

Examples of the specific patients complaints sent to Caresource (all complaints were ignored – no response and no ethical committee review performed in violation of Caresource Compliance Policy, state and federal regulations including HEDIS).

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

4.9.2018

~~XXXXXXXXXX~~
PATIENT NAME: ~~XXXXXXXXXX~~

COMMUNICATION LOG

DATE/TIME	NOTES
	TO: CARESOURCE
	Caresource disrupted my medical care w/ DR. MARGOLIN in my Nov. 2017 until 2018
	I tried to contact them to answer my questions VERY UNPROFESSIONAL
	My life was on hold because my disability was not like to be heard - this doesn't happen to anyone else
	Fanny [Signature]

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Comprehensive Pain Management Institute

PATIENT NAME:

COMMUNICATION LOG

DATE/TIME

NOTES

4/3/8

Care source block my access
to care to Dr. Margolin

The Dis-Respected my medicine
propies and try switch
me back care source dishonest
W/Dr. I think care source
not honest and don't care
about members

Thank you
Mon

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Comprehensive Pain Management Institute

COMMUNICATION LOG

PATIENT NAME:

Anna [redacted]

DATE/TIME	NOTES
2/16/18	<p>Care source has not helped me since Nov 2017 and I want to thank Dr. Margolin. Care source has blocked my access to care and it was very difficult for me. It was not right what they did to you. God I would like to thank Dr. Margolin for seeing me and caring for me.</p>

[Signature] [redacted]

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

~~THANE~~ COMMUNICATION LOG
PATIENT NAME

DATE/TIME	NOTES
2/15/2018	<p>Insurance blocked my care with Dr. Margolin which in turn I had to switch insurance plans because of caksoide down thru I had to change all of my insurance information both my pharmacy as well as my endo. This took many hours. It was an aggravating thing and I appreciate Dr. Margolin and his staff for working with me until I switched to Molina.</p>

~~THANE~~
2/15/2018

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Comprehensive Pain Management Institute

COMMUNICATION LOG

PATIENT NAME

STEPHANIE

DATE/TIME

NOTES

7-9-18

CARE SUPERVISOR DROPPED
MOM ASKS CARE TO DO TO
MOM ASKING IF TRICK TRICKS
NOT RIGHT, I THINK CARE
SUPERVISOR CARE ABOUT
THEIR PATIENTS
THEY DIDN'T CARE
CARE TO LEAVE ME WITH
A DOG LIKE MR. MACKIN
I THINK MY DOG FOR
STILL SEEMING

STEPHANIE

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

Amber E. [REDACTED] COMMUNICATION LOG
PATIENT NAME:

DATE/TIME	NOTES
07/01/10	Care source was given me a hard time so I had to get a new insurance driver but Dr. Urvashi helps me a lot making sure I'm okay.
	Care source blocked my insurance to Dr. Margolin and this is NOT right
	Amber [REDACTED]
	Thank you!

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COMMUNICATION LOG

PATIENT NAME:

Annoinetta [REDACTED]

DATE/TIME	NOTES
1-30-18	Care source blocked my access for care and I went thru severe pain and discomfort. I am very thankful to Dr. Margolin for his medical care.
	Annoinetta [REDACTED]



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Comprehensive Pain Management Institute

COMMUNICATION LOG

PATIENT NAME:

Alyce [REDACTED] 1/26/18

DATE/TIME

NOTES

I learned very abruptly that
CareSource stopped paying my medical
bills with Dr. Margolin. Thank fully
Dr. Margolin continued to care for
me while CareSource blocked me.

Alyce [REDACTED]

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

Rebecca
PATIENT NAME:

COMMUNICATION LOG

DATE/TIME	NOTES
1-16-18	To Whom it may concern Care Source blocked my access to care with DR Margolin very abruptly. It has caused me extreme hardship. I think it is unfair and inappropriate for them to do so. Thank goodness that DR Margolin still seen me until I was able to switch insurance. Because I do not know what I would have done.
	Thank you [Redacted]

COMMUNICATION LOG

PATIENT NAME:

[REDACTED]
[REDACTED]
[REDACTED]

1-16-18

DATE/TIME	NOTES
	<p>A few Months ago Circumstances blocked my access to Dr. Margolin off of Pan Pain Management and Tim working 2 Jobs to support my family. Dr Margolin Cared me for 2 months to help me out + I believe without his help I would not have been able to make it. I Really appreciate the kindness Dr Margolin + his Staff showed me during that time. And IT WAS NOT FAIR TO Cut Payments to him.</p>
	<p>[REDACTED]</p>

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Comprehensive Pain Management Institute

COMMUNICATION LOG

PATIENT NAME:

Diniece [REDACTED]

DATE/TIME

NOTES

01-11-18

As a patient of Dr. Margolin carrying Caresource insurance I was refused necessary services to help with everyday activities of life.

