OPINION NO. 2005-008

Syllabus:

1. R.C. 4121.121, R.C. 4121.44, R.C. 4121.441, and R.C. 4123.66 grant the Bureau of Workers' Compensation sufficient authority to adopt the provisions appearing in 10 Ohio Admin. Code 4123-6-21(L).

2. The language of 10 Ohio Admin. Code 4123-6-21(L) providing that the Bureau of Workers' Compensation or its pharmacy benefits vendor may "be responsible for maintaining a drug formulary" by necessary implication provides authority for the Bureau to first create a drug formulary.

To: James Conrad, Administrator, Ohio Bureau of Workers' Compensation, Columbus, Ohio

By: Jim Petro, Attorney General, March 1, 2005

We have received your request for a formal opinion concerning the ability of the Ohio Bureau of Workers' Compensation to implement a drug formulary pursuant to 10 Ohio Admin. Code 4123-6-21(L). You have asked the following questions:

March 2005
1. Is the adoption by the Bureau of Workers' Compensation of 10 Ohio Admin. Code 4123-6-21(L) supported by sufficient statutory authority?

2. If so, does 10 Ohio Admin. Code 4123-6-21(L), which provides that the Bureau of Workers' Compensation or its pharmacy benefits vendor may "maintain" a drug formulary, also provide the Bureau with authority to first "create" a formulary?

For the reasons below, we answer both of these questions in the affirmative. We find that R.C. 4121.121, R.C. 4121.44, R.C. 4121.441, and R.C. 4123.66 grant the Bureau of Workers' Compensation sufficient authority to adopt the provisions appearing in 10 Ohio Admin. Code 4123-6-21(L). We find, further, that the language of 10 Ohio Admin. Code 4123-6-21(L) providing that the Bureau of Workers' Compensation or its pharmacy benefits vendor may "be responsible for maintaining a drug formulary" by necessary implication provides authority for the Bureau to first create a drug formulary.

10 Ohio Admin. Code 4123-6-21(L)

Your questions pertain to 10 Ohio Admin. Code 4123-6-21(L), which states:

The bureau [of workers' compensation] may contract with a vendor to perform drug utilization review and on-line bill processing, maintain a pharmacy provider network and prior authorization program for medications, and provide management reports. The bureau or its vendor may also contract rebate agreements with drug manufacturers, be responsible for maintaining a drug formulary, and establish and enforce dispensing limitations. The bureau or its agent may utilize other services or established procedures of the vendor which may enable the bureau or its agent to control costs and utilization and detect fraud.

10 Ohio Admin. Code 4123-6-21(L) (emphasis added).¹

Although your questions refer to the entire paragraph designated as division (L), your specific concern is the authority of the Bureau to implement a drug formulary. The term "formulary" is not defined in the statutes governing the Bureau of Workers' Compensation. However, the definitions appearing in Chapter 4123-6 of the Ohio Administrative Code include the following:

(W) "Formulary" means:

A list of medications determined to be safe and effective by the food and

¹ 10 Ohio Admin. Code 4123-6-21, including division (L), was initially adopted by the Bureau of Workers' Compensation with an effective date of January 27, 1997. See [1996-1997 Ohio Monthly Record, vol. 2] Ohio Admin. Code 4123-6-21, at 1380-81. The rule was amended effective January 1, 2003, but the provisions of division (L) were not changed. See [2002-2003 Ohio Monthly Record, vol. 1] Ohio Admin. Code 4123-6-21, at 1447. You have asked about the statutory authority for the Bureau to adopt division (L) and, in addressing your question, we consider only that statutory authority. We are not considering whether rule 4123-6-21 was properly adopted and is valid in other respects, though we have no reason to question its validity.
drug administration which the bureau shall consider for reimbursement. The list shall be regularly reviewed and updated by the bureau to reflect current medical standards of drug therapy.

