STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

COVENANT HOSPICE, INC.,

Petitioner,

vs. Case No. 17-6836RU

AGENCY FOR HEALTH CARE ADMINISTRATION,

Respondent.
_____/

FINAL ORDER

Pursuant to notice, a final hearing was held in this matter on March 19 through 23, 2018, in Tallahassee, Florida, before Administrative Law Judge Yolonda Y. Green of the Division of Administrative Hearings ("Division").

APPEARANCES

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For Respondent: Rex D. Ware, Esquire
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STATEMENT OF THE ISSUE

Whether Respondent, Agency for Health Care Administration ("Respondent" or "AHCA"), has relied on any statements of general applicability regarding reimbursement of Medicaid

expenses which are agency rules, as defined in section 120.52(16), Florida Statutes,[1/] but have not been adopted as rules in accordance with section 120.54(1)(a), Florida Statutes.

PRELIMINARY STATEMENT

Petitioner, Covenant Hospice, Inc. ("Petitioner" or "Covenant"), an authorized provider of Medicaid services, was audited by Respondent's Office of Medicaid Program Integrity ("MPI") for the claims period January 1, 2011, through December 31, 2012 ("Audit Period"), and found to be in violation of certain Medicaid provider policies. Respondent prepared a Final Audit Letter on August 9, 2016, informing Petitioner that it was overpaid $714,518.14 for services provided during the Audit Period and imposing fines ($142,903.63) and costs ($131.38). That proceeding is pending as DOAH Case No. 17-4641MPI (the "Overpayment Case").

On August 29, 2017, Petitioner timely requested an administrative hearing challenging Respondent's determination of overpayments and imposition of fines and costs. The undersigned scheduled this matter for a final hearing on October 23 through 25, 2017. On October 5, 2017, the parties filed a Joint Motion for Continuance and the hearing was rescheduled for February 5 through 9, 2018.

On December 18, 2017, Respondent filed its Petition for Formal Hearing to Challenge Agency Statements Defined as Rules

("Unadopted Rule Challenge"). Petitioner filed the instant Unadopted Rule Challenge alleging that AHCA's determination of overpayment was based, at least in part, on findings that are improperly based on statements of general applicability that have not been subject to the rulemaking requirements of section 120.54, in violation of section 120.54(1)(a). On December 20, 2017, the undersigned entered an Order consolidating the Unadopted Rule Challenge with the Overpayment Case.

On January 9, 2018, Petitioner moved for a continuance, which the undersigned granted. On January 12, 2018, Respondent moved for continuance, which was also granted. This matter was rescheduled for hearing on March 19 through 23, 2018.

The parties filed a Joint Pre-hearing Stipulation, which contains facts that have been incorporated into the Findings of Fact below, to the extent relevant.

On March 19, 2018, the final hearing convened as scheduled and concluded on March 23, 2018. At the final hearing, Joint Exhibits 1 through 121, 124 through 167, and 169 were admitted into evidence.

AHCA presented the live testimony of four witnesses: Robert Reifinger, FCCM, a program administrator of AHCA's MPI office; Mike Armstrong, the auditor in charge for Health Integrity, LLC ("Health Integrity"); Nada Boskovic, M.D., AHCA's

expert in hospice and palliative care; and Charles D. Talakkottur, M.D., AHCA's expert in internal medicine. AHCA also presented by deposition Dr. Todd Eisner, AHCA's expert in internal medicine and gastroenterology. Covenant presented live testimony of David McGrew, M.D., FAAHPM, HMFC, Covenant's expert in hospice and palliative care; and James Smith, DO, Covenant's interim chief medical officer and corporate medical director for Covenant.

The parties ordered a copy of the hearing transcript. The seven-volume Transcript of the final hearing was filed with the Division on April 6, 2018, after which the parties filed a Joint Motion Regarding Deadlines and Page Limits for Proposed Orders. The undersigned granted the motion, thereby increasing the page limit for the proposed final orders ("PFOs") to 50 pages and extending the deadline for submittal of the PFOs to May 18, 2018. The parties timely filed PFOs, which have been considered in preparation of this Final Order.

FINDINGS OF FACT

Based on the evidence presented at the final hearing and the record in this matter, the following Findings of Fact are made.