Within not receiving care for over 30 days I have been affected negatively due to having to wait long period of time for change of insurance. Now I am having hardships & having to pay for meds that I did not before all due to Caresource refusing payments to Dr. Margolin.

This is an unacceptable way to practice. Blessings to Dr. Margolin for not dropping as a patient due to the inconvenience of non payment by Caresource.

Please rectify the matter

Thank you,

[REDACTED SIGNATURE]

PATIENT NAME

COMMUNICATION LOG

W. Moore [REDACTED] 2092

DATE/TIME

NOTES

7/26/74

11-17-74

I'm rather dismayed with the care
 I'm having major interstitions in
 my back, including many medications
 Add in it was my intention this
 was causal issues with effective
 pain control that is based the same
 of control of you. My Medical
 Provider as care same was also
 denied service at my home and insurance
 I am very concerned about this
 I filed a Complaint About Care Service
 Once Again. The issue is with insurance
 and their continuing to restrict access
 and deny coverage to pain control
 medicine and procedures. My doctor
 Glenn Marshall was so thorough and
 planned to try to help me through
 what was a very hard time. I was
 very happy to see my doctor. I'm
 grateful that they have been but
 his staff to help [REDACTED] when
 care same keeps trying to
 shut me out of care. I hope
 they can help me get what I need
 about what happened to [REDACTED]
 at home.

----- Forwarded message -----

From: **Leon Margolin** <leon3087@gmail.com>

Date: 2017-03-29 14:01 GMT-04:00

Subject: business integrity/management concern and patient safety concern

To: Craig.Thiele@caresource.com, Kurt.Lenhart@caresource.com

Cc: Pamela.Morris@caresource.com

By e mail and certified mail

Dear Dr. Thiele,

In continuation of our conversation, and your letter from February 2017 I followed your recommendation, I have submitted a detailed re evaluation request. This letter is not part of the re evaluation request and drafted to address additional concerns.

The independent experts we used, pointed out that Caresource position is not compliant with Caresource policies, Medicare integrity manual and can not survive scrutiny under Ohio and federal law.

The independent expert Frank Cohen (please find his testimonial; enclosed) states: "Not only is this unreasonable, but I believe that most people would agree that it is not a viable business practice."

In a sense we are in the forefront of the "opioid epidemic" fight. We hope to see Caresource as an ally in this fight rather than an adversary who tries to avoid payments for the appropriate services based on these guidelines.

I hope that these concerns will be properly addressed and we will be able to build a collegial relationship with Caresource to benefit the care and safety of our mutual patients.

Please address according to the established policy (page 15):

<https://www.caresource.com/documents/corporate-compliance-plan-2015/>



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03/29/2017

E mail and certified letter

Dear Dr. Thiele,

In continuation of our conversation, and your letter from February 2017 I followed your recommendation and have submitted a detailed re evaluation request. This letter is not part of the re evaluation request and drafted to address additional concerns.

I am the medical director for the Comprehensive Pain Management Institute, LLC ("CPMI"). I am board certified by both the American Board of Physical Medicine and Rehabilitation and the American Board of Pain Medicine. I am committed to providing our patients with the most up to date and highest level of care, as evidenced by my participation in many continuing education courses. Our commitment to our patients can be seen in patient testimonials available on the CPMI webpage www.painhelp.us (many of these patients are Caresource members).

I have personally received a Physician's Recognition Award from the American Medical Association (2008 and 2014), a Resident/Fellow Award from the American Society of Regional Anesthesia and Pain Medicine, Certificates of Merit of the American College of Physicians, the Medical Society of Pennsylvania Award, The Pfizer Scholars in Pain Management Award, and have appeared in approximately 30 publications.

Compliance is important to us. In order to document organic pathology in compliance with the accepted guidelines for the proper pain medication prescription, we perform fluoroscopy (X ray) examination and nerve conduction studies when it is indicated based on patient's history examination and prior record review (medical necessity is documented for each test).

