Medicare Red Tape Relief Project
Submissions accepted by the Committee on Ways and Means, Subcommittee on Health

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Statutory X  Regulatory X

Please describe the submitting organization's interaction with the Medicare program:

The American Academy of Dermatology Association (AADA) represents more than 13,500 U.S.-based dermatologists. Dermatologists diagnose and treat more than 3,000 different diseases. Dermatologists in the United States practice in every type of medical practice setting. However, the vast majority of dermatologists are in solo practice or in small group practices consisting of 10 or fewer clinicians.

A significant portion of the Medicare patient population rely on dermatologists for the care and treatment of acute and chronic diseases. The Medicare program is highly influential to the entire health care system. The payment policies and claims coverage Medicare implements influence the practice of dermatology and how dermatologists treat all of our patients, both inside and outside Medicare.

The AADA is committed to excellence in the medical and surgical treatment of skin disease; advocating high standards in clinical practice, education, and research in dermatology and dermatopathology; and supporting and enhancing patient care to reduce the burden of disease. The AADA welcomes the opportunity to share with the Committee and Subcommittee on how to ease regulatory burdens to further enhance the practice of dermatology and the care provided to our patients.

Regulatory Relief Priorities:

1. MACRA Implementation

2. Streamline Drug Prior Authorization Requirements
   a. Appendix 1: Recommendations for Streamlining Prior Authorization in Medicare

3. Increase Physician Appeal Rights under the Medicare Quality Payment Program

4. RAC Audits and Statistical Sampling

5. Exempt Physicians from Compounding Facility Requirements
**Short Description:** MACRA Implementation

**Summary:**

The Medicare Access and Chip Reauthorization Act (MACRA) requires significant effort from physician practices to participate in its quality payment program (QPP), which could cause substantial financial and administrative burdens for dermatologists and their practices. Such burdens also have the potential to contribute to the growing trend of physician burnout. To the extent MACRA combines and repurposes the Centers for Medicare and Medicaid Services’ (CMS) reporting programs, including use of electronic health records (EHR) often referred to as Meaningful Use (MU), regulatory relief could lessen the burdens placed on physicians by these programs.

**Related Statute/Regulation:**

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA; P.L. 114-10); Medicare Quality Payment Program (81 FR 77008)

**Proposed Solution:**

The American Academy of Dermatology Association (AADA) appreciates the efforts CMS has made to propose changes to the QPP for 2018 that mitigate the burden on physician practices. In particular, AADA supports the accommodations that CMS is proposing, including the proposed raised low volume threshold, the increased opportunities for quality scoring, the recognition that cost attribution problems exist and delaying cost scoring for an additional year, and the expanded submission options. The AADA recommends that the time period for determining practice size be shorter and closer to the performance period, that members of virtual groups should have the same exemptions as clinicians in small practices, that all practices with fewer than 15 clinicians (the CMS definition of small groups) should be allowed to join virtual groups, that clinicians should receive 10 points for participation in a clinical data registry, and that the current 60 day Advanced Alternative Payment Model (APM) performance period should be maintained. The AADA is concerned with the proposed requirement that at least half of the members of a group report an improvement activity for members of the group to receive credit for that activity and seek additional guidance on the Physician-Focused Payment Models Technical Advisory Committee (PTAC) APM development process, including improved access to and assistance using Medicare data.
Short Description: Streamline Drug Prior Authorization Requirements

Summary:

Physicians face significant burdens meeting Medicare Part C and D plans’ prior authorization (PA) requirements for medically necessary medications for their patients. The American Academy of Dermatology Association (AADA) conducted a survey of dermatologists and dermatology practices in 2016 that revealed the extent of the prior authorization burden. Most respondents to the survey reported processing six or more prior authorizations for drugs daily. Physician practices reported it taking at least 30 minutes and often an hour to complete each PA form. Dermatologists reported that they are spending up to three hours a day of their time completing PAs. This time could be better spent providing direct care to patients. Dermatologists and their practices shared that there is a lack of uniformity in PA forms and processes that greatly contributes to the amount of time each PA takes.