Parties

1. Covenant is a provider of hospice and end-of-life services and at all times relevant to this matter, the program

was an authorized provider of Medicaid services pursuant to a valid Medicaid provider agreement with AHCA.

2. AHCA is the state agency responsible for administering the Florida Medicaid Program. Medicaid is a joint federal/state program to provide health care and related services to qualified individuals, including hospice services.

3. AHCA is authorized to recover Medicaid overpayments, as deemed appropriate. § 409.913, Fla. Stat.

Medicaid Audit Process

4. The U.S. Department of Health & Human Services, Centers for Medicare and Medicaid Services ("CMS"), contracted with Health Integrity, a private vendor, to perform an audit of Covenant. Health Integrity retained a company called Advanced Medical Reviews ("AMR") to provide peer physician reviews of claims to determine whether an overpayment occurred.

5. On or about December 3, 2013, Health Integrity commenced the audit of Covenant. The scope of the audit was limited to Medicaid recipients that received hospice services from Covenant during the period of January 1, 2011, through December 31, 2012. Generally speaking, the files were identified for review using the following criteria: a) the recipient was not dually eligible (eligible for both Medicaid and Medicare); and b) Covenant provided hospice services for 182 days or longer, based on the recipient's first and last day

of service within the Audit Period. Thus, the objective of the audit was to determine whether certain Medicaid patients were eligible for hospice benefits provided by Covenant.

6. When Health Integrity applied the audit criteria to the Medicaid claims paid by AHCA to Covenant, Health Integrity determined that Covenant had provided hospice services to 62 Medicaid recipients for 182 days or longer during the Audit Period.

7. Covenant provided Health Integrity with medical and related financial records ("Covenant's Records") in order to support the eligibility of these 62 patients for Medicaid benefits paid by AHCA.

8. To qualify for the Medicaid hospice program, all recipients must, among other things: a) be certified by a physician as terminally ill with a life expectancy of six months or less if the disease runs its normal course; and b) voluntarily elect hospice care for the terminal illness. See Florida Medicaid Hospice Services Coverage and Limitations Handbook, (January 2007 edition) ("Handbook") at page 2-3, as adopted by Fla. Admin. Code. R. 59G-4.140 (effective Dec. 24, 2007); see also § 400.6095(2), Fla. Stat., (2010-2012).

9. Health Integrity employs claims analysts who performed an initial review of Covenant's medical records to determine if

the recipients were eligible for Medicaid hospice benefits. All Health Integrity claims analysts are registered nurses.

10. If the Health Integrity claims analyst is able to assess that the patient's file contains sufficient documentation to justify eligibility for hospice benefits for the entire length of stay under review in the audit, there was no imposition of an overpayment for that file and, thus, the claim is not evaluated further.

11. If the Health Integrity claims analyst is unable to assess whether the patient's file contains sufficient documentation to determine eligibility for hospice benefits, or if only a portion of the patient's stay could be justified by the Health Integrity claims analyst, the file is then forwarded to an AMR physician to make the ultimate determination as to eligibility for Medicaid hospice benefits and whether an overpayment is due the Florida Medicaid program.

12. With respect to the Covenant audit, the Health Integrity claims analysts reviewed Covenant's medical files for the 62 initially identified recipients and determined that no further action was warranted with respect to 10 recipients. As a result, 52 files were referred for physician peer review by AMR.

13. AMR maintains a secure portal ("AMR Portal") that Health Integrity personnel access to transmit all received

provider files to AMR. AMR's peer review physicians, in turn, use the AMR Portal to review the totality of the provider's submitted documentation, including all medical case records, and provide their comments.

14. As required by section 409.9131, AHCA referred Petitioner's records for peer review to determine whether there was a medical necessity for a hospice program.

15. Section 409.9131(2), Florida Statutes, sets forth the following definitions:

> (b) "Medical necessity" or "medically necessary" means any goods or services necessary to palliate the effects of a terminal condition or to prevent, diagnose, correct, cure, alleviate, or preclude deterioration of a condition that threatens life, causes pain or suffering, or results in illness or infirmity, which goods or services are provided in accordance with generally accepted standards of medical practice. For purposes of determining Medicaid reimbursement, the agency is the final arbiter of medical necessity. In making determinations of medical necessity, the agency must, to the maximum extent possible, use a physician in active practice, either employed by or under contract with the agency, of the same specialty or subspecialty as the physician under review. Such determination must be based upon the information available at the time the goods or services were provided.
>
> (c) "Peer" means a Florida licensed physician who is, to the maximum extent possible, of the same specialty or subspecialty, licensed under the same chapter, and in active practice.