Obviously, there is a cost for the test and procedures required to document organic pathology, document compliance and provide alternatives to narcotic medications pathology in compliance with the accepted guidelines. In my experience the cost of our program is significantly lower than similar services and tests provided in bigger hospital based program. In addition, the cost of non compliance (ER visit, emergency hospitalizations, and chronic morbidity) is much higher.

We are concerned that Caresource sees such a program as a burden and tries to avoid payments for appropriate services. I would like to mention the ethical and legal obligation of Caresource to assist with such tests and procedures and avoid potential pain medication diversion, overdoses and deaths rather than putting patients at risk.

Please comment on this issue .



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Our patients are extremely complex, we take pride in creating individualized treatment plans which do require a significant amount of one-on-one time with each patient. However, this allows our patients to achieve an extraordinary level of function relative to managing their pain.

At the same time we have to deal with difficult patient suffering from mental comorbidities and aberrant drug seeking behaviors. We sometimes face verbal aggression, threats of violence (we even requested a protection order in the past and just about a month ago got a threat from a cocaine positive patient to "bring a gun and get us". In a sense we are in the forefront of the "opioid epidemic" fight. We hope to see Caresource as an ally in this fight rather than an adversary who tries to avoid payments for the appropriate services based on these guidelines.

Interventional Pain Medicine is a highly regulated and sub-specialized field of medicine. Pain medicine is a separate and distinct sub-specialty according to the American Board of Medical Specialties.

We are concerned whether Caresource fully appreciates that in conducting of statistical analysis and using the standards applicable to Pain Medicine.

The Center for Medicare and Medicaid Services states that it may be a "violation" if it places an emphasis on providing NCS in conjunction with needle EMGs. The Department of Health and Human Services, Office of the Inspector General ("OIG"), in an April 2014 publication titled "Questionable Billing for Medicare Electrodiagnostic Tests" reproduced a note from the Centers for Medicare and Medicaid Services ("CMS") stating that "it [CMS] is prohibited from providing guidance on the practice of medicine to physicians and, therefore, it may be a violation to emphasize the importance of providing NCTs in conjunction with needle EMGs." In response to CMSs' note, the OIG clarified that the recommendations in its April 2014 publication that it is not recommending that CMS "provide guidance on the practice of medicine to physicians."

Despite these restrictions noted by CMS, CareSource's Letter interpreting the AANEM Policy in Section A and in its CareSource Policy in Section B, is attempting to mandate the manner in which physicians practice medicine, which is prohibited by CMS. Moreover, such a practice is also prohibited by the Provider Agreement at Sec. 5.2 and this is a general concern for us.

CareSource took a position that conflicts with all controlling ethical and legal guidelines regarding the use of informed consent and patient autonomy including the AANEM's own policy as set forth in its "Guidelines for Ethical Behavior Relating to Clinical Practice Issues in Neuromuscular and Electrodiagnostic Medicine." (attached) In these clinical guidelines, AANEM states that physicians "MUST obtain valid verbal or written consent from the patient." Section 1.3. More importantly, the physician "MUST disclose information that the average person would need to know to make an appropriate medical decision." Emphasis added, Section 1.3. Based on the Caresource policy, the AANEM is the source relied upon by CareSource as the basis for its own Medical Policy. More importantly, the CareSource statement regarding informed consent also conflicts with all ethical and



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legal mandates from every other professional association and that imposed by Ohio's Medical Practice Act (RC Ch.4731).

Please comment of this issue since our practice is to keep using and respecting patient informed consent in compliance with the accepted guidelines mentioned above.

Caresource has a very complex automated claims review system in place to verify that billing that does not meet medical policy denies upon receipt. At no time during the almost 4 year period (close to 2000 tests) in question did Caresource ever deny NCV billing as not meeting medical policy. Our billing company reported that we find that most often the Caresource system will deny claims in error for not meeting medical policy when in fact they do. We know that this is a system in place to prevent items from being paid that should not, but in this circumstance there was never a time that these claims were denied by Caresource (billing expert report enclosed). In summary, Caresource payed for about 2000 properly billed tests indicated by the guidelines over close to 4 year period and then requested repayment for of these tests. We find this tactics inappropriate.

In May of 2015, CareSource reviewed many of CPMI's policies, procedures, and medical equipment, including policy, procedure, and equipment used in furtherance of NCS. In response to our meeting with CareSource, CareSource stated in writing that it was impressed with everything done by CPMI in furtherance of patient care (see the document attached). Our NCS policy and procedure remains unchanged since this meeting.