10 Ohio Admin. Code 4123-6-01(W). Thus, the term "formulary" is used in rule 4123-6-21(L) to describe a list of medications (determined to be safe and effective by the Food and Drug Administration) that the Bureau considers for reimbursement. By definition, the list must be reviewed and updated on a regular basis so that it reflects current medical standards of drug therapy. The term "formulary" is commonly used in this or a similar manner. See, e.g., R.C. 1753.21 (requirements that apply when a policy, contract, or agreement of a health insuring corporation uses a restricted formulary of prescription drugs, including a procedure for providing coverage of nonformulary drugs in certain circumstances); Upjohn Co. v. Ohio Dep't of Human Servs., 77 Ohio App. 3d 827, 829, 603 N.E.2d 1089 (Franklin County 1991) (the Ohio Medicaid Drug Formulary "lists drugs that qualify for automatic reimbursement"; a provider is generally reimbursed for other drugs only with prior authorization).

Ohio Bureau of Workers' Compensation

The Ohio Bureau of Workers' Compensation is created pursuant to R.C. 4121.121 and administered by the Administrator of Workers' Compensation. The Administrator has various powers and duties regarding the provision of compensation to workers and their dependents for death, injuries, or occupational disease occasioned in the course of their employment. R.C. 4121.121; see also Ohio Const. art. II, § 35 ("[f]or the purpose of providing compensation to [workers] and their dependents, for death, injuries or occupational disease, occasioned in the course of such [workers'] employment, laws may be passed establishing a state fund to be created by compulsory contribution thereto by employers, and administered by the state, determining the terms and conditions upon which payment shall be made therefrom"); a board may be established and empowered "to collect, administer and distribute such [state] fund, and to determine all right of claimants thereto").

Among the duties of the Administrator is the responsibility of establishing and maintaining a medical section to assist the Administrator in establishing standard medical fees, approving medical procedures, and determining eligibility and reasonableness of payments for medical, hospital, and nursing services, and also in establishing guidelines for payment policies that recognize usual, customary, and reasonable methods of paying for covered services. R.C. 4121.121(B)(16). The Administrator also has general authority (with the advice and consent of the Oversight Commission) to adopt rules for the operation of the Bureau. R.C. 4121.121(B)(20); see also State ex rel. Michaels v. Morse, 165 Ohio St. 599,
603, 138 N.E.2d 660 (1956) (Ohio Const. art. II, § 35 provides a broad grant of power to establish and administer the state fund for workers' compensation without limitation).

The Administrator is also responsible for directing the implementation of the Health Partnership Program (HPP), which is administered by the Bureau to provide medical, surgical, nursing, drug, hospital, and rehabilitation services and supplies to employees for their compensable injuries or occupational diseases. R.C. 4121.44(B); R.C. 4121.441. Under the Health Partnership Program, initially authorized in 1993, the Bureau certifies external vendors, known as managed care organizations, to provide medical management and cost containment services. R.C. 4121.44(B); see 1993-1994 Ohio Laws, Part II, 2990 (Am. Sub. H.B. 107, eff. July 21, 1993, with HPP statutes eff. Oct. 20, 1993, per sec. 21, uncodified); Northwestern Ohio Bldg. & Constr. Trades Council v. Conrad, 92 Ohio St. 3d 282, 282-83, 750 N.E.2d 130 (2001); State ex rel. Haylett v. Ohio Bureau of Workers’ Comp., 87 Ohio St. 3d 325, 328-29, 720 N.E.2d 901 (1999). Procedures are established for the resolution of medical disputes arising under the Health Partnership Program. R.C. 4121.441(A)(1); 10 Ohio Admin. Code 4123-6-043, 4123-6-044, 4123-6-045, 4123-6-16, and 4123-6-161; see also R.C. 4123.511. Rule 4123-6-21 is among the rules adopted to implement the Health Partnership Program.

Authority to adopt rule 4123-6-21(L)

Your first question concerns the statutory authority granted to the Bureau of Workers’ Compensation. You have asked whether this authority is sufficient to support the Bureau’s adoption of rule 4123-6-21(L), which authorizes the Board to maintain a drug formulary as part of the implementation of the Health Partnership Program.

