Ohio | Common Sense Initiative

Mike DeWine, Governor
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Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Medicaid

Rule Contact Name and Contact Information:

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Regulation/Package Title (a general description of the rules' substantive content):

OAC rule 5160-22-01, Ambulatory surgery center (ASC) services: provider eligibility, coverage, and reimbursement

Rule Number(s): OAC 5160-22-01

Date of Submission for CSI Review: 3/31/2020

Public Comment Period End Date: 4/7/2020

Rule Type/Number of Rules:

New/___ rules | **No Change/____ rules (FYR? ___)**

Amended/ 1**rules (FYR?** No**)** | **Rescinded/____ rules (FYR? ___)**

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☒ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☐ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☐ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

Rule 5160-22-01, entitled Ambulatory surgery center (ASC) services: provider eligibility, coverage, and reimbursement, is being proposed for amendment. Rule 5160-22-01 sets forth provider eligibility, coverage, and reimbursement methodology for ASCs subject to the Enhanced Ambulatory Patient Grouping (EAPG) system prospective payment methodology. The proposed amendments to this rule recalibrate relative weights used to calculate ASC reimbursement in order to facilitate a change from EAPG version 3.90 to EAPG version 3.14. The amendments also update the methodology used to determine ASC base rates, which include adjusting payments to ASCs that focus on eye procedures in order to prevent an un-intended cut in Medicaid payments to these ASCs.

The following changes are proposed for the ASC EAPG payment formula: the EAPG base rate for ASCs is updated to ninety per cent of the statewide average outpatient hospital EAPG base rate; EAPGs 00134 and 00149 will no longer receive an enhanced payment; for the eye procedure

enhancements, EAPG 00233's payment is multiplied by one hundred forty five per cent and EAPG 00485's payment is multiplied by two hundred thirty three percent.

EAPG codes are no longer specified when describing items which may be paid outside of EAPG.

Regulatory restrictions are being removed.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

   Section 5164.02 of the Revised Code authorizes the Agency to adopt these rules.

4. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**
   If yes, please briefly explain the source and substance of the federal requirement.

   No, the regulation does not implement a federal requirement.

5. **If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

   ASC services are not one of the categories of services that are federally mandated by the federal government to be covered under the Medicaid program. However, coverage of surgical services rendered by ASC's are mandated in the hospital outpatient setting, and ODM has determined it to be cost effective and beneficial to the Medicaid program to cover procedures in the ASC setting. The only requirement to be a Medicaid ASC provider is a valid Medicare agreement. CMS requires ASCs to be in compliance with the federal requirements set forth in the Medicare Conditions for Coverage (CfC) in order to receive payments from a Medicaid program. (See 42 CFR 488.6). The Medicare conditions and requirements to be an ASC provider are defined in 42 CFR 416 subpart B.

6. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

   The purpose of this rule filing is to update the ASC reimbursement methodology to accommodate the implementation of EAPG 3.14, so that ASC can continue to be paid for the services they rendered to Medicaid individuals, and to adjust payments to ASCs that focus on eye procedures, in order to prevent an un-intended cut in Medicaid payments to these ASCs.

7. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

   The measurable outcomes of this regulation are that ASC claims are properly paid under the updated reimbursement methodology and to prevent an un-intended adverse financial impact on some ASCs.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
   If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.
   No, the proposed rule package is not being submitted pursuant to the aforementioned laws.

Development of the Regulation

9. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
   If applicable, please include the date and medium by which the stakeholders were initially contacted.

   ODM reviewed the draft changes with the Ohio Association of Ambulatory Surgery Centers (OAASC) via conference call on October 9, 2019.

10. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

    OAASC was supportive of ODM's draft changes to 5160-22-01. No further changes were requested.

11. **What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

    Previous years of data from Outpatient EAPG claims and ASC EAPC claims were examined. The currently proposed base rates and payment enhancements for ASCs are meant to achieve neutrality in payments from the most recent year of data.

12. **What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**

    None. ODM determined Administrative Code rules to be the most appropriate type of regulation for the provisions included in this rule. The Ohio Administrative Code already has an existing rule regarding Ambulatory Surgery Center Services that outlines Ohio Medicaid's payment methodology for ASCs. Since a rule for ASCs already exists, Ohio Medicaid determined the most efficient course of action would be to make updates to that existing rule.

13. **Did the Agency specifically consider a performance-based regulation? Please explain.** ***Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.***

    No. Medicare's regulations set forth in 42 C.F.R. 416 already require quality assessment and performance improvement standards for ASCs to be accredited.

