MSSNY COMMITTEE ON INTERSPECIALTY
Thursday, June 30, 2016 10:00 a.m.

Approval of the Minutes of the February 25, 2016 Committee meeting

Dr. Steven S. Schwalbe, presiding, called the meeting for June 30, 2016 to order. The first order of business was to approve the minutes from the last meeting held on February 25, 2016. The minutes were accepted and approved written.

Committee Evaluation for the following of HOD Resolution:

The Committee has been asked by Council to reevaluate an HOD resolution on Mobility Impairment.

2016-268 Mobility Impairment Increases Risk of Illness
Introduced by Medical Society of the County of Kings

The Committee received emails from Dr. McCormack and from Dr. Buchness; they seem to agree on their viewpoint on this particular issue. It appears that neither is in favor of this resolution at all.

The Committee needs to hear from the author of the resolution. Ms. Liz Harrison, the Executive Director of Kings County explained that the author, Dr. Monica Sweeney, is currently indisposed and asked if the discussion could be tabled until the next Committee meeting.

Our next Committee meeting is expected to be in October 2016. So, we will table the discussion it until October. We will also accept comments by email in advance of that meeting if anyone wants to make comments. In addition, Dr. Schwalbe extended the Committeeôs best wishes for recovery.

Medicare CAC Local Coverage Determinations (LCDs) for consideration -

Dr. Schwalbe introduced Dr. Laurence Clark. Dr. Clark is the NYS Medical Director for NGS Medicare, the JK MAC ï Medicare Administrative Contractor. The JK MAC processes Fee-For-Service (FFS) Medicare Part A and Part B claims for Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, and Vermont

Dr. Clark addressed the JK LCD DL33558 Cataract Extraction

Dr. Clark indicated that Dr. Pattie McLaughlin the Medicare CAC representative for Ophthalmology has already commented on this LCD. She could not make the meeting. However, she is already in touch with NEOS, the New England Ophthalmology Society and Dr. McLaughlin is very much part of the discussion. This policy addresses impairment and visual function. There is new language for bilateral procedures, weighing the advantages and disadvantages in the senior population. So, that is the first policy under review.

DL33616 Osteopathic Manipulative Treatment

Dr. Clark explained that the reason for the development of this OMT policy is that recently, NGS Medicare has seen a very high error rate in terms of osteopathic manipulative treatment. It is not the delivery of the service; rather it seems to be the actual documentation of the service in the medical record. There appears to be a problem of the interface with OMT procedure codes and the performance of the E&M service on the same day. The medical record needs to document a significant, separately identifiable reason for the E&M when provided on the same day. There is an expectation that E&M do accompany OMT. As such, the E&M would be submitted with a Modifier 25 in support of the patientôs documented medical record.

There is a pre and post service to OMT, which is documented by the E&M service. There has been some misunderstanding by the American Osteopathic Association (AOA). The requirements for documenting an E&M service are still the same as for the rest of the house of medicine. There is nothing in this policy that says Medicare does not expect the E&M service to be delivered on the same day as OMT, as long as it is accurately documented.

Dr. Robert B. Goldberg, Physical Medicine and Rehabilitation, Committee Advisor and previous Medicare CAC Co-Chair addressed the Committee on this LCD. Dr. Goldberg has been active in the CAC process since the first meeting in 1992.

Dr. Goldberg has had longstanding involvement and experience with policy development under the Medicare CAC process. Sometimes an LCD is introduced and when the particulars of the issue are hashed out it is not an LCD or a policy that needs to be put forth. It is education that is required.

Osteopathic manipulation is performed by a licensed physician that is only an MD or DO. When OMT was originally considered by the Harvard study in the mid 1980ôs, there were no pre, intro or post components for relative value to be placed upon those. Over the years, the LCD has been introduced to adjust OMT. Dr. Goldberg stated that the RUC did take a look at it a few years later and they did realize there has been some pre and post work for osteopathic manipulation; but, they did not include an E&M. The current LCD goes way beyond that and I would like to talk about a few things that may be important.