> (d) "Peer review" means an evaluation of the professional practices of a Medicaid physician provider by a peer or peers in order to assess the medical necessity, appropriateness, and quality of care provided, as such care is compared to that customarily furnished by the physician's peers and to recognized health care standards, and, in cases involving determination of medical necessity, to determine whether the documentation in the physician's records is adequate.

Peer Review

16. Each AMR peer reviewer retained to review the respective recipient's patient records prepared a written report, which was based on the reviewer's opinion regarding whether the patient had a terminal diagnosis, with a life expectancy of six months or less to live if the recipient's terminal illness followed its natural course.

17. The peer reviewers formulated their opinions based on their own training, experience, and the generally accepted standards in the medical community within the respective specialty. The factors for formulating an opinion include the terminal diagnosis, comorbidities, and any other factors that provide a complete picture in evaluating the eligibility for the hospice program. After the AMR peer review physicians reviewed the 52 Covenant recipient files loaded into the AMR Portal, the AMR physicians determined that 23 recipients were eligible for Medicaid hospice services and 29 patients were ineligible.

18. On February 12, 2016, Health Integrity presented the Draft Audit Report ("DAR") to Covenant for comment and response. Covenant provided a response to the DAR, and contested the overpayments for each of the 29 recipients. Covenant's response was provided to the AMR peer review physicians, who, after reviewing the response, revised their opinions for four recipients. Therefore, the number of recipients in dispute was reduced to 25 patients.

19. Health Integrity then prepared a Revised Draft Audit Report ("RDAR"), which assessed an overpayment amount of $714,518.14, relating to the 25 recipients. Health Integrity presented the RDAR to CMS and AHCA for approval.

20. After the RDAR was approved by CMS and AHCA, Health Integrity prepared and issued the Final Audit Report ("FAR"), upholding the overpayments identified in the RDAR, and submitted it to CMS. CMS provided the FAR to AHCA with instructions for AHCA to initiate the state recovery process and to furnish the FAR to Covenant.

21. The FAR contains the peer review physicians' basis for determining why each of the 25 recipients at issue was not eligible for Medicaid hospice services.

22. The FAR determined that Petitioner was overpaid $714,518.14 for services provided to the 25 recipients during the Audit Period. The FAR also imposed a fine of $142,903.63

and assessed costs of $131.38. However, the parties have since reduced the number of disputed patients from 25 to 17 patients. As a result, AHCA is seeking a revised amount of overpayment in the total amount of $677,023.44, with a corresponding revised fine amount of $135,404.68, for the remaining files in dispute.

23. At the heart of Petitioner's rule challenge are allegations that AHCA relied on agency statements of general applicability regarding a patient's eligibility for hospice services.

24. To be eligible for Florida Medicaid hospice services, a recipient must be certified by a physician as terminally ill with a life expectancy of six months or less, if the disease runs its normal course. The Handbook also requires:

> Documentation to support the terminal prognosis must accompany the initial certification of terminal illness. This documentation must be on file in the recipient's hospice record. The documentation must include, where applicable, the following:
>
> • Terminal diagnosis with life expectancy of six months or less if the terminal illness progresses at its normal course;
>
> • Serial physician assessments, laboratory, radiological, or other studies;
>
> • Clinical progression of the terminal disease;
>
> • Recent impaired nutritional status related to the terminal process;

- Recent decline in functional status; and
- Specific documentation that indicates that the recipient has entered an endstage of a chronic disease.

Unadopted Rule Challenge

25. Covenant alleged that AHCA relied on the following three types of statements and alleges that those statements are unadopted rules: 1) certain observations included in the peer review physicians' reports; 2) anticipated findings in the Audit Test Plan; and 3) the inconsistent application of the phrase "where applicable" as found in the Handbook.

