue to bill Medicare for IVIg and related therapies. Above all, your agency has employed these tactics with reckless disregard to the impact your efforts have had, and will have on patients whose lives are dependent on this treatment.

To say the least, your third IVIg audit of Dr. Nemechek in four years, of virtually the identical subset of patients, falls far short of the stated purpose in your latest audit letter (August 26, 2004 – [Exhibit 2](#)) that purports to be legitimized as follows:

“The purpose of the Medicare Medical Review unit is to provide education to providers so we can reach CMS's goal of paying claims right the first time.”

We believe that the transparent and overriding objective of your office is to target Dr. Nemechek based solely upon the fact that he has a high IVIg billing ratio compared to other regional physicians. This belief is grounded in the fact that you have repeatedly cited the fact that Dr. Nemechek's high IVIg usage rates were the sole reasons for targeting him. Through the course of two prior audits your offices have had ample opportunity to evaluate the basis upon which his practice has a larger IVIg patient base. Through the audits you have twice confirmed the legitimacy of his higher IVIg usage rates. Furthermore, you have twice made specific audit findings that indicate that Dr. Nemechek's IVIg claims were paid correctly “the first time”. Yet you have the audacity to assert that a third audit is necessary for the purpose of providing Dr. Nemechek physician education on the proper payment of claims. To properly demonstrate the utter disingenuous nature of the stated purpose of your most recent audit letter, a brief history of this matter must be provided.

B. First Audit and Audit Findings.

Dr. Nemechek was audited on January 7, 2000 letter ([Exhibit 4](#)) at which time your offices demanded recovery of alleged overpayments of \$168,783.05. Without granting Dr. Nemechek a single hearing or opportunity to respond to your audit allegations, your offices concluded that Dr. Nemechek was not “without fault” for billing certain IVIg codes under the then current LMRP policy and that he was therefore required to repay this oppressive sum to Medicare.

Dr. Nemechek vigorously contested your audit assertions. He exposed the complete lack of candor by your purported expert whose medical opinions your agency wholeheartedly wed itself to in its decision to demand overpayment recoveries from Dr. Nemechek. After much time and effort was expended to justify his claims, on May 3, 2000, Dr. Nemechek was met with a letter from Medicare where your agency quickly reversed its audit findings in letter form

attached hereto as [Exhibit 5](#). Your intermediary reduced the massive repayment obligation to a meager \$129.15 with a corollary finding that the claims and documentation submitted by Dr. Nemechek for billing code 279.00 (hypogammaglobulinemia, unspecified) were supported by appropriate medical records for the diagnosis rendered and were otherwise appropriate under the requirements of the LMRP.

In any event, included in the original January 7, 2000 letter which was issued before the audit was even conducted, your offices imbedded the following direct threatening overture as its parting sentiments:

“A [sic] Carrier for the Medicare Program, it is our responsibility to advise you that if you *continue* to bill for services which are determined to [sic] medically unnecessary and the billings are determined to be willful and intentional, this could result in you being excluded from the Medicare program, as outlined in Section 1128(b)(6) of the Social Security Act. Also *continuation* of these incorrect billings could result in application [sic]f Civil Monetary Penalties of \$10,000.00 per line item as provided under the Civil Monetary Penalty Fund of 1981 Section 1128A of the Social Security Act... *As problems were identified, another review of your practice will be conducted after six months and if errors are still identified, refunds may be obtained and your case may be referred to the Fraud Area for appropriate action.*” See. [Exhibit 4](#), p.3. Emphasis added.

In light of the fact that your audit resolved on May 3rd, 2000 wholly in favor of Dr. Nemechek and found no noteworthy problems with claims submitted by Dr. Nemechek, the threat of an additional audit contained in your January 7, 2000 letter was rendered moot. Given the breadth of the audit conducted by your offices, it was clearly inappropriate to have not removed the threat of civil monetary penalties and referral of Dr. Nemechek to the Fraud Area given that an almost infinitesimally small 0.00076518 percent of his claims ended up at issue post audit.