In the enactment of statutes governing workers’ compensation, “[t]he General Assembly has delegated broad rulemaking authority to the administrator of workers’ compensation.” Northwestern Ohio Bldg. & Constr. Trades Council v. Conrad, 92 Ohio St. 3d at 286. R.C. 4121.121 authorizes the Administrator to “[e]stablish the overall administrative policy of the bureau” and to “ensure, by rules, the impartial and prompt treatment of all claims.” R.C. 4121.121(B)(1) and (13). R.C. 4121.121 also authorizes the Administrator to “[p]repare and submit to the oversight commission ... the administrator’s recommendations, in the form of administrative rules, for the advice and consent of the oversight commission, for the health partnership program.” R.C. 4121.121(B)(21).

R.C. 4123.66 provides express authority for the Administrator to adopt rules with respect to the provision of medicine for injured workers or disabled workers, as follows:

In addition to the compensation provided for in this chapter, the adminis-
rator of workers' compensation shall disburse and pay from the state insurance fund the amount for medical, nurse, and hospital services and medicine as the administrator deems proper. The administrator may adopt rules, with the advice and consent of the workers' compensation oversight commission, with respect to furnishing medical, nurse, and hospital service and medicine to injured or disabled employees entitled thereto, and for the payment therefor.

R.C. 4123.66(A) (emphasis added). This provision grants the Administrator of Workers' Compensation authority to use money from the State Insurance Fund to pay for medicine for injured or disabled workers, and the related authority (with the advice and consent of the Workers' Compensation Oversight Commission) to adopt rules with respect to furnishing medicine to injured or disabled employees and paying for the medicine. See *Indus. Comm'n v. Klaff*, 123 Ohio St. 451, 455, 175 N.E. 697 (1931) (G.C. 1465-89 (predecessor to R.C. 4123.66) granted Industrial Commission power to adopt rules respecting the furnishing and payment of medical, nurse, and hospital services and medicine, “thus giving it supervisory authority over them”); 10 Ohio Admin. Code 4123-7-23 and 4123-7-24. It has been found that the Administrator's responsibilities under R.C. 4121.121 and R.C. 4123.66 include the authority to disapprove costs for treatment or medications that are inappropriate, unnecessary, or unreasonable in a particular case. See *State ex rel. Sugardale Foods, Inc. v. Indus. Comm'n*, 90 Ohio St. 3d 383, 386, 738 N.E.2d 1238 (2000) (“the BWC and the [industrial] commission share the power to oversee and determine the reasonableness and necessity of health care expenditures”); *State ex rel. Nutt v. City of Cincinnati*, 70 Ohio St. 3d 594, 597, 639 N.E.2d 1196 (1994) (the Industrial Commission “is obligated to address treatment [including medication] that may be inappropriate, unnecessary or unreasonable”); *State ex rel. Breno v. Indus. Comm'n*, 34 Ohio St. 2d 227, 298 N.E.2d 150 (1973) (upholding denial of benefits where authorization was not made in accordance with rules and the record failed to show necessity for treatments); 1973 Op. Att’y Gen. No. 73-085 at 2-324 (R.C. 4123.66 “has been interpreted to grant broad discretion on the part of the Industrial Commission in the determination of payments to be made for medical services”).

R.C. 4123.66(A) grants the Administrator discretion to pay for medicine the amounts that the Administrator “deems proper.” See *State ex rel. Ohio v. Bureau of Workers' Comp.*, 87 Ohio St. 3d at 331. It does not require that the Administrator pay all amounts requested for medicine. Rather, like R.C. 4121.121(B)(16), it permits the Administrator to exercise judgment in determining the amounts deemed proper, even to the extent of completely excluding payments for particular medicines.

Further, the language of R.C. 4123.66(A) authorizing the adoption of rules “with respect to” the furnishing of, and payment for, medicine for “injured or disabled employees entitled thereto” permits rules governing any aspect of the furnishing of and payment for medicine, and does not require that every medicine be eligible to be furnished and paid for. See *State ex rel. Ohio v. Bureau of Workers' Comp.*, 87 Ohio St. 3d at 329 (“only medical services and supplies that are medically necessary for the diagnosis and treatment of allowed conditions and that are causally related to those conditions will be considered for payment”). The determination of when an employee is “entitled” to medicine may be addressed in the rule, as may other matters “with respect to” furnishing and paying for medicine, including limitations upon the medicines that may be furnished or paid for.