In the abstract of the LCD in paragraph 2, there is a description of somatic dysfunction and the description should be much more comprehensive. Dr. Goldberg recommended the referral to an official book called the Glossary of Osteopathic terminology. Itôs published by the American Association/College of Osteopathic Medicine. Also, in the abstract there is mention about the positional and motion aspects of somatic dysfunction. Then, 3 parameters are described. But, that is limited and is not how osteopathic physicians use it in practice because there are other conditions where osteopathic manipulation might be used.

For physiological example, to monitor an immune response to a pneumococcal or influenza vaccine and perform a double blind study consisting of one group of patients given osteopathic manipulation and another group is given just the vaccine. There is a significant monumental difference in the immunological response. It is believed it is through lymphatic channels combined with mechanical but the 3 parameters do not address it.

In reading the LCD, it is almost as though the policy is trying to say CMT or chiropractic manipulation instead of OMT. When it is said to be used to prevent diseases - that is not how

osteopathic works. Physicians do not use or conceive of OMT that way. Dr. Goldberg went on to indicate that it appears that a lot of cut and pasting was used in this draft LCD.

Under indications, it is stated ñwhen such treatment is likely to result in improved symptoms (e.g. less pain) or functional statusò. However, in the example just given, immunological response vasomotor changes that are the result.

Now for the E&M, the coding initiative does recognize the importance of E&M. The policy should include the descriptor for the Modifier 25, when documented in the patientôs medical record. This is a physician service not a chiropractic service and it should be addressed that way. The description of documentation for use of a Modifier 25 in this LCD is not consistent with the AMA-CPT guidelines and should be removed from the LCD.

Under Limitations, the LCD reads ñOsteopathic Manipulative Treatment is not covered when used for non-definitive or palliative treatment or when further clinical improvement cannot be reasonably expectedò. However, examples were given where

Under Documentation Requirements on the draft LCD, Plan of Care is discussed. This is part is lifted directly from the physical therapy physical medicine protocol. This is not how osteopathic physicians identify or describe or plan the use of osteopathic manipulative therapy and should really be removed.

After much continued discussion, Dr. Clark identified that this policy is the result of a geographic anomaly from three counties in the state of Maine. In Maine there are outliners. When we look to see how OMT is used in other areas, the utilization is not the same. Medicare needs to ensure that patients are having access to care. Medicare needs to be cautious or we will end up restricting patient care, quality and treatment because of what is happening in one small area.

NGS Medicare noted that in the state of Maine, over 50% of primary care is provided by Osteopathic physicians, which is absolutely fine. However, stressing the understanding documentation requirements is probably more important there than our other jurisdictions. Commentary on this and the other LCDs is needed by August 13, 2016.

DL33584 Implantable Miniature Telescope

Dr. Clark discussed the next policy, IMT. It is a telescope prosthetic device that replaces the natural lens. It is specifically for people with bilateral advanced age-related macular degeneration in order to enlarge the retinal image. Dr. McLaughlin has expertise in this particular arena and already is disseminating it to the Ophthalmologic Society. So NGS Medicare is anticipating positive feedback in that Medicare is covering this technology.

DL36749 Air Ambulance Services

For the next policy, Air Ambulance Services, Dr. Clark provided some background. NGS Medicare is dealing with issues with the OIG that involves proprietary of investment of hospital systems into air ambulance transfer. A growing issue is the designation of facilities as stroke centers. Unfortunately, NGS Medicare is seeing, particularly in New England and upstate New York areas with greater distances, increased use of rotary helicopter and air ambulance transport.

It is becoming a significant economic issue allowing appropriate access where you have snow, ice, high winds and general difficulty getting these patients, with intracranial bleeds, cardiac shock, etc. getting patients to the appropriate locations, expeditiously. NGS Medicare has to be judicious, and as a Medicare contractor, we see some places that are not the appropriate treatment centers. NGS Medicare is not wedded to any particular direction; but is looking for input and commentary by August 13, 2016.

DL35000 Molecular Pathology Procedures

Dr. Clark stated that NGS Medicare needs to have a policy in order to auto-adjudicate claims. NGS Medicare has a tremendous amount of molecular diagnostic claims and sees this as a policy that will be coming back for discussion many times. Again, NGS Medicare is looking for input and commentary on this draft LCD by August 13, 2016.