14. **What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

    Medicaid rules were reviewed by Ohio Department of Medicaid staff, including legal staff. Ohio Administrative Code rule 5160-22-01 is the only regulation that defines how ambulatory surgery centers are reimbursed by Ohio Medicaid.

15. **Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

    A Medicaid Transmittal Letter will be posted on ODM's website that will describe the changes for the ASCs. ASC providers can also obtain necessary assistance by emailing hospital_policy@medicaid.ohio.gov.

Adverse Impact to Business

16. **Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:**
    a. **Identify the scope of the impacted business community; and**

       This rule impacts all Ambulatory Surgery Centers who are or want to be an Ohio Medicaid provider.

    b. **Identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance,); and**

       This rule requires ambulatory surgery centers to have a valid agreement with CMS to provide ASC services in the Medicare program and execute an Ohio Medicaid Provider Agreement. The nature of the adverse impact is the fee for the Medicare agreement and the employee time to fill out and submit an application for the Medicare and Medicaid agreements. This rule requires ASCs to request prior authorization in order to receive reimbursement for certain services. The services that require prior

authorization are published in accordance with Revised Code 5160.34. They are generally cosmetic or experimental, therefore ODM requires these to be authorized in advance to ensure they are appropriate and medically necessary. The nature of the adverse impact is the employee time to gather information and complete and submit the prior authorization form. These requirements are part of the currently effective rule and the proposed changes will not impact these requirements.

c. Quantify the expected adverse impact from the regulation.
The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.

In order to obtain a valid agreement with CMS to provide ASC services in the Medicare program there is an estimated $3000-$5000 fee for accreditation (Source: The American Association for Accreditation of Ambulatory Surgery Facilities). There is a minimal time impact of about one hour (and de minimis associated cost) to fill out and submit an application for the agreement with CMS. After obtaining an agreement with CMS, there are no more fees for ASCs to obtain a Medicaid provider agreement. However, there is also a minimal time impact of about one hour (and de minimis associated cost) to fill out and submit an application to become a Medicaid provider. There is no expected adverse impact on existing ASC providers as they already meet the requirements. In regard to requesting prior authorization for services provided in an ASC, the Department estimates that for those services which would require prior authorization, that the ASC staff would spend about one hour to gather the information and complete authorization form on the web site. Of the 5,800 procedure codes covered in the ASC setting only 258 are flagged as requiring prior authorization.

17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The Agency determined that the regulatory intent justifies the adverse impact to the ASCs because a Medicaid Provider Agreement is required for participation in the Medicaid program and there must be some standards for participation in the Medicaid program. Using the same standards as Medicare and requiring ASCs to have a valid agreement with CMS causes the least impact to providers and eliminates multiple certification processes and fees. Ohio Medicaid justifies its use of prior authorization requirements because prior authorization is used to prevent providers from administering medically unnecessary services

to Medicaid members. Prior authorization also helps Ohio Medicaid manage the cost of its services.

Regulatory Flexibility

18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

No, the rules are the same for all ASC providers regardless of size.

19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

There are no penalties or fines associated with this rule.

20. What resources are available to assist small businesses with compliance of the regulation?

ASCs may email questions regarding OAC rule 5160-22-01 to Hospital_policy@medicaid.ohio.gov

Providers needing enrollment assistance may contact ODM provider services at http://medicaid.ohio.gov/PROVIDERS/EnrollmentandSupport/ProviderEnrollment.aspx or hospital services at Hospital_policy@medicaid.ohio.gov .

DRAFT - NOT FOR FILING

5160-22-01 Ambulatory surgery center (ASC) services: provider eligibility, coverage, and reimbursement.

Effective for dates of service on or after the effective date of this rule, eligible ambulatory surgery centers as defined in paragraphs (A)(1) and (B) of this rule are subject to the enhanced ambulatory patient grouping system (EAPG) and prospective payment methodology utilized by the Ohio department of medicaid as described in this rule.

(A) Definitions, for the purposes of this rule the following meanings apply.

(1) An "ambulatory surgery center (ASC)" is any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization.

(2) "Enhanced ambulatory patient grouping (EAPG)" is a group of outpatient procedures, encounters, or ancillary services, which reflect similar patient characteristics and resource utilization and which incorporate the use of ~~"International Classification of Diseases"~~international classification of diseases (ICD) diagnosis codes, current procedural terminology (CPT) ~~code set~~procedural codes, and healthcare common procedure coding system (HCPCS) procedure codes.