C. Discovery Of Information Revealing Your Intermediaries True Agenda.

Soon thereafter it became evident that your audit motivation was far more ominous than an audit of claims submitted for purposes of educating the physician or ensuring claims were submitted and paid appropriately the first time. Eleven days before your first audit began your offices modified the LMRP dramatically. Your offices attempted to use those LMRP changes as the basis for your first audit by applying your new rules to claims properly submitted under the prior LMRP. Having failed in that attempt as was outlined by your own hearing officer in her audit findings of May 3, 2000², on July 11, 2001 your agency simply instituted another audit on the pretextual basis that:

² [Exhibit 5](#), p.3,¶2.

“In our letter of January 7, 2000 you were advised we would be reassessing your practice.” See [Exhibit 4](#).

In light of the fact that your offices made findings in the first audit as to the appropriateness of the bulk of Dr. Nemechek’s submitted claims, a reassessment was neither necessary nor appropriate. Notwithstanding the foregoing, your offices knew you had changed the LMRP and were intent on auditing Dr. Nemechek again to carry through with your original **scheme**.³

In discovery, Medicare turned over an internal memorandum to Dr. Nemechek’s legal counsel, a copy of which is attached hereto as [Exhibit 6](#). The memo reveals, in pertinent part, the true purpose and perpetrator of your carrier’s scheme:

“J1562 is aberrant over threshold for specialty 11 family practice in KC. This code was also selected because the carrier % of change was 125.54. *This means basically that our usage of this procedure code has increased 125%...*

Dr. Murti is in the process of *rewriting the Immune Globulin policy* and we will *nab that as the corrective action*. I would preliminarily like to suggest looking at least one provider Nemechek E56236 as he is driving the aberrancy.” Emphasis added.

By definition the scheme was set in motion as follows. Your agency noted a high IVIg usage rate. Your agency was determined to curb utilization. Dr. Murti, your agency’s own Medical Director, the one person you would hope would look at the interest of the patient to be effected by his action, is directly implicated in re-writing the LMRP IVIg policy to curb utilization. Your agency purposefully singled out Dr. Nemechek for audit based solely upon high usage of IVIg. Your agency then affected the audit in a direct effort to *nab* Dr. Nemechek and others. Your audits were clearly founded upon financial considerations as opposed to legitimate audit grounds sounding in medical necessity or physician education.

Your agency committed to its design of curbing utilization by instituting the first audit. Your agency didn’t even wait long enough for the policy changes it crafted to take effect and you audited claims submitted under prior LMRP policy. The only glitch that temporarily derailed your agency’s efforts was the surprising findings of your hearing examiner. She didn’t partake in the plan by specifically noting the obvious; the current revised LMRP rules were improperly applied by your expert to IVIg claims submitted under the LMRP which existed prior to Dr. Murti’s ostensible re-write of the revised LMRP.⁴

D. Second Audit And Audit Findings.

³ Black’s Law Dictionary, Sixth edition, at 1344, defines a scheme as “A design or plan formed to accomplish some purpose...Such connotes a plan or pattern of conduct which is intended to or is reasonably calculated to deceive persons of ordinary prudence and comprehension.”

⁴ ID at footnote 2.

Under the cloak of governmental immunity, your agency swiftly proceeded with its scheme by issuing a second audit letter on July 11, 2001, a copy of which is attached here as [Exhibit 7](#). As mentioned above, by instituting this audit your agency purposefully disregarded the fact that a follow up audit to the first audit was rendered unnecessary. Given that the first audit concluded in Dr. Nemechek's favor, absent your scheme, there was no reason to follow through with the second audit when doing so was premised on the mistaken first audit allegation that Dr. Nemechek originally filed claims lacking medical necessity or filed them incorrectly.