Other CAC Information – Medicare Legislative Update
MACRA

Ms. Kathy Dunphy provided the Committee member with a brief overview of the MACRA legislation.

The following information is from the CMS website and should be educational for our members:

On April 27, 2016, CMS issued a Notice of Proposed Rulemaking (NPRM) to put in place key parts of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). MACRA, bipartisan legislation, replaces the flawed Sustainable Growth Rate formula by paying clinicians for the value and quality of care they provide.

The proposed rule would make these changes through a single framework called the "Quality Payment Program". The Program has two paths:

- The Merit-based Incentive Payment System (MIPS)
- Advanced Alternative Payment Models (APMs)

This short video can give you the details.

Where can I find more information?

Here's new information CMS just posted:

- Upcoming & past webinars
- Learn more about Physician Focused Payment Models (PFPMs) Technical Committee.
- Quality Payment Program training slide decks:
- short version
- extended version
- consumer version

Get the latest updates sent to you; join the Quality Payment Program list serv

Here's what CMS posted in the past:

Proposed rule & the Quality Payment Program

- Fact sheet
- Our press release
- The Secretaryôs blog
- Timeline
- Quality Payment Program All-Payer Overview
- Find out about support and flexibility for small practices

Advancing Care Information

- Fact sheet
- Blog from Acting Administrator Slavitt and National Coordinator Karen DeSalvo on Advancing Care Information
- Advancing Care Information slide deck

The Merit-based Incentive Payment System (MIPS)

- MIPS training slide deck
- Quality Performance Category training slide deck
- Resource Use Performance Category slide deck
- Clinical Practice Improvement Activities Performance Category slide deck
- MIPS Scoring Methodology slide deck

Dr. Mary Fowkes, Pathology, expressed opposition to MACRA. Pathologists do not often have any face-to-face encounters with patients. Therefore, it will be quite difficult for the specialty to comply with the legislation. The College of American Pathologists did submit commentary to CMS based of the Notice of Proposed Rule Making for MACRA. The commentary will be provided as an attachment for Committee Members.

Dr. Ron Kaufman, Urology, also expressed opposition. Dr. Kaufman stated that the problem is that MACRA in the most basic essence is for primary care doctors; it is not designed for specialists. In addition, the next big problem is the time frame. The CMS final rule is not expected to be published any sooner than November 1st and then start date for implementation is expected to be January 1, 2017.

The AUAôs commentary can be found here:
http://www.auanet.org/common/pdf/advocacy/advocacy-by-topic/AUA-Comments-on-MIPS-APM-Proposed-Rule-6-27-2016.pdf

Subsequent to this Committee meeting, Andy Slavitt Acting Administrator Centers for Medicare & Medicaid Services provided testimony before the Senate Finance Committee. His testimony can be found here: http://www.finance.senate.gov/imo/media/doc/CMS%20Testimony%20-%20MACRA%20(A.%20Slavitt)%207.13.16.pdf

Revalidation

NGS Medicare has many medical practices that need to revalidate their Medicare provider number(s). There are around 3,000 providers in the Queens, NY area with 2 months away from the deadline for the revalidation timeline. Ms. Dunphy advised that she will be working with the county society and MSSNY to accomplish the task.

MSSNY Legislative Update

Mr. Moe Auster provided the committee with information about bills that were addressed before close of this legislative session.

1. Legislation that would establish specific criteria for physicians to request an override of a health insurer step therapy medication protocol when it is in the best interest of their patientsô health. A letter can be sent **here**.
2. Legislation that would ease the onerous reporting burden on physicians every single time that they need to issue a paper prescription in lieu of e-prescribing. A letter can be sent **here.**
3. Legislation to permit a pharmacy to transfer an e-prescription to another pharmacy, such as when the initial pharmacy does not have the medication in stock. The letter can be sent **here.**

The step therapy bill (S.3419-C, Young/A.2834-D, Titone) would require a health insurer to grant a physicianôs override request of an insurer step therapy protocol if one of the following factors are present: 1) the drug required by the insurer is contraindicated or could likely cause an adverse reaction; 2) the drug required by the insurer is likely to be ineffective based upon the patientôs clinical history; 3) the patient has already tried the required medication, and it was not effective or caused an adverse reaction; 4) the patient is stable on the medication requested by the physician; 5) the medication is not in the best interests of the patientôs health. An insurer decision must be made within 3 days, 24 hours where the patientôs health is in serious jeopardy if they do not receive the physician requested medication.