Related Statute/Regulation:

42 CFR 422.568

Medicare Prescription Drug Benefit Manual, section 30.1.5 of Chapter 6 (30.1.5) and sections 30.1 and 30.2 of Chapter 18

Proposed Solution:

Physicians are facing significant burdens meeting Medicare Part C and D plans’ prior authorization requirements for medically necessary drugs. The AADA recommends that CMS alleviate this burden by requiring Medicare Advantage and Medicare Part D participating plans to shorten the turnaround time for prior authorizations and to extend the length of the prior authorization appeal period. The AADA also recommends that CMS encourage plans to allow for electronic prior authorization and require plans to provide detailed explanations for prior authorization denials, including the clinical rationale, provide the plan’s covered alternative treatment, and provide details on the provider’s appeal rights. The AADA recommends that CMS standardize the PA form across all Medicare Advantage and Medicare Part D plans, as well as the time the payer has to make and inform the provider of the PA decision and of the appeal period.

Physicians also face difficulties in accessing the prior authorization requirements for specific plans. Therefore, the AADA recommends that plans be required to make the following information publically available in a searchable electronic format: the prior authorization requirements, necessary documentation and information necessary for completing a prior authorization and the telephone number for physicians and their staff to call regarding prior authorizations (not the main prior authorization line). Additionally, the AADA recommends that all exceptions decisions be made by a provider who (a) is of the same specialty, and subspecialty, whenever possible, as the prescribing/ordering provider.

The AADA strongly encourages the Centers for Medicare and Medicaid Services (CMS) to enforce the provisions of 42 CRF section 162.1302(c) that requires the development and implementation of a uniform standard for use in electronic PA requests, as well as the provisions of 42 CFR 422.568 that require Medicare Advantage plans to standardize timelines for PA decisions. CMS could also streamline PA through sub-regulatory action, that is, by modifying the Medicare Prescription Drug Benefit Manual. The AADA recommends changes to section 30.1.5 of Chapter 6 (30.1.5) and sections 30.1 and 30.2 of Chapter 18 and has attached proposed language as an appendix to this form. The AADA also recommends that CMS review the work of the National Council for Prescription Drug Programs (NCPDP) on electronic transactions for electronic prior authorizations. These standards aim to both streamline the prior authorization process and provide real-time prescribing and pricing information for physicians.
American Academy of Dermatology Association

Appendix 1:
Recommendations for Streamlining Prior Authorization in Medicare
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Medicare Prescription Drug Benefit Manual

Chapter 6-Part D Drugs and Formulary Requirements

30.2.2.3 – Application of Prior Authorization
30.1.5 - Formulary Management

Part D sponsor’s P&T committee will consider the following:

- The formulary does not discourage enrollment by any group of enrollees; and
- Provides appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time.

Chapter 18

30.1 - Prior Authorization or Other Utilization Management Requirements

Part D plan sponsors must determine how to categorize requests that involve PAs or other UM requirements on a case-by-case basis because some of these requests are subject to the exceptions process while others are not. If the request does not contain adequate information for the plan sponsor to ascertain whether an enrollee is attempting to satisfy a PA requirement or asking the plan to waive a PA requirement, the plan sponsor must make reasonable and diligent efforts to obtain the necessary information.

Attempting to Satisfy a PA or other UM requirement

A case where an enrollee/physician/other prescriber is attempting to satisfy a PA requirement (i.e., the enrollee/physician/other prescriber is aware that a PA requirement exists and, for example, submits a PA form to the plan sponsor in an attempt to satisfy the PA requirement) should be processed as a coverage determination. The plan must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision no later than 24 hours after receiving the request for expedited cases, or no later than 48 hours after receiving the request for standard cases. Where an enrollee/physician/other prescriber is attempting to satisfy a PA requirement and the plan has a PA form available for seeking prior authorization for the requested drug, the plan should promptly provide the physician or other prescriber with the PA form. The following information must be publicly available in a searchable electronic format. This information must also be kept current:

- Prior Authorization requirements
- Necessary documentation and information for completing the prior authorization
- The telephone number (if applicable) for physicians and their staff to call regarding prior authorizations (not the main prior authorization line)

An enrollee, physician or other prescriber may use the model Medicare Part D Coverage Determination Request Form to request an override to a PA or other UM requirement: http://cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Forms.html.