As a result of the second audit your carrier made a hefty demand upon Dr. Nemechek's relatively small practice and demanded recovery of \$167,192.60 for alleged overpayments, primarily from claims made for HCPCS code j1562 (*Injection, Immune globulin, Intravenous, 5mgs*). Your scheme appeared to have finally met its purpose. However, Dr. Nemechek appealed your audit findings. After many months of compliance with your agency's second audit and the appeal that followed, your offices again concluded deeply in favor of Dr. Nemechek per its unapologetic letter of October 11, 2002 (See: [Exhibit 8](#)).

Your offices reinstated Dr. Nemechek's billed services for code j1562 and reduced the alleged overpayment allegations to a mere \$146.20.^{5, 6} If you are keeping score, in agreement with your first audit results, your agency reversed 99.99912556 percent of the alleged overpayments it had sought in the second audit.

E. Failure To Follow Your Own Medicare Part B Physician's Manual – Post Payment Medical Review Policy.

Your offices were not ready to abandon its attempts at preventing Dr. Nemechek from treating patients with IVIg. In carrying out its scheme, your offices failed to follow its own Medicare Part B Physician's Manual Post Medical Review Policy by not providing any error rate information to the doctor relative to either of the first or second audits.⁷ The policy provides in pertinent part that:

“...After all sampled claims have been reviewed; an overall provider error rate will be calculated for the probe sample...”

It is important to note that the provider error rate is based on the dollar amount and not based on number of claims. This error rate,

⁵ I would note that in response to the first audit Dr. Nemechek authored a series of letters to HCFA Medicare Medical Director S. Satya-Murti to clarify the appropriateness of the billing codes and medical necessity of IVIg (Intravenous immunoglobulin) being used. Dr. Nemechek requested firm confirmation that the billing codes being used were appropriate for IVIg claims given his patient profiles. Dr. Nemechek was left with only conclusory statements by Dr. Murti who indicated that payments were unlikely to be denied in the future given Dr. Nemechek's current utilization principles for prescribing IVIg. It was upon this basis, that Dr. Nemechek continued his use of IVIg therapy with Medicare patients. See: [Exhibit 9](#) Letter of Murti dated August 15, 2000.

⁶ I would further note that in response to Dr. Nemechek sending a letter to your carrier with each claim submission, Jeannette Curtis contacted one of Dr. Nemechek's employees and antagonistically informed her that Dr. Murti did not appreciate the letters requesting prior approval. A copy of Dr. Nemechek's employee e-mail relating these events is attached as [Exhibit 10](#).

⁷ See: Medicare Part B Physician's Manual, Medical Review Section – Rev. 2.37 (12/2001) P. 3, attached here in its entirety as [Exhibit 11](#).

along with other factors; such as, the providers past billing history, past education, etc., will be used to assess the nature of the problem as *minor, moderate, or significant*.

After the extent of the problem has been analyzed, feedback from the review is given. This feedback includes the nature of the problems identified; *what steps the provider should take to address these problems; and what steps we will take to address the problems. The overall goal for providing this feedback is to ensure proper documentation and billing practices so that claims will be submitted and paid correctly.*" Emphasis Added.

Your offices did not provide any error rate feedback to Dr. Nemechek. Not a single error rate suggestion or conclusion is to be found in either of your first or second audit conclusions. Hence, Dr. Nemechek was left to conclude that by virtue of the fact no statistical error rates were ever reported to him was a dispositive indication that not even minor problem under your own classification guidelines ever occurred.

F. Continuation Of Your Agency Making Criminal And Civil Penalty Threats.

After years of pressure brought to bear by your offices and along with the news that Dr. Nemechek had done nothing wrong in the second audit, your agency unrepentantly continued its efforts to curb utilization of IVIg by preserving an ominous threatening overtone in its October 11th, 2002 audit conclusions. In your closing statements you reiterated the following unsubstantiated threats:

“As Carrier for the Medicare Program, it is our responsibility to advise you that if you continue⁸ to bill for services which are determined to be overstated, the documentation is either lacking or insufficient, and the billings are determined to be willful and intentional, this could result in you being excluded from the Medicare Program, as outlined in Section 1129 (b)(6) of the Social Security Act. Also, continuation of these incorrect billings⁹ could result in application of Civil Monetary penalties of \$10,000.00 per line item as provided under the Civil Monetary Penalty Law of 1981, Section 1128A of the Social Security Act {42 I[sic]SC 1320a-7a}...