We know the insurers are strongly fighting this bill, so the Governorôs office needs to hear your support.

The e-prescribing exception reporting simplification bill (S. 6779-B, Hannon/A.9335-B, Gottfried) would allow physicians and other prescribers to make a notation in the patientôs chart when they have had to invoke one of the three statutory exceptions to the mandatory e-prescribing law in lieu of having to report such information to DOH every single time they must write a paper prescription. Currently, DOH asks that each time a paper/fax/oral prescription is issued, the prescriber must electronically inform the DOH of their name, address, phone number, email address, license number, patientôs initials and reason for the issuance of the paper prescription.

This creates an onerous burden for all physicians, particularly in situations where there is a protracted technological failure, and the physician needs to report dozens upon dozens of paper prescriptions. This legislation would address this needless burden.

The e-prescription transfer bill (A.10448, Schimel/S. 7537, Martins) would address the situation where a physician must re-submit e-prescriptions to multiple pharmacies if the initial pharmacy receiving the e-prescription is out of stock of the requested for the medication for the patient. Currently, e-prescriptions cannot be transferred by one pharmacy to another thereby requiring the patient to return to or call the prescriberôs office to ask that he/she transmit the e-prescription to another pharmacy creating unnecessary burdens on the patient and delaying timely access to their medication.

Any specialty specific issues:

From Urology - discussion on: I-STOP and starting the process to change the status of testosterone replacement from a controlled drug to a non-controlled one which is the case in many states.

Dr. Ronald Kaufman, the specialty of Urology, presented the Committee with his concern about testosterone being considered a controlled substance in NY. Prior to the enactment of I-Stop, physicians could write a paper prescription and include a notice for a 3-month refill. Now, with I-Stop and the electronic filing mandate, these scripts have to be done on a monthly basis. In addition, physicians have to go to I-Stop every time a renewal is needed by the patient. Dr. Kaufman advised that it is a lot of work and he believes that it is incorrect to think that testosterone is being used for abusive purposes as a narcotic. Many urologists and primary care doctors prescribe this drug. In addition, he stated that NY is unique in so far as there are a great many migratory patients that go to Florida, North Carolina and other warmer climates in the winter months. Dr. Kaufman is asking the Committee to start the process to remove testosterone from controlled substances list or at least downgrade it on the level of the schedule of narcotic drugs.

Dr. Kaufman stated that the vast majority of patients do not abuse testosterone. Certainly there are some instances where people, bodybuilders, etc. are abusing this drug. Or, they are not getting them legitimately. We are talking about people with hypogonadism that are being legitimately and responsibly treated.

Dr. Steven Lee Allen, Hematology and Oncology, said hematologists are seeing a fair number of patients that are abusing androgens and are being referred for very high hemoglobin. He indicated that patients are not being asked where they are getting the drugs from; but it is not uncommon.

Dr. Kaufman stated that looking at the guidelines it is not a concern unless the hematocrit is over 54. That is usually a just a dose/titration issue. It should not be a safety issue. Testosterone should not be in an I-Stop process in order to prescribe and renew every month. It is very costly and laborious to patients and practitioners. Because of I-Stop, NY is very unique and Dr. Kaufman seeks the Committeeôs support to change the level of testosterone on the schedule of controlled substances for drugs.

Dr. Allen indicated that many clinic patients are prescribed testosterone and are bodybuilders. For most of them, the testosterone is prescribed. As an oncologist it is difficult when you have woman with metastatic breast cancer and you are treating them with an androgen. It is off topic

but a lot of the drugs oncologists use are in programs that can only be prescribed one month at a time and that is just part of our practice and it is done all the time.