26. Covenant's Exhibit "A" to its Petition identified what it alleges are the statements relied upon by Covenant peer reviewers when determining whether the disputed patients were eligible for hospice. Covenant alleges the statements are "rules" as defined in section 120.52(16).

27. The statements referenced by Covenant in Exhibit "A" include observations regarding the medical condition of the patients referenced. Based on the medical records for each recipient, the statements made by the peer reviewers were opinions formulated based on their medical expertise and experience. The opinion of a peer reviewer is not a standard used to determine the eligibility of a patient, but rather an opinion based on expertise and experience.

28. Based on the testimony, live or by deposition, of AHCA's peer review physicians, the peer reviewers use the six criteria set forth in the Handbook to determine the respective patient's eligibility for hospice services. The observations and comments made by the peer reviewers in their reports were based on the medical records for each terminally diagnosed patient.

29. Petitioner argues that AHCA has not engaged in rulemaking to adopt the expert's opinions based on medical standards.

30. The documented statements in the peer review physician's opinions were medical determinations made by AHCA's peer review physicians. They are not standards used to determine the eligibility of each recipient. The peer review physicians evaluated the presence of disease progression, decline in status, increased symptom burden, or severity of the patient's illness to determine whether the progression of illness would lead to death within six months.

31. Although Covenant challenged statements offered by peer reviewer, Dr. Ankush Bansal, Dr. Bansal's claims were re-reviewed and AHCA offered the testimony of the new peer review physician to support its claim of overpayment. Thus, the alleged statements documented by Dr. Bansal are not properly before the undersigned for consideration.

Anticipated Findings

32. Health Integrity claims analysts reviewed Covenant's claims and determined whether the claims should also be reviewed by a peer review physician. If the claims analyst determined that a claim needed further review, they were required to have that claim forwarded to a qualified peer review physician who would make a final determination of eligibility. None of the overpayment claims in the DAR or the FAR, as amended, was the result of any decision made by any Health Integrity claims analyst nurse.

33. There was no evidence offered at hearing to demonstrate that the peer review physicians relied on the anticipated findings in the audit process or thereafter. The peer review physician, not the claims analyst, made the determination regarding eligibility, which was based on the criteria in the Handbook.

34. Covenant offered no evidence at hearing that the observations or comments listed in its Petition were the determinative factor for any peer reviewer's determination that a patient was ineligible for Medicaid hospice services.

35. AHCA's peer reviewers relied on factors within the patient's records to make a determination of eligibility for hospice services. Their reliance on their experience and expertise to evaluate eligibility of each patient does not

transform their respective statements into a rule. The statements were specific to the individual patient, not general statements of general applicability.

Application of "Where Applicable" Language

36. The third and final type of statement challenged by Covenant is the alleged inconsistent application by the peer review physicians of the phrase "where applicable," which is found in the Handbook.

37. The evidence offered at hearing demonstrates that each peer review physician applied the criteria from the Handbook to determine a patient's eligibility for hospice services. According to the record, the peer reviewers applied the six criteria in the Handbook based on the patient records, including medical history and diagnosis.

CONCLUSIONS OF LAW

38. The Division of Administrative Hearings has jurisdiction over the parties and subject matter in this proceeding pursuant to sections 120.56(4), 120.569, and 120.57(1), Florida Statutes (2017).

39. AHCA is the agency with the statutory duty to provide oversight of the Florida Medicaid program, and to ensure the integrity of the program, including requiring "repayment for

inappropriate, medically unnecessary, or excessive goods or services from the person furnishing them . . . ."
§ 409.913(11), Fla. Stat.

40. Covenant is an approved provider and is subject to the jurisdiction and regulation of the MPI Office of AHCA.

41. An agency statement that comes within the definition of a rule must be adopted according to the rulemaking process. Envtl. Trust, Inc. v. Dep't Envtl. Prot., 714 So. 2d 493 (Fla. 1st DCA 1998); Christo v. Dep't of Banking and Fin., 649 So. 2d 318 (Fla. 1st DCA 1995).

42. Section 120.56(4) provides that a person substantially affected by an agency statement that meets the definition of a rule, but which has not been adopted by rulemaking procedures, may challenge that statement.