Since the consultant feels that the majority of the services audited were reasonable and necessary based on the resubmitted documentation in the medical records; we are closing the file at this time. However, if future audits are conducted and errors are identified, refunds may be obtained and/or **your case may be referred to the Fraud Unit for the appropriate action.**" See: [Exhibit 8](#), p.2, ¶¶ 4-5, emphasis added.

⁸ No notable overstated billings were found or alleged from your audit findings upon which your offices could reasonably have based this statement upon.

⁹ No notable incorrect billings were found or alleged from your audit findings upon which your offices could reasonably have based this statement upon.

III. PRESENT DISPOSITION OF MATTER AND THIRD AUDIT ANALYSIS.

A. Lack Of Any Legitimate Basis To Conduct Third Audit.

Ms. Jacquelyn Stanard, a Health Insurance Specialist at CMS, was consulted about your most recent August 9, 2004 and August 26, 2004 letters. Dr. Nemechek explained his well grounded belief that your agency's scheme to prevent IVIg payments on otherwise legitimate claims, focusing directly on HIV patients, was now manifesting itself by virtue of your prepayment review audit. Dr. Nemechek explained his confusion to Ms. Stanard as to how medical necessity and claims processing was determined to be proper in his two prior audits, but now, under the exact same claim submissions the medical necessity or claims processing may not be proper.

Ms. Stanard responded by providing clarification about the underlying permitted purposes of an audit. She believes you certainly have the right to undertake audits, but was very concerned about the appropriateness of your agency's right to repeatedly conduct audits under circumstances where virtually no problems were identified in back to back prior audits. Ms. Stanard consistently focused on the notion that audits were have to be conducted only for the express purpose of educating the physician community and to ensure claims are submitted and paid correctly the first time they are presented. Furthermore, clarity as to your audit scope was gleaned through reference given to the applicable Medicare regulations which provide specific guidance as to what services are excluded from coverage, particularly "any services that are not reasonable and necessary for...the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."¹⁰ Simply stated, Medicare's review should be limited to reviewing whether IVIg is medically necessary if a claim is otherwise properly administratively filed.

The facts of this case establish that your agency's audits of Dr. Nemechek have been implemented for an improper financial purpose. Otherwise legitimate origins for a third audit are plainly eliminated as follows:

- i. **Medical Necessity:** Medical necessity was never a focal point in either of your prior audits, nor the present audit. Furthermore, you have been provided hundreds of pages of medical treatise on the subject from Dr. Nemechek alone during the prior audits and have not questioned the medical literature or the efficacy of the treatments for many years.
- ii. **Proper Submission and Payment of Claims:** From a plain reading of Dr. Murti's letter referenced in footnote 5 above, and from a reading of both audit findings conducted to date, your offices have universally concluded that the documentation, billing codes and use of IVIg by Dr. Nemechek have been exceedingly proper. Notwithstanding these findings, your carrier continues to attempt to curb utilization and circumvent payment of IVIg claims to patients whose very lives are at stake. Your carrier's motivation for their actions cannot honestly be tied to proper payment of claims.

¹⁰ See: (42 C.F.R. §411.15(k)(1))

- iii. **Education of the Physician:** Evasive and inconsistent information has been given to Dr. Nemechek when requested of Dr. Murti. No “feedback from the review” was given to Dr. Nemechek at the conclusion of either of the first two audits per your agency’s own Medicare Part B Physician’s Manual. Dr. Murti’s suspected LMRP revisions are properly viewed as anything but educational to the physician community. Your offices maintain cryptic readings of the LMRP to exclude co-existing HIV diagnosed adult patients as will be more fully reviewed below. Furthermore, your agency has made revisions to its “procedural methodology” in reviewing IVIg claims under the current LMRP without providing any documented justification or instruction therefore.