When read in conjunction with other provisions granting the Administrator
responsibility for approving medical procedures and discretion to determine reasonable charges, see, e.g., R.C. 4121.121(B)(16), the general terms set forth in R.C. 4123.66(A) grant the Administrator broad authority to determine when and how medicine should be furnished and paid for, including the authority to select certain medicines to be eligible for reimbursement when used to treat certain conditions, and to determine that other medicines are not eligible for reimbursement. These statutory provisions also include the authority to determine that drugs that are not approved for use in the United States by the Food and Drug Administration are ineligible for reimbursement. See generally 1973 Op. Att’y Gen. No. 73-085 (approving practice of paying for only those chiropractic services authorized by Medical Board rules).

A major reason for maintaining a drug formulary is to secure financial savings. Ohio statutes provide for such savings in connection with the Health Partnership Program, under which the Bureau certifies managed care organizations to provide medical management and cost containment services. R.C. 4121.44(B); see also R.C. 4121.441(A)(4), (5), (6), and (8). See generally Northwestern Ohio Bldg. & Constr. Trades Council v. Conrad, 92 Ohio St. 3d at 283; State ex rel. Ohio v. Bureau of Workers’ Comp., 87 Ohio St. 3d at 333 (‘[t]he governmental interest involved is primarily financial. The MCO [managed care organization] program is designed, at least in part, to minimize the amount expended, while ensuring that the workers’ compensation system serves its primary function of meeting the needs of its constituents’); Upjohn Co. v. Ohio Dep’t of Human Servs., 77 Ohio App. 3d at 833 (the decision of the Ohio Department of Human Services to remove certain drugs from the Ohio Medicaid Drug Formulary ‘as the means to achieve its cost-savings objective represented a choice among policy alternatives’).

To provide for the implementation of the Health Partnership Program, R.C. 4121.441 authorizes the Administrator to adopt rules governing the provision of drugs at discounted prices, as follows:

(A) The administrator of workers’ compensation, with the advice and consent of the workers’ compensation oversight commission, shall adopt rules ...

for the health care partnership program administered by the bureau of workers’ compensation to provide medical, surgical, nursing, drug, hospital, and rehabilitation services and supplies to an employee for an injury or occupational disease that is compensable under this chapter or Chapter 4123., 4127., or 4131. of the Revised Code.

The rules shall include, but are not limited to, the following:

(4) Appropriate financial incentives to reduce service cost and insure proper system utilization without sacrificing the quality of service;

(8) Discounted pricing for all in-patient and out-patient medical services, all professional services, and all pharmaceutical services . . . .

Division (4) thus authorizes the adoption of rules that provide financial incentives to
reduce the cost of service and insure the proper utilization of the system without sacrificing the quality of service. The use of a drug formulary may be effective to reduce costs and insure proper use of pharmaceuticals. If the maintenance of a drug formulary under rule 4123-6-21(L) reduces the costs of drugs without sacrificing the quality of service, then the maintenance of the drug formulary is consistent with legislative intent. See also 10 Ohio Admin. Code 4123-6-01(W).

Division (8) requires that the rules provide discounted pricing for all in-patient and out-patient medical services, all professional services, and all pharmaceutical services. The drug formulary permits discounts for pharmaceutical services, as required by this provision. To be capable of reasonable application, the word "all" in this provision must be read as referring to "all" the medical services, professional services, and pharmaceutical services that are provided pursuant to the Health Partnership Program. The term cannot reasonably be construed in a global sense to encompass "all" that an individual might seek or obtain, but must reasonably be limited to "all" that are part of the Health Partnership Program, whether inpatient and out-patient medical services, professional services, or pharmaceutical services. See R.C. 1.42 ("[w]ords and phrases shall be read in context ..."); R.C. 1.47 ("[i]n enacting a statute, it is presumed that: ... (C) [a] just and reasonable result is intended ... "). The requirement for discounted pricing thus applies to "all" the drugs included in a formulary created as part of the Health Partnership Program.