Asking a Plan Sponsor to Waive a PA or other UM Requirement
Where an enrollee or an enrollee's prescribing physician or other prescriber is asking a plan sponsor to waive a PA or other UM requirement (e.g., a physician or other prescriber indicates that an enrollee would suffer adverse effects if he or she were required to satisfy the PA requirement), he or she is asking for an exception and the prescribing physician or other prescriber must submit a statement to support the request consistent with the requirements set forth in 42 CFR 423.578(b)(5). A physician or other prescriber may use the model Medicare Part D Coverage Determination Request Form to request an exception and/or submit a supporting statement. If the request or supporting statement is made in writing, plan sponsors are prohibited from requiring a physician or other prescriber to submit the request or supporting statement on a specific form. If the exception request involves benefits not yet received, the plan must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision no later than 24 hours after receiving the physician’s or other prescriber’s supporting statement for expedited cases, or no later than 72 hours after receiving the physician’s or other prescriber's supporting statement for standard cases. If the exception request involves reimbursement for benefits already received, the plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision (and make payment when appropriate) no later than 14 calendar days after receiving the request.

30.2 - Exceptions
(Rev. 9, 2/22/13)
Coverage determinations include a plan sponsor’s decision on an enrollee’s exception request. Enrollees may request an exception to a plan's tiered cost-sharing structure, or formulary. All exceptions decisions should be made by a provider who (a) is of the same specialty, and subspecialty, whenever possible, as the prescribing/ordering provider

All exceptions submitted to plans will have standardized clinical information based on a model template developed by CMS.

30.2.1.1 – Supporting Statement Criteria
(Rev. 9, 2/22/13)
The physician's or other prescriber's supporting statement must indicate that the drug in the lower cost-sharing tier for the treatment of the enrollee's condition--

(1) Would not be as effective as the requested drug in the higher cost-sharing tier; and/or
(2) Would have adverse effects; and/or.

(3) has been tried by the patient while under their current or a previous health carrier or health benefit plan, or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event; and

(4)The patient is stable on a prescription drug selected by their health care provider for the medical condition under consideration:

30.2.1.2 - Processing Timeframes
(Rev. 9, 2/22/13)
Requests for Benefits
If an enrollee or an enrollee’s prescriber is requesting an exception for a benefit not yet received, the 24 hour (expedited request) or 7248-hour (standard request) timeframe for resolving the request does not begin until the enrollee’s prescribing physician or other prescriber provides a supporting statement indicating factor(s) (1) and/or (2) discussed in § 30.2.1.1. See §§40.2 and 50.4. Also see §30.2.1.3.

30.2.2.1 – Supporting Statement Criteria
(Rev. 9, 2/22/13)

The physician's or other prescriber's supporting statement must indicate that the requested prescription drug should be approved because:

(1) All covered Part D drugs on any tier of a plan's formulary would not be as effective for the enrollee as the non-formulary drug, and/or would have adverse effects;

(2) The number of doses available under a dose restriction for the prescription drug: (a)

Has been ineffective in the treatment of the enrollee’s disease or medical condition or,

(b) Based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug’s effectiveness or patient compliance; or

(3) The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements:

(a) Has been ineffective in the treatment of the enrollee’s disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug’s effectiveness or patient compliance; or

(4) has been tried by the patient while under their current or a previous health carrier or health benefit plan, or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event; and

(5) The patient is stable on a prescription drug selected by their health care provider for the medical condition under consideration.