In summary, your agency’s continued targeting of Dr. Nemechek for audit; its failure to raise issues of medical necessity; its failure to substantiate any procedural claim filing errors; Dr. Murti’s unresponsive and intransigent approach in failing to work closely with Dr. Nemechek in written requests for interpretation of the LMRP; Dr. Murti’s suspected purposeful revisions to the LMRP without ever consulting Dr. Nemechek and presumably other providers who will be affected by such changes; altogether overwhelmingly evidence that your agency has absolutely no intent to educate the physician community or are otherwise interested in ensuring proper processing of claims. The scheme remains constant. Your carrier plainly wants to reduce utilization rates of medically appropriate, substantiated tested, life-saving IVIg to save a few bucks at the cost of human life.

B. Changes In Processing Of Claims For IVIg Targeting the HIV Infected Patient.

Your agency’s plan to preclude IVIg claims has long revolved around a disguised platform of claim denials for patients who have co-existing HIV and hypogammaglobulinemia diagnosis. This follows from the fact that many of Dr. Nemechek’s patients are HIV positive and Dr. Murti apparent attempt at “nabbing” them through LMRP manual changes. Most recently you personally re-employed this theory by setting forth the following in your August 10, 2004 article attached hereto as [Exhibit 12](#):

“For coverage under this section of the LMRP the hypogammaglobulinemia must be from a *primary* deficiency, and not due to *secondary* causes such as medications that interfere with production of IgG, systemic diseases such as renal or gastrointestinal, and certain types of malignancies, or viruses such as Epstein-Barr, Cytomegalovirus and **HIV**”. Emphasis added.

Further, your August 26, 2004 audit letter specifically recites:

“Diagnosis 279.00 – Hypogammaglobulinemia, unspecified is a non-specific diagnosis and is not sufficient to describe any of the 5 covered diseases.”

Only one day before you published your August 10, 2004 article, you issued Dr. Nemechek the August 9, 2004 letter¹¹ as a clear precursor to a third audit. Then, in the tradition of your agency's long standing scheme, a mere two weeks later you issued the third audit demand on August 26, 2004.¹²

In this third audit you singled 5 out of ten patients who have already been audited in one or both of your prior audits. You then asserted each IVIg claim submitted for such patient would be subject to audit again the very next time Dr. Nemechek provided IVIg treatment to them. Each patient you targeted was conveniently HIV positive, even though many of Dr. Nemechek's IVIg qualified patients have no co-diagnosis of HIV and Common Variable Immunodeficiency (CVI). You purposefully changed the rules again such that even though such a claim would have been fine during the days, months and years before the September 1, 2004 deadline you employed, the very same claims were subject to your newly injected scrutiny. After your predecessors had levied recurrent threats of criminal fraud prosecution into Dr. Nemechek's conscience, in your latest audit letter *you essentially dared Dr. Nemechek to file another claim!*

You know that claims submitted by him have always been appropriate from a medical necessity standpoint. You know his claims have been universally sound from a submission standpoint. You know that the underlying medical science has not changed and that the need for this therapy is manifest. You know if IVIg is withdrawn that people will become ill and possibly die. Yet you endeavored to change the entire substance of the LMRP IVIg guidelines with another swipe of the pen by reviving this nonsensical primary vs. secondary deficiency argument. I ask that you revisit the patient letters submitted herewith as [Exhibit 3](#) and consider the real effect your tactics are now postured to have.¹³

C. Code 279.00 Is Sufficient To Describe One Of The 5 Covered Diseases.

I reiterate that your past and present attempts to bootstrap the primary versus secondary co-diagnosis of HIV as a reason not to approve IVIg therapy is found nowhere within the LMRP. Your argument in this regard has been so poor that you have now resorted to gleaning the "intent" of the ICD-9 code itself and changing your "processing methodology" to act in concert with your interpretation of the "intent" of the ICD-9 code.¹⁴ Your argument can only be viewed as another deliberate attempt to circumvent a fair reading of the current LMRP. In doing so you are ignoring your agency's own procedural requirements when seeking to modify a particular LMRP, which require public comment and proper debate.