The independent experts we used, pointed out that Caresource position is not compliant with Caresource policies, Medicare integrity manual and can not survive scrutiny under Ohio and federal law.

The Ohio Administrative Code states that an "audit" means,

a postpayment examination, made in consideration of generally accepted auditing standards, of a medicaid provider's records and documentation to determine program compliance, the extent and validity of services paid for under the medicaid program and to identify any inappropriate payments. The department shall have the authority to use statistical methods to conduct audits and to determine the amount of overpayment. An audit may result in a final adjudication order by the department.

OAC § 5160-1-27. As shown in the above regulation, Medicaid is permitted to conduct post payment audits of a medicaid provider's records so long as it employs generally accepted auditing standards.



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Under Ohio law, "statistical sampling methods used to extrapolate a total disallowance figure have been consistently upheld provided there exists an opportunity to rebut the initial determination of overpayment." In re *Bailey*, 64 Ohio App. 3d 291, 294 (Ohio App. 10 Dist. 1989). In *Bailey*, the Appellant was ordered to repay \$100,717.97 in Medicaid overpayments. Medicaid audited a total of 71 claims out of a total of 13,880 billed during the period at issue. Medicaid determined that 61 out of 71 should have been disallowed, this rate was applied to the total sample, and the Appellant was charged with repaying the total.

Importantly, The *Bailey* Court further held that the rationale underlying that conclusion comes from the application of the factors which must be considered when evaluating administrative procedures. The factors that must be weighed are: 1) the private interest affected by the official action; 2) the risk of erroneous deprivation; and 3) the governmental interest, including the function involved in the financial and administrative burdens that additional procedures would entail. *Id.* CareSource failed to apply these factors.

CPMI Faces a Substantial Risk of Erroneous Deprivation. As in *Bailey*, CPMI stands to lose a significant private interest, \$302,884.87. The *Bailey* Court further stated that the burden on the state that would result from a case-by-case audit of each claim made by every provider far outweighed the appellant's private interests. However, in *Bailey*, the appellant failed to demonstrate any "significant risk of erroneous deprivation." Distinguishable from *Bailey*, here there is not only significant risk of erroneous deprivation, but documented errors.¹ Please find expert reported attached.

¹ CPMI has not been advised as to the identity of the 30 patients selected for CareSource's sample.



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CareSource failed to perform a meaningful clinical review. For the date range January 3, 2013 – October 7, 2014, CareSource selected 30 patient records and concluded that Code 95912 was not properly billable as these records showed an absence of needle EMG on the same date of service. CareSource failed to review the records for the presence of “other unique circumstances.” CareSource cites the AANEM position statement titled “Recommended Policy for Electrodiagnostic Medicine” as the standard to which these 30 patient records were held. In the Letter, CareSource quotes from the AANEM position statement and states that NCS should not be performed without needle EMG “except in unique circumstances.” CareSource concluded based on this sample that 100% of claims submitted during the range were improperly billed. According to CareSource’s own Letter, there exist other circumstances whereby code 95912 can be billed in the absence of a needle EMG, but puts forth no evidence suggesting a clinical review was conducted.

Caresource demand to review all patients on the list was unreasonable and unfair. Given the 60 day timeframe, it was impossible to evaluate the patient records for all 981 claims applicable to the Section B of the letter claims, let alone the additional 1,086 claims at issue in the Section A findings, and maintain a medical practice (Caresource refused to provide any extention or accommodation despite our requests). Of note, during our conference the SIU manager and the medical director said they have no knowledge on how the lists (the sample and the universe) were generated.

For example, some 164 patients in the Caresource list had Neck Pain as a diagnosis. CPMI documents carpel tunnel evaluations as part of the Neck Pain NCV testing, a unique circumstance, in its patient records – but does not bill for such evaluations. In addition, we have identified more than 120 patients on the Caresource that actually did have the needle examination (contrarily to Caresource letter position). This creates serious doubts about methods and procedures implemented by Caresource.

There is no evidence CareSource engaged in a clinical review to determine whether these 30 patients were diagnosed with Neck Pain. Unable to ascertain the identities of the 30 patients at issue, CPMI is unable to confirm or deny the incidence of Neck Pain relative to these patients.