30.2.2.3 - Requests for Additional Information
(Rev. 9, 2/22/13)

Written Supporting Statements

If the physician or other prescriber provides a written statement indicating factor(s) (1), (2), and/or (3) discussed in §30.2.2.1, but the plan sponsor believes it needs additional information to support one of those factors, the plan sponsor must obtain the additional information, make its decision, and notify the enrollee and/or physician or other prescriber, as appropriate, within 24 hours (expedited requests for benefits), 72 hours (standard
requests for benefits), or 14 calendar days (reimbursement requests) after receiving the initial written statement (i.e., the time frame is not tolled if the plan asks for additional information after it has received a written supporting statement indicating one of the three factors).

CMS has developed a model notice that Part D plan sponsors can use to request a supporting statement and/or additional information (see Appendix 11). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

Plan sponsors are prohibited from requiring a physician or other prescriber to submit a supporting statement on a specific form.

**CMS: Updated Guidance on Outreach for Information to Support Coverage Decisions, February 22, 2017**

*Part D Sponsors*

If the Part D sponsor does not obtain the information, it must make a decision within the applicable timeframe based on the available information. If the plan issues an adverse decision due to the inability to obtain medical information needed to approve coverage, the plan should clearly identify that basis and the necessary information in the written denial notice. Specifically, the notice should specify the missing information, list the covered alternative treatment and appeal rights process.

**Other**

*Point of Sale Pilot*

At this time there is no easy way to determine the price of a drug at the time of prescribing in the medical office. Patients are often unaware of the cost of a drug until they are at the pharmacy. If coverage and costs information was more easily accessible to the provider when making treatment decisions it could help increase price transparency of treatments at the point of prescribing. The AADA supports having the information in the EHR/eRX system to include but not be limited to the following: medications’ formulary status, co-pay tier, out-of-pocket cost, and coverage restrictions (prior authorization, step therapy, quantity limits, etc.). Furthermore, the AADA supports CMS reviewing the work of the National Council for Prescription Drug Programs (NCPDP) on electronic transactions for electronic prior authorizations. These standards aim to both streamline the prior authorization process and provide real-time prescribing and pricing information for physicians.
Discriminatory Plan Designs

We share CMS’ concern that the number drugs eligible for specialty tiers continues to increase despite the threshold being modified and appreciate that the agency will continue to monitor this situation. In the notice CMS also cites its 2017 call letter where it stated that it will continue reviewing drug formularies to ensure they are not discriminatory to those with specific chronic conditions. We once again commend CMS’s efforts to survey formularies for adverse tiering and high cost sharing that may discourage enrollees are important in ensuring continued access to necessary medications.

Streamline the Prior Authorization Process to Reduce the Burden on Physicians and Patients

Dermatologists and their staff often find it is difficult to determine the prior authorization requirements and contact information for each Medicare plan. The AADA recommends CMS require this information to be easily accessible to physicians. Clarity is also required for the information sent back to the physician’s office for a denial. Such little information or reasoning is provided as a reasoning for the denial that often times it is unclear why the appeal is denied. The AADA calls on CMS to address the burden of prior authorizations to ensure physicians get patients the affordable and effective treatments they require.
Short Description: Increase Physician Appeal Rights under the Medicare Quality Payment Program

Summary:
There are currently very limited opportunities for providers to appeal decisions by the Centers for Medicare and Medicaid Services (CMS) regarding inclusion in Alternate Payment Models (APM) or determinations about the Merit-Based Incentive Payment System (MIPS) or APM reporting on quality, electronic health record (EHR) use, resource use, or improvement activities. CMS should develop opportunities for clinicians and APMs to have meaningful review and appeals.