¹¹ See [Exhibit 1](#).

¹² See [Exhibit 2](#).

¹³ Your agency has long injected this non-medically based rationale to audit Dr. Nemechek by focusing on a "primary" versus a hypothetical "secondary" diagnosis coverage issues not otherwise defined or found in the LMRP or in any related materials. The primary focus has been targeting patients with co-diagnosis of common variable immunodeficiency and HIV. For discussion of the folly of your carriers' historical efforts in this regard, I attach as [Exhibit 13](#) hereto a copy of our firm's letter to your agency dated May 1, 2002, which contains exhaustive discussion of this topic found in pages 1 – 26 therein. Consequently, Dr. Nemechek, and his patients, are not proper targets of a new audit.

¹⁴ Your interpretations of the intent of code 279.00 are recited in your letter of August 9, 2004 ([Exhibit 1](#)) to Dr. Nemechek and in your August 10, 2004 publication of the Change in Processing Claims article ([Exhibit 12](#)).

Specifically, you assert that ICD-9 code 279.00 is inappropriately vague when used for an IVIg claim submission. You fail to cite a single competent shred of support for limiting its broader application. You assert that the intent of the inclusion in the ICD-9 code of 279.00 was to be isolated to a limited secondary diagnosis billing exclusively appropriate for chronic lymphocytic leukemia. You should be well aware that the ICD-9 code is merely a coverage manual not otherwise subject to tests of intent. Nonetheless, by your assertion that ICD-9 code 279.00 was intended to be used only as a secondary diagnosis for chronic lymphocytic leukemia, you imply that it is therefore not an appropriate independent criterion for providing coverage for Common Variable Immunodeficiency (hereafter sometimes “CVI”).

You thereafter provided no guidance as to which ICD-9 code would otherwise be appropriate and no medical or legislative support for your interpretation of the “intent” of ICD-9 code 279.00. Hence, you have left Dr. Nemechek, and all others trying to interpret the LMRP and your article, with absolutely no guidance as to proper coding, while simultaneously auditing Dr. Nemechek on his very next attempts at coding IVIg claims!

Whereas Common Variable Immunodeficiency (CVI) is one of the five covered Primary Humoral Immunodeficiencies you recite must be a pre-requisite to payment in your most recent LMRP “processing methodology” article, the use of code 279.00 (**Hypogammaglobulinemia, Unspecified**) should be adequate by all measures. In fact, code 279.06 sets forth specific subsets of CVI, including **Hypogammaglobulinemia** under the very heading of “**Common Variable Immunodeficiency**”! Your offices have systematically failed to address the breadth of medical literature Dr. Nemechek has provided you, which suggests that the terms “common variable immunodeficiency”, “hypogammaglobulinemia” and “dysgammaglobulinemia” are simply synonymous in the medical field.¹⁵ Given that CVI is synonymous with the term hypogammaglobulinemia, coding under the term hypogammaglobulinemia would certainly be a fair descriptor for coding purposes.

In any event, if your letter merely stated that code section 279.06 was more appropriate, Dr. Nemechek would have clearly conformed to such a billing procedure. Instead, you left him without straight answers and dared him to make a single coding mistake under threat of claim denial, \$10,000.00 per line item sanction and referral to the Fraud Area.

D. CMS’s Involvement in Third Audit.

Given the import of the impending threat of a third audit existing by virtue of your August 9, 2004 letter, Dr. Nemechek was compelled to seek assistance from CMS representatives directly. Dr. Nemechek explained his belief that it was simply not coincidental that you drafted a “change in processing of claims” letter on August 9, 2004, drawing a line in the sand as to your intention not to pay claims under ICD-9 coding of 279.00 hypogammaglobulinemia – unspecified with a September 1, 2004 effective date. He explained his belief that your agency was in essence daring him to submit claims which by their very submission would fall under immediate scrutiny. Dr. Balanoff and Ms. Stanard were quickly convinced that your cumulative audits were peculiar and agreed to contact your offices about the matter.