Dr. Kaufman expressed that because of the NYS I-Stop legislation; medical practices are caving in and have to perform unnecessary work. The cost of medicine - the cost to the practitioner is going the wrong way. Medical practices are forced to employ people to do seemingly unnecessary work for no reason. Dr. Kaufman would like to put a stop to it.

Dr. Lana Kang added that it would be important to find out why testosterone was made a controlled substance. She agreed that it is unnecessary, too.

The next question was whether this would need federal or state action.

The FDA lists testosterone as a Schedule III drug. The NYS DOH lists it as a Schedule II, meaning NYS considers the drug to be a higher threat that requires more scrutiny.

To address this properly, there would need to be a two-pronged approach - 1) Dr. Kaufman would need to seek support from the AUA for reconsideration at the federal level; and 2) he can ask the Committee to support a resolution to be recommended to MSSNYôs Council to seek legislative reconsideration at the NYS level.

Dr. Kaufman will contact his national specialty society, the AUA, for their support and asks that the Committee agrees to the following recommendation for Council consideration:

RECOMMENDATION:

> **RESOLVED, That the Medical Society of the State of New York seek NYS legislation to have testosterone reclassified from a Schedule II narcotic and removed from the I-Stop process as an exception for the proliferation of men's health in the State of New York.**
>
> ~~***(For Council Approval)***~~

Subsequently, Ms. Patricia Clancy, VP of MSSNYôs Public Health and Education staff, provided the following information. The NYS DOH issued a document entitled: What Every Practitioner Needs to Know About Controlled Substance Prescribing. The document contains the following Q&A clarification:

4. Controlled substances may only be prescribed in a maximum thirty-day supply.

False: A practitioner may issue a prescription for up to a three month supply of a controlled substance, including chorionic gonadotropin, or up to a six-month supply of an anabolic steroid by writing on the face of the prescription either the diagnosis or code for the treatment of the following conditions:

Code Diagnosis

A	Panic Disorder
B	Attention Deficit Disorder
C	Chronic debilitating neurological conditions characterized as a movement disorder or exhibiting seizure, convulsive or spasm activity
D	Relief of pain in patients suffering from conditions or diseases known to be chronic or incurable
E	Narcolepsy
F	Hormone deficiency states in males; gynecologic conditions that are responsive with anabolic steroids or chorionic gonadotropin; metastatic breast cancer in women; anemia and angioedema

Here is the full publication: www.health.ny.gov/publications/1477/

Based on this information, the Committee voted not to support the recommendation since a six month supply of testosterone can be prescribed and checking the PMP does not need to be done on a monthly basis.

From Allergy and Immunology - discussion about the issue of compounding medications.

Dr. Robert Corriel, Allergy and Immunology, provided the Committee with an update on compounding medications.

The U.S. Pharmacopeial Convention (USP) is a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide. USPôs drug standards are enforceable in the United States by the Food and Drug Administration, and these standards are used in more than 140 countries.

As an allergist, we have compounded allergen extract for subcutaneous injection for our patients for years. Several years ago, USP which makes regulations for FDA in terms of compounding, gave allergists a waiver from the very strict regulations that are required for compounding in hospitals. Allergists can continue to compound extracts in the office. Allergists must use a sterile surface, wear gowns, gloves, caps and masks. These regulations have been followed in the office.

USP published its revision of its current recommendation in March/April, which if followed would have made it impossible for allergists to continue to compound allergen extracts. The USP put in an end of use of 44 days from the time it is mixed until it expires.

Through the professional organizations, allergists have publically voiced opposition to this recommendation to FDA, USP, etc. It is anticipated that there will be a favorable decision; but it may take as long as 2 years to resolve.

On a related note, there was a meeting of the Federation of State Medical Boards; they had a resolution in support of the USP regulation. After a recent meeting in California, their resolution has been tabled after hearing from allergists. Dr. Corriel asked the MSSNY legislative staff to have an open ear and have this on their radar. If compounding is discussed, the specialty needs to be alerted.

There being no additional business for todayôs meeting, it was mentioned that the next meeting will be sometime in October and the conference call ended at after noon. Dr. Schwalbe thanked the attendees for their participation.

Respectfully submitted,

Steven S. Schwalbe, MD, Chairman