Further, in authorizing the adoption of rules, R.C. 4121.441(A) states that the rules "shall include, but are not limited to" the provisions listed in the statute. Thus, even though a drug formulary is not expressly mentioned in R.C. 4121.441(A), and apart from the types of rules specifically listed, the Administrator may adopt rules providing for a drug formulary, if a drug formulary is deemed reasonably necessary to implement the purposes of the Health Partnership Program.

R.C. 4121.44(C) sets forth certain capabilities that a vendor (managed care organization) must demonstrate in order to be certified for participation in the Health Partnership Program. Any vendor selected must demonstrate arrangements and reimbursement agreements with a substantial number of the pharmacy providers currently being utilized by claimants. R.C. 4121.44(C)(1). In addition, each vendor must have "[a] prescription drug system where pharmacies on a statewide basis have access to the eligibility and pricing, at a discounted rate, of all prescription drugs." R.C. 4121.44(C)(4). Again, the intent to provide drugs at discounted prices is clear. Again, the word "all" is reasonably read to mean all drugs covered by the Health Partnership Program. The operation of a drug formulary is designed to carry out the statutory intent of securing savings in the provision of medicine.

The provisions of R.C. 4121.121, R.C. 4121.44, R.C. 4121.441, and 4123.66 thus grant the Administrator authority (with the advice and consent of the Oversight Commission) to adopt rules with respect to the furnishing of, and payment for, medicine as part of the Health Partnership Program. Rule 4123-6-21(L) is a reasonable exercise of this authority. Rule 4123-6-21(L) permits the Bureau to maintain a pharmacy provider network and prior authorization program for medications, to contract rebate agreements with drug manufacturers, to be responsible for maintaining a drug formulary, to establish and enforce dispensing limitations, and to use a vendor to carry out these functions. This rule provides a framework within which the Administrator may exercise the statutory authority to disburse, furnish, and
pay for medicine, as the Administrator deems proper, in the reasonable exercise of the Administrator’s discretion. We conclude, accordingly, that R.C. 4121.121, R.C. 4121.44, R.C. 4121.441, and R.C. 4123.66 grant the Bureau of Workers’ Compensation sufficient authority to adopt the provisions appearing in 10 Ohio Admin. Code 4123-6-21(L).

In addressing the Bureau’s rulemaking authority, the Ohio Supreme Court has stated:

It is axiomatic that if a statute provides the authority for an administrative agency to perform a specified act, but does not provide the details by which the act should be performed, the agency is to perform the act in a reasonable manner based upon a reasonable construction of the statutory scheme. See Swallow v. Indus. Comm. (1988), 36 Ohio St.3d 55, 57, 521 N.E.2d 778, 779. A court must give due deference to the agency’s reasonable interpretation of the legislative scheme. Id. See, also, Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc. (1984), 467 U.S. 837, 843, 104 S. Ct. 2778, 2782, 81 L.Ed.2d 694, 703 (“if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency’s answer is based on a permissible construction of the statute”).

... As the United States Supreme Court has noted, “[t]he power of an administrative agency to administer a * * * program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly,” by the legislature. (Emphasis added.) Morton v. Ruiz (1974), 415 U.S. 199, 231, 94 S.Ct. 1055, 1072, 39 L.Ed.2d 270, 292. Our own Swallow case implicitly recognized that no set of statutes and administrative rules will answer each and every administrative concern. Id., 36 Ohio St.3d 55, 521 N.E.2d 778. When agencies promulgate and interpret rules to fill these gaps, as they must often do in order to function, “courts * * * must give due deference to an administrative interpretation formulated by an agency that has accumulated substantial expertise, and to which the General Assembly has delegated the responsibility of implementing the legislative command.” Id. at 57, 521 N.E.2d at 779. We accord due deference to the BWC’s interpretation, so long as it is reasonable. See State ex rel. McLean v. Indus. Comm. (1986), 25 Ohio St.3d 90, 92, 25 OBR 141, 143, 495 N.E.2d 370, 372 (holding that commission did not abuse discretion in awarding compensation for loss of foot even though claimant suffered amputation five inches below the knee).