¹⁵ This information was provided to you in exhaustive fashion under yet another legal response offered to your offices on March 7, 2000 at pages 6-7 of that 22 page submission which is attached hereto as [Exhibit 14](#).

Not surprisingly to us, but as a shock to Ms. Stanard, you confessed to her that you had in fact issued a third audit letter before a single claim had been submitted. We are advised that you were asked to attempt to prevent the third audit letter from going out in the mail that very day, but the mail had already been sent “before you could stop it”. Your agency was caught with its collective hands in the cookie jar at the very moment Dr. Nemechek took his complaints to CMS reciting his belief that your “process methodology” letter was a mere transparent set up for yet another audit aimed at nabbing him. If CMS needed proof, you gave it to them. When you were caught, you couldn’t reverse the damage and Dr. Nemechek did, in fact, thereafter receive your third audit letter.

In an effort to preclude imminent litigation in the matter, Ms. Jacquelyn Stanard and Dr. Balanoff made numerous suggestions to Dr. Nemechek. Among other discussions that occurred, Dr. Nemechek was advised that your offices would defer the audit requirements set forth in the August 26, 2004 letter. He was further advised that any claims submitted for patients listed on your August 26 letter after September 1, 2004 need not comply with the voluminous additional documentation requirements as set forth in said letter. It was suggested that your offices would permit him to submit claims under Code 279.06 as a primary common variable immunodeficiency where appropriate without reference to the fact that the patients have a co-diagnosis of HIV. It was also suggested that dosages used in the treatment of either primary or secondary humoral immunodeficiencies would be based on dosages commonly accepted in the medical literature (400-600 mg/kg/month)¹⁶. Finally, it was suggested that your carrier would not be permitted to audit Dr. Nemechek in the future without approval of Ms. Stanard’s offices and that he should not be concerned about an audit in the future. Unfortunately, neither your offices nor CMS have ever reduced these statements to writing.

IV. CONCLUSION.

Your agency’s scheme of targeting Dr. Nemechek’s HIV/IVIg patients is clear and undeniable. Through regular LMRP changes, varied interpretations thereof and through a pattern of strong arm harassment tactics we can summarize the facts by which you have employed your methods as follows:

1. Your carrier has misused statistical data to constantly assert that since Dr. Nemechek’s utilization rate exceeds other physicians in the area, he remains an appropriate target for constant and recurrent audits.
2. Your agency has had multiple opportunities to isolate the reason his practice has higher than normal utilization rates. Simply stated this is due to his specialty immunological practice. Not surprisingly, he

¹⁶ Another audit trap lurking within your current LMRP policy was the IVIg dosage rates listed therein at 100-200/kg. This was wholly inconsistent with the medical literature on the subject as was clearly reported in the very medical article you cited in your August 9, 2004 letter under number 6 of your references. Park, C.L. Common Variable Immunodeficiency, at p. 15, Section 7 of 10, attached hereto as [Exhibit 15](#) states “**The overall consensus among clinical immunologists is that a dose of IVIg of 400-600 mg/kg/r maintains trough serum IgG levels greater than 500 mg/dL is desirable.**” Upon presenting these inconsistencies to CMS’ Dr. Balanoff by reference to your own article, Dr. Nemechek was advised that your agency understood the appropriate usage rates but remain unwilling to revise the LMRP accordingly, leaving unwary physicians like Dr. Nemechek potential targets for over-utilization claims despite your own medical literature.

maintains a higher statistical patient base suffering from immune deficiencies.