Related Statute/Regulation:
The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA; P.L. 114-10), Section 1848(q)
Medicare Quality Payment Program 42 C.F.R. § 414.1300

Proposed Solution:
The regulations at 42 C.F.R. § 414.1385 permit MIPS eligible clinicians or groups to request a targeted review of the calculation of the MIPS payment adjustment factor. The American Academy of Dermatology Association (AADA) has encouraged CMS to provide further guidance on the process for seeking such review. In addition, under sections 1869 and 1878 of MACRA, there are no appeal rights regarding the determination of whether an eligible clinician is a qualified provider (QP) or Partial QP, whether an APM Entity is an Advanced APM Entity, nor the determination of the amount of the APM Incentive Payment. The AADA encourages CMS to consider whether this provides an undue risk on physicians who disagree with the determination that they are not deemed to be a qualified APM provider.
Short Description: RAC Audits and Statistical Sampling

Summary:

The Affordable Care Act (ACA) requires physicians and health care providers to report and return overpayments within 60 days of identification. The implementing regulations have provided the government the authority and framework to investigate allegations of 60-Day Rule violations and prosecute providers who fail to timely report and return an identified overpayment under the False Claims Act. Under this rule, penalties for False Claims Act violations quickly add up beginning with the 61st day. A false claim is subject to triple the charges for each improper claim.

Related Statute/Regulation:

42 C.F.R. § 455

Proposed Solution:

The American Academy of Dermatology Association (AADA) recommends Congress pass legislation to expand the period for reporting and returning overpayments beyond the 60 days currently statutorily required by the ACA. Eliminating this regulatory requirement would reduce the burden on practices to quickly identify and report overpayments within a 60-day period. It would also reduce the overall penalties by extending the time to identify and return overpayments, which would start the accumulation of penalties at a later date. In addition, it would shift more of the burden to CMS to ensure that accurate payments are made to physicians. It would not, however, eliminate the overarching requirement to return overpayments.
**Short Description:** Exempt Physicians from Compounding Facility Requirements

**Summary:**

The Food and Drug Administration’s (FDA) implementation of the Drug Quality and Security Act (DQSA) created access issues to physician in-office and office-use compounded drugs. Physicians buffering lidocaine, reconstituting botulinum toxin, and compounding other drugs in the office setting would be subject to the FDA Insanitary Conditions guidance (currently in draft form). While not technically Medicare policy, the FDA’s implementation of the DQSA stands to impact dermatologists’ ability to provide the care that many Medicare patients need.

Though the DQSA was not intended to restrict physician in-office compounding, under this draft guidance, physicians’ offices are considered “compounding facilities.” The FDA proposes that physicians compound in an ISO 5 cleanroom, under a laminar flow hood, using gowning, and other onerous requirements that are unreasonable for low-risk and low volume practices. Also, pursuant to the Prescription Requirement Final Guidance, physicians cannot obtain office-use drugs from Section 503A compounding pharmacies without a patient-specific prescription as they have previously done, and dermatologists have difficulties locating and purchasing these drugs for a reasonable price from Section 503B outsourcing facilities. Buffering lidocaine and reconstituting botulinum toxins are an integral part of dermatology practice that dermatologists are trained to and have experience performing in a safe and effective manner. Dermatologists rely on having compounded drugs in their offices to administer when patients are present; preserving the ability of dermatologists to compound in the office setting would help ensure that dermatologists are able to provide their patients with the care they need. Depending on the practice mix, having access to compounded drugs in the office setting is especially important for enabling dermatologists to treat children and other patients with rare conditions and special or urgent needs.

**Related Statute/Regulation:**

Drug Quality & Security Act (DQSA), P.L. 113-54; FDA Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act Final Guidance; FDA Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application Draft Guidance; FDA Insanitary Conditions at Compounding Facilities Draft Guidance

**Proposed Solution:**

As it relates to physician in-office compounding, the American Academy of Dermatology Association (AADA) recommends that the FDA remove physician practices from the definition of “compounding facilities” that are subject to the FDA draft guidance on insanitary conditions or in the very least, provide a 24-hour exemption for immediate/urgent use. In relation to the use of compounded drugs within the physician office, the AADA recommends that the FDA interpret DQSA in accordance with Congressional intent and allow Section 503A compounding pharmacies to dispense office-use compounded drugs to physicians without patient-specific prescriptions.