(3) "EAPG grouper" is the software provided by 3M health information systems to group outpatient claims based on services performed and resource intensity.

(4) "Default EAPG settings" are the default EAPG grouper options in 3M's core grouping software for each EAPG grouper version.

(5) "Discounting factor" is a factor applicable for multiple significant procedures or repeated ancillary services designated by default EAPG settings or both. The appropriate percentage (fifty or one hundred per cent) will be applied to the highest weighted of the multiple procedures or ancillary services payment group.

(a) "Full payment" is the EAPG payment with no applicable discounting factor.

(b) "Consolidation factor" is a factor of zero per cent applicable for services designated with a same procedure consolidation flag or clinical procedure consolidation flag by the EAPG grouper under default EAPG settings.

(c) "Packaging factor" is a factor of zero per cent applicable for services designated with a packaging flag by the EAPG grouper under default EAPG settings.

(6) "ASC invoice" is a bill submitted in accordance with Chapter 5160-1 of the Administrative Code, to the department for services rendered to one eligible medicaid beneficiary on one or more date(s) of service. For an invoice encompassing more than one date of service, each date will be processed separately as an individual claim.

(7) "ASC claim" encompasses the ASC services rendered to one eligible medicaid beneficiary on one date of service at an ASC facility.

(8) "Procedure code" is the ~~current procedural terminology (CPT) codes~~CPT code or ~~healthcare common procedure coding system (HCPCS)~~HCPCS code as identified in rule 5160-1-19 of the Administrative

Code.

(9) "Diagnosis code" is the ~~"International Classification of Diseases" codes~~ICD code as identified in rule 5160-1-19 of the Administrative code.

(10) "Relative weight" is a factor specific to each EAPG that represents that EAPG's relative cost compared to an average case. The relative weights for EAPGs are calculated as described in paragraph (F) of rule 5160-2-75 of the Administrative Code.

(11) "EAPG base rate" is the dollar value that ~~shall be~~is multiplied by the final EAPG weight for each EAPG on a claim to determine the total allowable medicaid payment for a visit. The EAPG base rate for ASCs is ~~eighty~~ninety per cent of the statewide average outpatient hospital EAPG base rate. Hospital EAPG base rates are calculated as described in paragraph (D) of rule 5160-2-75 of the Administrative Code.

(12) "ASC facility services" are items and services furnished by an ASC in connection with a covered ASC surgical procedure.

(13) "ASC Cost-to-charge ratio" is eighty per cent of the statewide average outpatient cost-to-charge ratio as calculated in rule 5160-2-22 of the Administrative Code.

(B) Eligible ASC providers.

(1) All ASCs that have a valid agreement with the centers for medicare and medicaid services (CMS) to provide services in the medicare program are eligible to become medicaid providers upon execution of the "Ohio Medicaid Provider Agreement."

(2) ASC providers ~~must~~ bill in accordance with rule 5160-1-19 of the Administrative Code. The department will reimburse an ASC for properly submitted claims for facility services furnished in connection with covered surgical procedures when the services are provided by an eligible ASC provider to an eligible medicaid recipient. Reimbursement for covered ASC facility services will be paid in accordance with paragraph (D) of this rule.

(C) Covered ASC services.

(1) Services include but are not limited to:

(a) Nursing, technician, and related services;

(b) Use of the ASC facilities;

(c) Drugs, biologicals (e.g., blood), surgical dressings, splints, casts and appliances, and equipment directly related to the provision of the surgical procedure;

(d) Diagnostic or therapeutic services or items directly related to the provisions of a surgical procedure;

(e) Administrative, record keeping, and housekeeping items and services;

(f) Materials for anesthesia;

(g) Intraocular lenses; and

(h) Supervision of the services of an anesthetist by the operating surgeon.

~~(2)~~ (2) ~~Services covered in an ASC are listed on the department's web site http://www.medicaid.ohio.gov/.~~

~~(3)~~ (2) Prior authorization (PA) ~~will be required~~is necessary for certain surgical CPT codes. The services ~~that require~~needing PA are ~~listed on the department's web site, http://www.medicaid.ohio.gov/,~~published in accordance with section 5160.34 of the Revised Code.

(D) EAPG payment formula.