3. Through your Medical Director's own apparent actions, your carrier orchestrated LMRP policy changes to "nab" the policy changes as corrective action to reduce utilization rates. Your agency thereafter specifically targeted Dr. Nemechek's immunological practice to implement the scheme.
4. Your carrier purposefully ignored the findings of each of your first two audits that concluded exclusively in favor of Dr. Nemechek as to medical necessity and processing accuracy in your third audit attempt.
5. Your offices confirmed the appropriateness of his use of billing codes for CVI and his general practice of using IVIg in patients with a separate and non relevant co-existing HIV diagnosis in two exhaustive, expensive and consecutive audits.
6. Your carrier twice strayed from its own Physicians Manual Post Payment Medical Review Policies by failing to provide feedback to Dr. Nemechek about his billing error rate, or more importantly the lack thereof, at the conclusion of his prior audits.
7. Your agency provided no guidance or insight into any problem with Dr. Nemechek's billing practices when re-assurances as to the appropriateness of submitting IVIg claims was specifically requested of Dr. Murti in writing after his first audit given the LMRP changes Dr. Murti authored.
8. Your agency audited Dr. Nemechek unmercifully for years and now has told him he is being audited for claims he has yet to even submit.
9. Your agency, as a practical matter has modified the LMRP by re-defining the processing methodology you intend to employ when reviewing IVIg claims with a view of excluding patients with a co-diagnosis of HIV and CVI.
10. Your agency has consistently kept Dr. Nemechek and other providers of IVIg out of the loop as to proposed changes in LMRP policy or of coverage concerns. In light of Dr. Nemechek's experience in the field and the fact that he will be impacted most notably from any such change, it would follow that he would have been contacted by your offices in advance of your latest volley of letters. However, this would have blocked your scheme.

The chronology of events reflected above and throughout the attachments to this letter has brought this matter to a head. Dr. Nemechek must cease the treatment of his IVIg patients altogether to avoid continued audits and threats of overpayment deficiencies given your constant threat of fraud claims. This will result in the certain death of some of these patients and hospitalizations with ghastly consequences for many others. Dr. Nemechek is committed to pursuing whatever avenues are available to him to expose the events which have transpired to date and to hold you, your carrier, Dr. Murti and others accountable for the improper purposes and devastating effects your audits have had to date if immediate resolutions are not concluded.

Make no mistake, Dr. Nemechek remains desirous of preserving his ability to provide IVIg to his Medicare patient base under terms that would not be litigious or public in nature. If Dr. Nemechek can beyond any doubt be:

- ✓ assured in writing of each of the understandings offered by CMS listed in Section III(D) above;

- ✓ assured that the process by which he may be audited in the future would not begin until an independent, non-CMS or CMS intermediary determination was made as to the necessity and appropriateness of such audit under Medicare guidelines;
- ✓ assured that neither CMS nor its intermediaries have any known past or present basis or intent upon which to pursue civil action for damages pursuant to the Civil Monetary Penalty Law of 1981 or to be referred to the Fraud Unit of CMS;
- ✓ offered the opportunity to assist Dr. Murti, with the aide and accompaniment of Dr. Balanoff and his counsel, to review and revise the current LMRP (A copy of which is attached hereto as [Exhibit 16](#)) if ever deemed necessary by CMS at any time;

Only upon assurances from his legal counsel that the foregoing are all certain will Dr. Nemechek refrain from taking all action necessary under the circumstances to protect the lives of his patients and practice. In the event your respective offices and the CMS regional offices can confirm each of these understandings in writing within three (3) days of this letter, we will refrain from sending this letter and the exhibits hereto to our sources and otherwise pursuing remedies available to Dr. Nemechek. Time is of the essence in this matter as lives are at stake. I look forward to your prompt action.

Very truly yours,

Schlagel, Damore & Gordon, LLC

Christopher A. Gordon

Cc: Dr. Patrick M. Nemechek, w/enc.
Michael R. Clarke, Esq., w/enc.
Dr. Arnold Balanoff, w/enc.
Jacquelyn Stanard, w/enc.