43. In order to prove standing, Petitioner must show that: 1) the agency statement of policy will result in a real or immediate injury in fact; and 2) the alleged interest is within the zone of interest to be protected or regulated. Jacoby v. Fla. Bd. of Med., 917 So. 2d 358, 360 (Fla. 1st DCA 2005).

44. Petitioner has standing to bring this action pursuant to section 120.56(4)(a), as AHCA has relied on the alleged statements at issue in determining the amount that Petitioner was overpaid by Medicaid during the Audit Period.

45. The Legislature has determined that agencies must adopt any policies meeting the definition of a rule as rules. § 120.54(1), Fla. Stat.

46. Section 120.56(4) provides in pertinent part:

> (a) Any person substantially affected by an agency statement may seek an administrative determination that the statement violates s. 120.54(1)(a). The petition shall include the text of the statement or a description of the statement and shall state with particularity facts sufficient to show that the statement constitutes a rule under s. 120.52 and that the agency has not adopted the statement by the rulemaking procedure provided by s. 120.54.
>
> (b) If a hearing is held and the petitioner proves the allegations of the petition, the agency shall have the burden of proving that rulemaking is not feasible or not practicable under s. 120.54(1)(a).

47. Section 120.52(16), in relevant part, defines the term "rule" as follows:

> "Rule" means each agency statement of general applicability that implements, interprets, or prescribes law or policy or describes the procedure or practice requirements of an agency and includes any form which imposes any requirement or solicits any information not specifically required by statute or by an existing rule.

48. An "unadopted rule" is defined as an agency statement that meets the definition of the term rule, but that has not been adopted pursuant to the requirements of section 120.54. § 120.52(20), Fla. Stat.

49. In this proceeding, Covenant has the burden of demonstrating by a preponderance of the evidence that the statements regarding the determination of eligibility for hospice services meet the definition of a rule and that the agency has not adopted the statements by rulemaking procedures. Sw. Fla. Water Mgmt. Dist. v. Charlotte Cnty., 774 So. 2d 903, 908 (Fla. 2d DCA 2001); § 120.56(4)(a), (b), Fla. Stat.

50. Covenant identified three types of alleged agency statements of general applicability in its Petition. Petitioner did not prove that the peer reviewer's findings regarding eligibility for hospice services were agency statements. Petitioner also did not prove that the statements made by each peer reviewer regarding certain patients were applied to any other patients.

51. Even if Petitioner was able to demonstrate that the AHCA peer reviewers applied the alleged statements to support their determination of eligibility for hospice services, that is not sufficient to raise those statements to the level of an agency statement of general applicability.

52. The courts have considered the various elements of this statutory definition in determining whether a statement constitutes an unadopted rule. Perhaps the most fundamental element is that the statement must be an "agency" statement - an expression of policy by the agency. First, it must be a

statement of the agency as a state institution, not merely the position of a single employee or group of employees. Second, to be a statement of the agency, it must go beyond the mere reiteration or restatement of policy already established by a properly adopted rule or by the implemented statute. St. Francis Hosp., Inc. v. Dep't of HRS, 553 So. 2d 1351 (Fla. 1st DCA 1989).

53. The concept of general applicability involves the force and effect of the statement itself. An agency statement that requires compliance, creates or adversely affects rights, or otherwise has the direct and consistent effect of law is a rule. State Bd. of Admin. v. Huberty, 46 So. 3d 1144, 1147 (Fla. 1st DCA 2010). A statement that does not do those things is not a rule.

54. An agency statement must also be consistently applied. In Department of Highway Safety and Motor Vehicles v. Schluter, 705 So. 2d 81, 82 (Fla. 1st DCA 1997), the court found three of the challenged policies not to be generally applicable because an employee's supervisor was not required to apply them, and therefore they could not be considered to have the "consistent effect of law." See also Coventry First, LLC v. Off. of Ins. Reg., 38 So. 3d 200, 205 (Fla. 1st DCA 2010) (examination manual provided to examiners of the Office of Insurance Regulation not

generally applicable because examiners had discretion not to follow it).

55. None of the challenged statements raised by Covenant is self-executing or by their own effect, create rights, require compliance, or otherwise have the direct and consistent effect of law.