Lack of clinical review is not compliant with the laws and regulations. First, a condition precedent to applying an extrapolation is that the selected sample be subject to a clinical review. In *Bailey*, Medicaid’s expert was able to conclude the CPT code at issue was improperly billed because many of the required tests were not performed. Here, the Letter sets forth no evidence that any of the 30 claims were reviewed against the AANEM Policy. In fact, the Letter simply describes a utilization review as the Letter summarily states all 30 claims were billed in the absence of a needle EMG. The AANEM Policy does not require needle EMG in all cases where NCS is billed. In *Bailey*, Medicaid’s clinical review applied the standards set forth in the CPT Codebook. Here, CareSource states it is applying the standards set forth in the AANEM Policy, however, CareSource presents no evidence of applying the AANEM Policy.



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Two, CareSource has not disseminated the identities of the 30 patients it selected incident to the extrapolation (despite multiple requests from CPMI). CareSource provided a spreadsheet with some 981 claims for the date range January 3, 2013 – October 7, 2014 whereby code 95912 was billed. This is evidence of a utilization review, not an extrapolation based on a clinical review.

As previously stated, assuming the reviewing entity performs a clinical review, extrapolations based on such clinical reviews are appropriate when the following factors are weighed: 1) the private interest affected by the official action; 2) the risk of erroneous deprivation; and 3) the governmental interest, including the function involved in the financial and administrative burdens that additional procedures would entail.

Caresource date range selection is not compliant with Ohio law. Almost as a parenthetical, CareSource states there were 142 claims billed with CPT code 95912 in the absence of a needle EMG for the date range October 8, 2014 – December 2, 2014 resulting in an overpayment in the amount of \$20,817.21. CareSource states it reviewed “claims data” for this date range. During this range, the claims are held to the standards set forth in the AANEM Policy, as these claims predate the CareSource Policy. Presumably, none of the 30 patients selected for the “extrapolation” had dates of service in this range. Either way, summarily concluding that all instances of code 95912 billed during this period, whether based on a claims review or on the improper extrapolation, is in violation of Ohio law.

Caresource refused to clarify it’s policy and the changes in the policy after December 2014. (despite our request in writing). Of note CPMI is not conducting automated studies. The Policy itself does not stand for the premise that an integrating needle must be used. As set forth in the Policy, in relevant part, “[w]hen the NCS is used on its own without integrating needle EMG findings, OR when an individual relies solely on a review of NCS data, the results can be misleading and important diagnoses may be missed.” See Policy, Section B, emphasis added. CPMI does not rely on a review of NCS data, but rather relies on a standard non automated EMG machine that allows duly qualified CPMI practitioners to review the NCS data in real time as a part of a very detailed history and physical evaluation, reducing the likelihood of misleading results. CPMI does not use or rely on automated NCV devices. Because CPMI is not conducting automated studies or relying on data, CPMI is in compliance with the alternative conditions set forth in the Policy.

For example the independent expert Frank Cohen (please find his testimonial; enclosed) states: “Not only is this unreasonable, but I believe that most people would agree that it is not a viable business practice.”

Finally, I want to mention again that the Caresource request of reimbursement in excess of \$300,000 (mentioned in your letter) for services provided to CareSource patients that are both necessary and consistent accepted guidance. Such an adjustment would not only significantly impact CPMI’s ability to function as a business, but would also put an extremely vulnerable patient population at risk. This



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concern based on the CPMI ability to function as a business and see patients in case of such an unfair reimbursement by Caresource even if our provider agreement remains active without any change.

As per your request we have indentified about 1800 specific Caresource members that have signed the enclosed CPMI consent for treatment document that identifies the following risk (safety concern):

"Withdrawal: Suddenly stopping or decreasing your intake of narcotic medication may bring on withdrawal. Symptoms of withdrawal include nausea, sweating, muscle tremor, agitation."

National guidelines state that in certain cases withdrawal can be debilitating and sometimes even life threatening.

It is our assessment that several hundred specific Caresource patients may be at immediate risk if Caresource takes such an unreasonable action.

As you know, it is difficult for many patients to find alternative providers. If left untreated, patients may turn to illicit means of obtaining substitute medications which drastically increases the risk of overdose and death.

We are concerned that Caresource took a position to disregard patient safety issue. Please clarify this in writing.

As a physician and medical director that is committed to the ethical treatment and care of my patients, this is deeply concerning.

I hope that these concerns will be properly addressed and we will be able to build a collegial relationship with Caresource to benefit the care and safety of our mutual patients.

Sincerely,

Leon Margolin MD, PhD