(1) Total EAPG payment is the sum across all paid line items on an ASC claim

(2) The payment for a paid line on the claim is calculated as follows, except as described in paragraph (E) or (F) of this rule:

(a) The ASC EAPG base rate times;

(b) The EAPG relative weight for which the service was assigned by the EAPG grouper, rounded to the nearest whole cent;

(c) For ~~EAPGs 00134 and 00149~~EAPG 00233, the result of paragraph (D)(2)(b) of this rule multiplied by one hundred ~~ten~~forty-five per cent, rounded to the nearest whole cent~~,~~. For EAPG 00485, the result of paragraph (D)(2)(b) of this rule multiplied by two hundred thirty three percent, rounded to the nearest whole cent;

(d) The result of paragraphs (D)(2)(a) and (D)(2)(b) of this rule, or, for EAPGs ~~00134 and 00149~~00233 and 00485, (D)(2)(a) to (D)(2)(c), times applicable discounting factor(s) as defined in paragraph (A)(5) of this rule, rounded to the nearest whole cent.

(E) Payment for laboratory services, radiological services, and diagnostic and therapeutic procedures.

An ASC may be reimbursed in addition to the facility fee for covered laboratory procedures, radiological procedures, and diagnostic and therapeutic procedures provided in connection with a covered ASC surgical procedure.

(1) Payment for laboratory services.

(a) An ASC may be reimbursed for covered laboratory services ~~they~~ actually performed.

(b) An ASC ~~may~~should not bill separately for the professional component of an anatomical pathology procedure.

(c) Laboratory services will be reimbursed the lesser of billed charges or the result of paragraph (D)(2)(d) of this rule.

(2) Payment for radiological services.

(a) An ASC may be reimbursed for covered radiological services ~~they~~ actually performed.

(b) An ASC ~~may~~should not bill the department for the professional component separately.

(c) Radiological services will be reimbursed the lesser of billed charges or the result of paragraph (D)(2)(d) of this rule.

(3) Payment for diagnostic and therapeutic procedures.

(a) An ASC may be reimbursed for the provision of diagnostic and therapeutic services when provided.

(b) An ASC ~~may~~should not bill separately for the professional component of a diagnostic and therapeutic procedure.

(c) Diagnostic and therapeutic services will be reimbursed the result of paragraph (D)(2)(d) of this rule.

(4) An ASC may also be reimbursed for laboratory, radiology and diagnostic and therapeutic services actually performed in the ASC in conjunction with covered services not eligible for an ASC facility payment.

(F) Items which may be paid outside of EAPG.

(1) Pharmaceuticals.

(a) Payments for covered pharmaceuticals will be made in accordance with the discounting factors as determined by the EAPG grouper. If no consolidation or packaging factors are assigned then the pharmaceutical line is separately payable and will pay according to paragraphs (F)(1)(b) and (F)(1)(c) of this rule.

(b) Reimbursement for separately payable covered pharmaceuticals shall be the lesser of billed charges or the payment amounts in the provider administered pharmaceutical fee schedule as published on the department's web site, http://medicaid.ohio.gov/, at the rate in effect on the date of service.

(c) If a J-code or Q-Code, that is covered for ASC facilities and separately payable, is listed as "by report" in the provider-administered pharmaceutical fee schedule, the line will be multiplied by sixty per cent of the ASC cost-to-charge ratio.

(2) Durable medical equipment (DME).

(a) ~~Payments for covered DME~~Additional payments may be made for all line items grouping to a DME EAPG ~~code 01001, 01002, 01003, 01004, 01005, 01006, 01007, 01008, 01009, 01010, 01011, 01012, 01013, 01014, 01015, 01016, 01017, 01018, 01019, or 01020~~type.

(b) Reimbursement for DME ~~shall~~will be the lesser of billed charges or the payment amounts in the medicaid non-institutional maximum payment schedule as published on the department's web site, http://medicaid.ohio.gov/, at the rate in effect on the date of service.

(c) Payments for DME will be made in accordance with the discounting factors as determined by the EAPG grouper.

(3) Dental services

Reimbursement for claims assigned to a dental service EAPG type will be paid as follows:

~~(a)~~ (a) ~~Payments for covered dental services may be made for all line items grouping to EAPG code 00350, 00351, 00352, 00353, 00354, 00355, 00356, 00357, 00358, 00359, 00360, 00361, 00362,~~

~~00363, 00364, 00365, 00366, 00367, 00368, 00369, 00370, 00371, or 00372.~~

~~(b)~~ (a) Reimbursement for dental services will be nine-hundred fifty-three dollars and sixty cents.

~~(c)~~ (b) Payments for dental services will be made in accordance with the discounting factors as determined by the EAPG grouper.