56. Regarding the peer review observations that Covenant asserts were statements of general applicability, the evidence in the record does not demonstrate that any observation made by an individual peer reviewer is a "rule." The evidence demonstrates that the alleged observations made by the peer reviewers did not appear in the file of each. Rather, patient records were reviewed by a peer reviewer on a case-by-case basis. The peer reviewers evaluated eligibility based upon their respective medical training, experience and judgment, and their observations of the patient's medical history. Thus, the observations could not be considered to have the "consistent effect of law."

57. Further, the courts have clearly held, where application of agency policy is subject to the discretion of agency personnel, the policy is not a rule. See Coventry First, LLC v. Off. of Ins. Reg., 38 So. at 204 (quoting McDonald v. Dep't of Banking & Fin., 346 So. 2d 569, 581 (Fla. 1st DCA 1977)). Here, the evidence demonstrated that the peer

reviewer's observations were made solely at the discretion of each individual peer reviewer, on a case-by-case basis, based upon his or her respective medical judgment, and upon review of each patient file. There was not sufficient evidence offered at hearing to demonstrate that a peer reviewer's final decision was determined solely upon the observations listed in Exhibit "A" to Covenant's Petition. Rather, the peer reviewers consistently testified that any observations noted in their review of a particular medical record was only one of several factors they considered when rendering their final opinions. The observations were in the context of each peer reviewer's training and experience as they applied the criteria of the Handbook.

58. The challenged observations are also not self-executing and require the exercise of discretion in their application. The statements at issue do not establish that the service provider owes money. Ag. for Health Care Admin. v. Custom Mobility, Inc., 995 So. 2d 984, 987 (Fla. 1st DCA 2008). The observations were statements made by different peer reviewers on a case-by-case basis as a factor in their respective determination regarding whether a particular patient was eligible for hospice services.

59. Regarding the term "anticipated findings," no evidence was offered to show that they were self-executing or required

compliance or had the effect of law. There was no testimony or other proof that any of the claims analyst nurses involved in reviewing the original files reviewed or even applied the "anticipated findings" in rendering any decision in the audit, much less that they were required to use them in judging the medical records they reviewed. Furthermore, the claims analyst nurses had no ultimate decision-making authority that would adversely affect Covenant. The ultimate determinations as to medical necessity were made by the peer reviewers who were not provided the "anticipated findings."

60. Moreover, there was not sufficient evidence offered at hearing to demonstrate that the "anticipated findings" were used to determine the eligibility of any specific patient, and no evidence was presented to indicate the "anticipated findings" are inconsistent with the requirements already codified in Florida Administrative Code Rule 59G-1.140.

61. The alleged inconsistent application of the term "where applicable" is not an unadopted agency statement.

62. Covenant failed to prove that any of the Challenged Statements were agency statements of general applicability that implement, interpret, or prescribe law or policy or describe the procedure or practice requirements of an agency, including any form, which impose any requirement or solicit any information not specifically required by statute or by an existing rule.

63. The appropriate forum for resolution of the observations and determinations contained in the FAR and AHCA's findings is the underlying Overpayment Case.

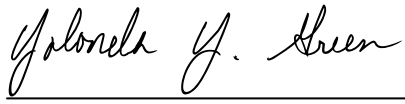
FINAL ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is

ORDERED:

That the Petition of Covenant Hospice to Challenge Agency Statements Defined as Rules is dismissed.

DONE AND ORDERED this 15th day of August, 2018, in Tallahassee, Leon County, Florida.



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Filed with the Clerk of the
Division of Administrative Hearings
this 15th day of August, 2018.

ENDNOTE

[1/] Except as otherwise indicated, all references to statutes and rules are to the versions in effect in 2011-2012, the time the statements alleged to be unadopted rules substantially affected Petitioner by virtue of Respondent's Final Audit Letter.

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NOTICE OF RIGHT TO JUDICIAL REVIEW

A party who is adversely affected by this Final Order is entitled to judicial review pursuant to section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing one copy of a Notice of Administrative Appeal with the agency clerk of the Division of Administrative Hearings and a second copy, accompanied by filing fees prescribed by law, with the District Court of Appeal, First District, or with the District Court of Appeal in the appellate district where the party resides. The Notice of Administrative Appeal must be filed within 30 days of rendition of the order to be reviewed.