Northwestern Ohio Bldg. & Constr. Trades Council v. Conrad, 92 Ohio St. 3d at 287-89. In the Northwestern Ohio Building & Construction Trades Council case, the Ohio Supreme Court upheld a rule permitting the Bureau to use money from the State Insurance Fund to pay certain administrative and performance incentive fees to managed care organizations, even though the statutes provided no express authority for that use of State Insurance Fund proceeds. See also Swallow v. Indus. Comm’n, 36 Ohio St. 3d 55, 521 N.E.2d 778 (1988) (finding that the Industrial Commission’s policy of making payments consecutively rather than concurrently had a reasonable basis, and upholding that policy). The analysis set forth in the Northwestern Ohio Building & Construction Trades Council case thus supports the conclusion that the statutory rulemaking authority of the Administrator is broad enough to
authorize the adoption of rules providing for the use of a drug formulary as part of the Health Partnership Program.

**Authority to create a drug formulary**

Your second question asks whether the language of rule 4123-6-21(L) providing that the Bureau of Workers’ Compensation or its pharmacy benefits vendor may “be responsible for maintaining a drug formulary” also provides the Bureau with authority to first “create” a drug formulary. Clearly, it does.

A grant of authority to maintain a drug formulary of necessity requires that such a formulary exist. See Webster’s New World Dictionary 854 (definition of “maintain” includes “to keep or keep up; continue in or with; carry on”) (2nd college ed. 1984). If no drug formulary has been created and the responsibility of creation is not expressly granted to another person, then the body with authority to be responsible for maintenance, by clear implication, must proceed to create the formulary so that it may then be maintained. See Morton v. Ruiz, 415 U.S. 199, 231 (1974) (“[t]he power of an administrative agency to administer a ... program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly,” by the legislature); Northwestern Ohio Bldg. & Constr. Trades Council v. Conrad, 92 Ohio St. 3d at 289 (administrative agencies may take reasonable action to formulate policy and fill gaps left by the legislature, and courts must give due deference to the administrative interpretation formulated by an agency that has accumulated substantial expertise and is given the responsibility of implementing the legislative command); see also R.C. 1.47 (“[i]n enacting a statute, it is presumed that: ... (D) [a] result feasible of execution is intended’’). Thus, the language of 10 Ohio Admin. Code 4123-6-21(L) providing that the Bureau of Workers’ Compensation or its pharmacy benefits vendor may “be responsible for maintaining a drug formulary” by necessary implication provides authority for the Bureau to first create a drug formulary.

This conclusion is appropriate in the instant case because of the broad general authority given to the Bureau of Workers’ Compensation to approve medical procedures, to determine the eligibility and reasonableness of compensation for medical, nursing, and hospital services, to adopt rules with respect to the furnishing and payment of medical, nursing, and hospital services and medicine, and to disburse and pay amounts for medical, nursing, and hospital services and medicine as the Administrator deems proper. R.C. 4121.121; R.C. 4123.66. Further, this conclusion serves the statutory directive for cost containment and discounted drugs in the Health Partnership Program. R.C. 4121.44; R.C. 4121.441. In order for the Bureau to carry out its responsibilities, it must be empowered to take the steps necessary to ensure that the drug formulary maintained pursuant to rule 4123-6-21(L) is created in accordance with the statutes directing and governing the workers’ compensation system.

**Conclusions**

For the reasons discussed above, it is my opinion, and you are advised, as follows:

1. R.C. 4121.121, R.C. 4121.44, R.C. 4121.441, and R.C. 4123.66 grant the Bureau of Workers’ Compensation sufficient authority to adopt the provisions appearing in 10 Ohio Admin. Code 4123-6-21(L).

2. The language of 10 Ohio Admin. Code 4123-6-21(L) providing that the
Bureau of Workers' Compensation or its pharmacy benefits vendor may "be responsible for maintaining a drug formulary" by necessary implication provides authority for the Bureau to first create a drug formulary.